14-4624

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General

Plaintiffs-Appellees,

v.

ACTAVIS plc AND FOREST LABORATORIES, LLC

Defendants-Appellants.

FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
CASE NO. 14-CV-7473 (RWS)

PAGE PROOF BRIEF OF DEFENDANTS-APPELLANTS (UNDER SEAL)

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Defendants Actavis plc and Forest Laboratories, LLC respectfully submits the following corporate disclosure statement:

Forest Laboratories, LLC is a wholly owned subsidiary of Actavis plc, a public limited company incorporated in Ireland. No publicly held company owns 10% or more of the stock of Actavis plc.

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INTRODUCTION

The nationwide injunction in this case creates an unprecedented and unworkable antitrust rule. The court below compelled a company to start producing a patented drug it no longer makes, and to keep doing so for the next seven months on judicially-dictated terms and conditions to ease the way for competitors. Forest Laboratories, LLC and its parent company Actavis plc (together "Forest") must "continue to make" Forest's ten-year-old, patented Alzheimer's drug, twice-daily Namenda IR® tablets, "available on the same terms and conditions applicable since July 21, 2013." SA-137. Forest had stopped making IR so that physicians would transition patients to Namenda XR®, a new and improved once-daily capsule using the same active ingredient, memantine. Starting in January 2015, patients would take Forest's next-generation drug XR, but would decide, with their physicians, whether to remain on XR or switch to generic IR in July 2015.

The nominally preliminary injunction instead forces Forest to keep offering patients the older drug through August 10, 2015. Because of its patent rights, Forest is now the only company selling memantine-based drugs. In July 2015, Forest's patent and regulatory exclusivities on IR end, and at least five generic manufacturers are poised to enter the market with generic versions. If Forest cannot transition patients to XR now, and must instead keep up IR production and

distribution, state drug laws in July will automatically convert 80-90% of current Namenda IR prescriptions into generic IR sales at the pharmacy. In other words: the more IR prescriptions Forest is forced to foster before July 2015, the more sales Forest guarantees its generic competitors.

How Forest is to comply with this injunction is anyone's guess. No antitrust court has entered an injunction like this before. The "terms and conditions applicable" to IR have varied over the 17 months. Yet the court rejected pleas for clarification: "I am not unaware of the difficulties that this creates …. You will have to see what you think [the injunction] means. I think I know what it means, but we will see. … Good luck." JA__ (12/15/14_Hr'g_47-48).

This injunction never should have issued. The decision justifying this injunction includes *seventy-seven* paragraphs copied virtually verbatim from New York's filings. Its reasoning contravenes every prerequisite for injunctive relief. There is no irreparable harm to prevent. New York's antitrust suit alleges that Forest tried to monopolize the memantine drug market and unlawfully exclude competition. Federal and state antitrust laws provide treble damages. New York's expert economist estimated damages at a remarkably precise [redacted], with the overwhelming majority attributable to healthcare plans. JA__ (Berndt_Decl_37-38). To repeat that figure is to demonstrate just how reparable

the alleged antitrust harm is. Yet the district court inexplicably deemed this monetary loss irremediable. SA-95, SA-131.

The injunction also rested on the court's finding that limiting IR distribution and getting physicians to migrate patients to XR would create potential medical risk for certain existing Alzheimer's patients. SA-55-56, SA-131. That holding is legally and factually indefensible. Antitrust law precludes a court from granting an antitrust injunction based on irreparable harm that is not cognizable under antitrust law. New York chose to bring an antitrust suit, and antitrust law only remedies economic loss.

Moreover, the claim of patient harm is an outrageous fiction. The *FDA* considers switching from IR to XR entirely safe. Hundreds of thousands of patients already switched from IR to XR; New York identified not *one* who suffered harm. Had New York any evidence that any patient has been put at any risk by switching from IR to XR, New York could have, would have, and should have offered it. The court should have demanded such evidence before charging Forest with putting patients at risk. But New York presented *no* expert medical testimony, and the court relied on Dr. James Lah, who was not (and disclaimed being) an expert. He admitted that he "ha[s] *no foundation* or basis on which to conclude that … an individual patient will have greater adverse effects going to XR from IR. It's a potential concern, *not a known concern*." JA__

(Lah_Dep_289) (emphasis added). And Namenda XR is improving the lives of countless Alzheimer's patients and caregivers—as the district court's opinion recognized elsewhere. Were that not enough, if a patient's doctor says that staying on IR is medically necessary, Forest (through a mail-order pharmacy) will ensure IR's availability to that patient. Irresponsible speculation that does not even allege a known risk is no basis for finding irreparable harm.

The district court's holdings on the merits are equally untenable. Bedrock principles of patent and antitrust law foreclose any likelihood that New York will succeed on the merits. At issue here is Forest's right under patent law to control whether to make, distribute, and sell a product to which Forest has valid patent rights—Namenda IR. Since 1790, federal patent law has struck a fundamental bargain with innovators: if they invest time and money in developing a novel product, a patent will guarantee them, for up to 20 years, the exclusive right to decide how much or how little of the patented product to make, distribute, and sell. After that, anyone can copy and sell competing versions. For over a century, the rule in America has been that patent law modifies antitrust law and relieves patent-holders of antitrust liability if they are exercising core rights within the scope of their patent. Yet the court inexcusably failed to even analyze this issue, and assumed Forest's patent rights were irrelevant.

There is more. A Section 2 monopolization claim requires a finding of exclusionary conduct that impairs competition, not competitors. Forest has done nothing exclusionary—it has not blocked generic competitors' access to suppliers or distributors, or their ability to enter the market come July. All that Forest's plans to reduce sales of Namenda IR would do is reduce its future rivals' ability to use state generic substitution laws to free-ride on Namenda IR prescriptions.

The district court created a new duty to comply with the "spirit" of federal and state laws so that competitors take over up to 90% of the market. That rule, if left undisturbed, would transform antitrust law's clear rules into an unmanageable series of imponderable questions. Forest sought to move patients from IR to XR by withdrawing IR from general distribution in the face of imminent generic entry. But, according to New York's expert, Forest could have *raised* the price of IR with antitrust impunity. Or perhaps Forest could have withdrawn IR a year earlier. And had New York deemed XR—in New York's words—"truly" better than IR, New York would not have sued. Left unexplained is how a court can or should determine whether a product is innovative enough to avoid treble damages.

Forest's actions are *pro*competitive. Forest has invested hundreds of millions of dollars to develop a new product, one that makes patients' and caregivers' lives better. And Forest has responded to generic competition with more competition: it sought to pit its newer, improved, and concededly beneficial

once-daily drug against generics' older, but likely cheaper, twice-a-day version, and let consumers decide which they prefer. XR eliminates any market need for IR by providing more convenient and beneficial once-a-day dosing. Nor are Forest's actions unusual: its conduct is common throughout the pharmaceutical industry. It is only under the district court's upside-down view that competition is furthered by maximizing the effect of state drug substitution laws and relieving generic manufacturers of the task of competing.

Left undisturbed, the decision below will insert courts into precisely the types of judgments for which they are least suited: whether an innovation is sufficiently novel to escape antitrust liability, and how businesses should set prices, terms, and conditions for their products. It must be reversed.

STATEMENT OF JURISDICTION

The district court has jurisdiction over New York's federal claims under 28 U.S.C. §§ 1331 and 1337, and jurisdiction over state-law claims under 28 U.S.C. § 1367(a). Forest seeks review of the district court's December 11, 2014 opinion granting a preliminary injunction (SA-1-136), and the December 15, 2014 preliminary injunction order (SA-137-38). Forest timely filed its notice of appeal on December 16, 2014. JA__. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

1. Whether the district court erred by entering an injunction without finding a clear likelihood of success on the merits and a strong showing of irreparable harm.

2. Whether the court erred in finding that New York showed irreparable harm based on compensable monetary harms and an unsubstantiated and legally irrelevant risk of medical harm.

3. Whether the Sherman Act requires a company to exercise its patent rights by selling its patented product, and to do so to facilitate sales of its competitors' products.

4. Whether the nationwide injunction ordering a company to make a product "available on the same terms and conditions applicable since" 17 months ago is overly vague and broad.

STATEMENT OF THE CASE

On September 15, 2014, New York sued Forest, seeking declaratory relief, an injunction, disgorgement, restitution, and damages under the theory that Forest violated federal and state antitrust law by limiting distribution of IR in favor of XR. SA-6-8. On December 11, after an expedited hearing, the district court (Sweet, J.) granted New York a preliminary injunction. SA-2, SA-136. The court held that Forest engaged in exclusionary conduct that would lower generic

manufacturers' future market share by depriving generics of the advantage of state substitution laws. SA-113-19. The court found irreparable harm based on higher prices for memantine and the risk of medical harm to patients. SA-130-32; *see* SA-55-56. That decision will be reported. *New York v. Actavis*, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014).

On December 15, the court ordered Forest to "continue to make [IR] tablets available on the same terms and conditions applicable since July 21, 2013." SA-137. The injunction is effectively permanent; it does not expire after a trial (none is scheduled), and will only be lifted "[30] days after July 11, 2015 (the date when generic memantine will first be available)." SA-138. On January 6, this Court granted expedited briefing but declined Forest's motion to stay the injunction. Dkt. No. 101.

STATEMENT OF FACTS

A. Regulatory and Industry Background

Brand drug manufacturers produce virtually all advances in prescription drugs. They do so both by developing new classes of drugs and incremental, yet meaningful, pharmaceutical innovations that significantly improve patients' lives. "[T]he vast majority of clinically important drugs … have resulted from … multiple, small, successive improvements within a pharmacological class," commonly called incremental innovations. JA __ (Kolassa_10/20/14_Decl_18)

(internal quotations omitted). "[I]mproved formulations, delivery methods and dosing protocols may also … improve[] patient compliance, [provide] greater efficacy … reverse[] adverse effects or … treat new patient populations." Ernst R. Berndt et al., *The Impact of Incremental Innovation on Biopharmaceuticals: Drug Utilization in Original and Supplemental Indications*, 24 Pharmacoeconomics (Suppl. 2) 69, 71 (2006).

It usually takes over a decade and $2.6 billion to get FDA approval for a new class of drug, and profits from that drug rarely cover those costs. Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), http://bit.ly/1Hfvx6G. Incremental advances also require significant effort and innovation. And revenues from incremental innovations are essential to investments in developing breakthrough drugs. Albert Wertheimer & Thomas Santella, *Pharmacoevolution: The Advantages of Incremental Innovation*, at 12-13 (Int'l Policy Network Working Paper 2005); Berndt, *supra*, at 71.

While generic drugs play an important role in the practice of medicine, generic manufacturers do not significantly invest in new drugs or incremental innovation. Rather, they copy brand drugs, and usually enter the market after the product's patent term and regulatory exclusivity period ends. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

1. The Hatch-Waxman Act

Until the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman, federal law generally required generics to undertake the same cumbersome and expensive drug approval process as brands. Hatch-Waxman now "allow[s] [a] generic to piggy-back on the … approval efforts" made by brand drug manufacturers, *FTC v. Actavis*, 133 S. Ct. 2223, 2228 (2013), if the generic is "bioequivalent"—meaning (for most drugs) that the body absorbs the active ingredient at a rate and extent that is 80% to 125% of the reference brand drug—and has the same dosage form and other characteristics. FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (34th ed.), at vii–x, http://1.usa.gov/1ypXL8s ("Orange Book"). Generic manufacturers thus spend "a few million dollars" to get a generic to market. Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 Geo. Pub. Pol'y Rev. 7, 13 (2003).

Through the "[P]aragraph IV" certification process, Hatch-Waxman also incentivizes generic manufacturers to challenge brand-drug patents and can give the first successful challenger a "180–day period of exclusivity [sometimes] 'worth several hundred million dollars.'" *Actavis*, 133 S. Ct. at 2228-29 (citation omitted). But nothing in Hatch-Waxman guarantees generics a set market share, or dictates what happens when they enter. Indeed, even during a first generic's 180-

day exclusivity period, the brand manufacturer can itself introduce a competing generic. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005).

2. States' Varied Generic Substitution Laws

Historically, physicians, in consultation with patients, decided which drug to dispense. But since the 1970s, states have encouraged, and—like New York—even forced, pharmacists to substitute lower-priced generics for brand drugs. State substitution laws, *not* Hatch-Waxman, prompt "automated switching" of generics for brands at pharmacies, so that generics capture 80-95% of sales. JA__ (Stitt_11/10/14_Hr'g_116); JA__ (Berndt_11/12/14_Hr'g_375-76).

States decide when generics can be substituted for brand drugs. Many states' laws incorporate the FDA's "Orange Book," which contains informal, non-binding "information and advice" on drugs the FDA considers similar enough to be substitutes. Orange Book, *supra*, at iv. The Orange Book designates generics as "AB-rated," and thus substitutable, if they are "therapeutically equivalent" to specific brand drugs referenced by generic applicants. *Id*. at vii. The Orange Book treats two drugs as "therapeutic equivalent[s]" if they "contain identical amounts of the same active drug ingredient in the same dosage form," among other criteria. *Id*. The FDA does *not* consider drugs therapeutically equivalent if they provide different dosages, regardless of therapeutic effect. *Id.* But the FDA deems two drugs therapeutically equivalent even if they differ in "shape, scoring

configuration, … colors, flavors, [or] preservatives," and even though consumers might consider these differences important. *Id.*; *accord* 44 Fed. Reg. 2932 (1979).

In New York, generic substitution is mandatory. Pharmacists must "substitute a less expensive drug product"—usually a generic—"[for] the drug product prescribed"—usually a brand—if the drug is on the state's list of acceptable substitutes. N.Y. Educ. Law § 6816-a (SA-185). New York lists generics as substitutes only if (1) the Orange Book "evaluated such drug product as pharmaceutically and therapeutically equivalent," *i.e.*, AB-rated, and (2) the generic contains "the same active ingredients, dosage form and strength as the drug product prescribed." *Id.*; N.Y. Pub. Health Law § 206(1)(o)(2) (SA-191-92).

When these conditions are met, New York compels pharmacies to disregard the physician's prescription and to substitute whatever "equivalent" costs least. N.Y. Educ. Law § 6816-a (SA-185). As New York's pharmacist witness, David Stitt, observed, "the element of choice is taken out of the equation by [New York's] law." JA__ (Stitt_11/10/14_Hr'g_115). Only if the physician specifies "Dispense As Written" on the prescription, or if there is a medical emergency and the generic is unavailable, may pharmacists provide the brand drug. *See* N.Y. Educ. Law § 6816-a (SA-185).

But New York legislators realize New York may have gone too far. Aware that consumers lack information about "the drawbacks … of taking a generic drug"

and should "have the right to … decide … whether the generic product is appropriate for them," the state's legislature has been considering a partial repeal of the mandatory substitution law. S. 6739, 2013-2014 N.Y. Sess. Laws, http://bit.ly/1tzJlA2. Legislators cited the generic version of the antidepressant Wellbutrin®: although the FDA initially deemed it equivalent to the brand, consumers reported significant side effects, the FDA reconsidered, and the generic was withdrawn. *See id.*

Thirty-nine states reject mandatory substitution: they allow pharmacists to substitute a cheaper generic, but if the pharmacist, patient, or physician prefers the brand, the pharmacist can dispense it.[1] *See* SA-24-25. And, critically, many states, unlike New York, do not rely on the Orange Book.[2] Arkansas permits generic substitution within a therapeutic class, even if the generic comes in a different dose. Code Ark. Reg. § 07-00-0010. Some states even allow pharmacists to substitute an entirely different class of drug if it has therapeutically similar effects.[3] Up to 20 states may let pharmacists unilaterally substitute generic IR for Namenda XR. JA__ (Cremieux_10/21/14_Decl_12); JA__ (Berndt_Decl_28).

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[1] *See* Jesse C. Vivian, *Generic-Substitution Laws*, U.S. Pharmacist, at tbl.2 (June 19, 2008), http://www.uspharmacist.com/content/s/44/c/9787.

[2] *E.g.*, Code Ark. Reg § 07-00-0010; Iowa Code Ann. §§ 155A.32, § 155A.3; Mich. Comp. Laws Ann. § 333.17755; Minn. Stat. Ann. § 151.21; Ohio Rev. Code Ann. §§ 3715.01, 4729.38; N.D. Cent. Code Ann. § 19-02.1-14.1; S.C. Code Ann. §§ 40-43-30, 40-43-86; Wash. Admin. Code §§ 246-899-030, 182-530-1050.

[3] Jesse C. Vivian, *Legal Aspects of Therapeutic Interchange Programs*, 28:08 U.S. Pharmacist (Aug. 15, 2003).

States with mandatory substitution laws achieve an 80-90% generic conversion rate through compulsion. Brand sales in those states generally occur when doctors specify "Dispense as Written" on the prescription. Vivian, *Generic-Substitution Laws*, *supra*, at 1-2. Elsewhere, generics rely on market intermediaries to achieve the same conversion rates. Pharmacies make more money on generics, and have enormous incentives to substitute them. JA__ (Kolassa_10/20/14_Decl_6-7); Dep't of Health and Human Servs. Office of Inspector General, *Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products*, at 5-6 (Mar. 2002), http://1.usa.gov/1Arzh3m. Pharmacists often call physicians to urge switching to a non-AB rated generic drug. *See* JA__ (Kolassa_11/14/14_Hr'g_793-95). One successful call means that physicians will likely switch other patients to the generic. *Id.*

Health care plans and insurers—third-party payors—have similar incentives to promote generics. SA-19-20. Payors use their enormous financial leverage to negotiate pricing with manufacturers. SA-60-62. Because generics increase the payors' profit margins, payors employ powerful tools to steer physicians and patients toward generics. *See* SA-25; JA__ (Kolassa_10/20/14_Decl_7-12); JA__ (Devlin_Decl_2). Payors pressure pharmacies and physicians to switch patients from brands to generics that treat the same conditions, even if the generics have different dosages. JA__, JA__ (Kolassa_10/20/14_Decl_4-5_App'x-1_1-6); JA__

(Kohrman_Dep_273-77). Some generic manufacturers also advertise. JA__ (Kolassa_10/20/14_Decl_16-17); JA__ (Harper_11/11/14_ Hr'g_320-26).

B. Factual Background

Forest (now owned by Actavis) manufactures drugs that treat many debilitating conditions, including depression (Celexa® and Lexapro®); hypertension (Bystolic®); cystic fibrosis (Zenpep®); chronic obstructive pulmonary disease (Tudorza® and Daliresp®); and irritable bowel syndrome (Linzess®). Forest, *Our Products* (2015), http://www.frx.com/Products. Actavis is also a major generic manufacturer. JA__ (11/10/14_Hr'g_25); JA__ (Saunders_11/11/14_Hr'g_257).

Forest makes two memantine-based products approved to treat moderate to severe dementia of the Alzheimer's type: Namenda® IR and Namenda XR®. SA-12, SA-30. Alzheimer's afflicts five million Americans. SA-13. In 2014, 469,000 new patients were diagnosed. Alzheimer's Association, *Alzheimer's Disease Facts & Figures*, at 19 (2014), http://bit.ly/1ihNu7U. Science has yet to find a cure.

Caregivers face tremendous challenges in caring for Alzheimer's patients. JA__ (Reisberg_Decl_7). Many patients resist medications and consider them an affront to their dignity. JA__, JA__ (Rovner_Decl_2,6); JA__ (Reisberg_Dep_137-39). Further, many patients "sundown"—their conditions decline significantly and their mental impairment and distress worsens once the

sun sets. JA__ (Jacobs_Decl_6); JA__ (Kohrman_Decl_5); JA__ (Rovner_Decl_11). Most patients abandon treatment within a year, partly because of the burden of complex pill-taking schedules. JA__ (Rovner_Decl_7).

1. Forest's Three Generations of Alzheimer's Treatments

a. Twice-A-Day Namenda IR

In January 2004, Forest introduced Namenda IR tablets, the first FDA-approved dementia treatment based on memantine, an NMDA receptor antagonist. *Id.* IR indisputably was a breakthrough, one that has helped Alzheimer's patients communicate with their families and perform daily tasks for longer periods. *E.g.*, JA__ (Rovner_Decl_10), JA__ (Reisberg_Decl_6). The German company Merz exclusively licensed IR to Forest in 2000 and Forest worked to develop and obtain FDA approval of IR for the U.S. market. SA-30.

In 2004, Forest introduced twice-daily tablet Namenda IR. In 2005, Forest introduced a twice-daily oral liquid version of IR for patients who have trouble swallowing. SA-32. But IR was a twice-daily drug in a market dominated by once-daily therapies; all other Alzheimer's drugs are once-daily, because that is the most convenient dosage for patients and caregivers. JA__ (Meury_IH_Tr_135); JA__ (Kohrman_11/13/14_Hr'g_739); JA__ (Solomon_Dep_154).

b. Once-Daily Namenda XR

Forest thus sought to develop XR, a once-a-day extended release capsule, which took years and about [redacted]. JA__ (Meury_10/21/14_Decl_2). (Overall, Forest invested [redacted] to develop, license, and obtain FDA approval for Namenda products, including XR. *Id.*). The FDA approved XR in June 2010; Forest launched it in June 2013. *Id.*; SA-7, SA-37.

New York does not question XR's clinical benefits. Its witness Dr. Lah testified that with XR available, IR is no longer medically necessary or needed in the marketplace. JA__ (Lah_11/10/14_Hr'g_71-72,85). XR's once-daily dosage significantly benefits patients and caregivers. By "reduc[ing] the frequency of medication administration," XR "can improve medication adherence, enhance patient self-efficacy, and reduce behavior problems, caregiver burdens, and healthcare costs." JA_ (Rovner_Decl_2); *see* JA_ (Kohrman_11/13/14_Hr'g_739-40); JA__ (Reisberg_11/13/14_Hr'g_727-29). As the district court acknowledged, XR especially helps patients who resist pills, or who "sundown" and resist them at night. SA-35-36. By reducing patients' and caregivers' pill burden, XR increases the odds that patients continue treatment. JA__ (Rovner_Decl_7). That may also delay the need for expensive long-term professional care. JA__ (Rovner_Decl_2,6); JA__ (Lah_11/10/14_Hr'g_95-96). The FDA also approved XR as administrable in applesauce, which is especially helpful for elderly patients.

Namenda XR Package Insert at 1, 2, http://bit.ly/1HN7lI6. Thus, "for many patients there is likely a preference for once-daily versus twice-daily Namenda." JA__(Berndt_11/12/14_Hr'g_441,455); *accord* JA__ (Lah_11/10/14_Hr'g_95).

c. Namzaric's Fixed Dose Combination

Forest recently developed Namzaric™, a "fixed dose combination [FDC] of Namenda XR with an acetylcholinesterase inhibitor," which eliminates yet another daily pill. JA __ (Kolassa_10/20/14_Decl_18). The FDA approved Namzaric on December 23, 2014. Actavis Press Release, http://bit.ly/141qffk.

2. Forest's Decision to Increase XR Production and Distribution and Limit IR Distribution

About 500,000 patients take IR tablets; some 240,000 patients take XR. *See* JA__ (Cremieux_10/21/14_Decl_24). Fewer patients take IR oral solution. SA-32, SA-75. As of June 2014, over 21,000 patients per month were switching to XR. JA__ (Kane_11/12/2014_Hr'g_551); JA__ (Cremieux_10/21/14_Decl_24); JA__ (Namenda_Longitudinal_Patient_Tracker_Slide_6). XR and IR typically cost patients the same amount, and XR costs wholesalers less than IR. JA__ (Meury_10/21/14_Decl_3). New York's competition expert, Dr. Berndt, confirms that these cost savings benefit consumers. JA__ (Berndt_11/12/14_Hr'g_465).

Forest's IR patent and regulatory exclusivities end on October 11, 2015. Pursuant to agreements, five generic manufacturers may start selling generic IR tablets sooner—on July 11, 2015. JA__ (Solomon_Decl_3). Another seven

generic manufacturers may start selling IR on October 11, 2015. *Id.* Thus, in July, New York pharmacists must switch patients from branded IR to generic IR without consulting patients or doctors. Pharmacists in permissive substitution states can choose to switch patients, and third-party payors will heavily pressure them to do so. SA-25; Vivian, *Generic-Substitution Laws*, *supra*, at 3-5. Within months, 80-90% of IR prescriptions will switch to generics. *See* SA-27.

Because XR supplants the market need for IR, leaving IR on the market only maximizes generics' free-riding on state substitution laws. To maximize returns on its substantial investment in XR, Forest by February 2014 decided to shift from IR tablets to XR and encourage physicians to transition patients to XR before 2015. Forest relied on substantial evidence that switching is safe and beneficial for patients. The FDA found switching safe, and instructions for switching appear in XR's labeling. JA__, JA__ (FDA Review); Namenda XR Package Insert, *supra*, at 1, 2. Clinical studies and five expert witnesses confirm "there is no risk in switching patients from Namenda IR to Namenda XR." JA__, JA__ (Rovner_Decl_2,13); *see* JA__ (Jacobs_Decl_6-7), JA__ (Reisberg_Decl_6); JA__ (Kohrman_Decl_6); JA__, JA__ (Ferris_Decl_1,7-8).

New York pointed to no instance of medical harm from switching, despite substantial and relevant empirical experiences. In June 2014, Forest's XR manufacturing process was unexpectedly disrupted. SA-63-64. Patients who had

switched to XR briefly switched back to IR tablets. These switches—IR to XR to IR—took place smoothly. JA__ (Kohrman_11/13/14_Hr'g_738-39,742); JA__ (Reisberg_Decl_6); JA__ (Kohrman_Decl_6).

In transitioning to XR, Forest considered discontinuing IR tablets entirely or instead limiting distribution channels. Both approaches are common in the industry. JA__ (Kolassa_10/20/14_Decl_2-4) (discussing six examples). Forest first planned to discontinue IR. Forest notified the FDA in February 2014 that it was discontinuing IR; it also informed patients, caregivers, physicians, pharmacies, third-party payors, and the public. Forest Press Release, Feb. 14, 2014, http://bit.ly/P61KWW.

The XR production disruption delayed the transition, and Forest announced in June 2014 that IR tablets would be available into the fall. Forest Press Release, June 10, 2014, http://bit.ly/1Bz6Uzc. Forest also announced in November 2014 that instead of discontinuing IR entirely, it would make IR available to patients whose doctors deemed IR medically necessary. Forest entered into an agreement with mail-order pharmacy Foundation Care to take over distributing IR to those patients as of January 2015. Actavis Press Release, Nov. 5, 2014, http://bit.ly/1KlNJgD. There is "no cap" on how many prescriptions Foundation Care can fill, but Forest expects a small number due to the lack of need. JA__ (Saunders_11/11/14_Hr'g_241-42); JA_ (Kane_11/12/14_Hr'g_551-52).

Five to six generic manufacturers are expected to enter the market in July 2015. JA__ (Berndt_11/12/14_Hr'g_460); JA__ (Solomon_Decl_3). Forest's decision to withdraw IR from general distribution has stopped none of them. After generic IR comes on the market in July 2015, existing XR patients, their caregivers, and physicians will choose between XR's benefits and the possible cost savings of generic IR tablets. Patients who start taking memantine after July will likewise choose between XR and generic IR tablets (or IR oral solution).

Once generic manufacturers introduce generic IR, they have many options for converting XR prescriptions to generic IR. They can advertise to persuade patients, caregivers, and doctors that possible cost savings outweigh XR's once-a-day benefits. JA__ (Clark_Dep_188-90); JA__ (Harper_11/11/14_Hr'g_321-25). They can rely on pharmacies and payors to pressure physicians to prescribe generic IR. JA__ (Kolassa_10/20/14_Decl_6-7). Generic manufacturer Mylan estimates that these tactics will convert up to [redacted] of XR prescriptions to generic IR. JA__ (Berndt_11/12/14_Hr'g_377-78,380,395). Meanwhile, generic manufacturers filed Paragraph IV certifications challenging Forest's XR patents, and seek to introduce generic XR immediately. SA-3. Litigation over the XR patents is pending. *E.g.*, *Forest Labs., Inc. v. Teva Pharm. USA, Inc.*, No. 14-cv-121 (D. Del.).

SUMMARY OF ARGUMENT

The district court entered a sweeping injunction forcing Forest to drop everything and start producing an outdated drug. It should be reversed.

Until the decision below, the standard for obtaining this kind of injunction was supposed to be high. The injunction ordered Forest to change course and restart production of its old drug. New York needed to be clearly right on the merits and make a strong showing of irreparable harm. New York did neither.

Until the decision below, a strong showing of irreparable harm required harms that are both legally cognizable and not compensable with money damages. Worse, the court traduced the company for putting at risk those afflicted with Alzheimer's, yet ignored the FDA and empirical and expert evidence establishing that switching patients from IR to XR is safe. And the court discounted the injunction's irreparable harm to Forest.

Until the decision below, patent law immunized companies from antitrust liability if they simply exercised core patent rights to decide how to price, produce, and distribute patented products. The district court cast that century-old rule aside without even acknowledging it.

Until the decision below, companies had no duty to affirmatively aid competitors by keeping an older product on the market that competes with the

company's new product. The court's rule is unworkable, untenable, and impossible to square with antitrust law as it currently exists.

Until the decision below, injunctions had to be precise and narrowly tailored. Critical questions remain about how Forest can provide IR tablets on terms and conditions prevailing over a 17-month period when those terms and conditions fluctuated. The court also failed to justify the injunction's nationwide scope or why it should apply to patients who start Namenda now.

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Salinger v. Colting*, 607 F.3d 68, 79 (2d Cir. 2010). This Court "review[s] the district court's entry of [a] preliminary injunction for abuse of discretion, which will be found if the district court applies legal standards incorrectly or relies upon clearly erroneous findings of fact, or proceed[s] on the basis of an erroneous view of the applicable law." *Corning Inc. v. PicVue Elecs., Ltd.*, 365 F.3d 156, 157 (2d Cir. 2004) (internal quotations omitted).

ARGUMENT

I. The District Court Applied the Wrong Legal Standard for Relief

The district court's injunction cannot stand under any standard, even the one the court applied. But the court erred at the outset by requiring New York to show merely a likelihood of success on the merits and a "substantial chance" of

irreparable harm, the test for prohibitory preliminary relief. SA-102, SA-131. A "heightened" standard applies when the relief sought is either (1) "mandatory" or (2) "will provide … substantially all the relief sought." *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 34-35 (2d Cir. 1995) (internal quotations omitted). When either condition is met, the plaintiff must make "a clear showing" that its claims would succeed, *id.* at 34, and a "strong" showing of irreparable harm, *Doe v. New York Univ.*, 666 F.2d 761, 773 (2d Cir. 1981). The heightened standard applies here because both conditions are met.

The injunction is mandatory. The district court held otherwise because the injunction supposedly "maintain[s] the status quo." SA-100. But "[t]he distinction between mandatory and prohibitory injunctions … cannot be drawn simply by reference to whether or not the *status quo* is to be maintained or upset." *Abdul Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d Cir. 1985). What matters is "whether [Forest] is being ordered to perform an act." *Id.* *Any* injunction "order[ing] an affirmative act or mandat[ing] a specified course of conduct" is "mandatory." *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 454 F.3d 108, 114 (2d Cir. 2006). If even "one provision … is arguably mandatory," or "arguably alters the status quo" by requiring a defendant to "do[] more than is required" absent the injunction, the "heightened standard" applies. *Tom Doherty*, 60 F.3d at 35.

The injunction's plain language is mandatory. Forest "shall … make Namenda IR … available." SA-137. Forest "shall inform healthcare providers, pharmacists, patients, caregivers, and health plans" of its court-compelled future conduct. SA-137-38. These orders command "positive act[s]." *Tom Doherty*, 60 F.3d at 34. And they upset the "status quo," even if that is considered to be "continu[ing] [Forest's] current Namenda IR sales and distribution activities." SA-100. Forest had stopped making IR batches and has been implementing plans to limit distribution for months. JA__ (Stewart_12/14/14_Decl_4-5). Now the injunction forces Forest to dramatically alter its plans. This Court considered "mandatory" an injunction that would have made a company keep supplying a single patient a drug. *See Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 406 (2d Cir. 2011). This infinitely broader injunction is also mandatory.

Second, the injunction "render[s] a trial on the merits … meaningless." *Tom Doherty*, 60 F.3d at 35. The injunction compels Forest to keep selling IR, not until an as-yet-unscheduled trial, but until "[30] days after July 11, 2015," when generics enter. SA-138. That order would look no different had the court entered a permanent injunction. And there would be no damages to collect, as the injunction will prevent any supposed damages. The injunction has surely given New York "substantially all the relief sought." *Tom Doherty*, 60 F.3d at 34.

II. New York Failed to Show Irreparable Harm

The district court profoundly erred in finding that New York established "irreparable harm[,] … the single most important prerequisite for the issuance of a preliminary injunction." *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009) (internal quotations omitted). The court found that Forest's conduct would harm competition and increase prices once generics enter the market in July 2015. SA-95, SA-131. But even if this harm materialized, it is quintessentially *reparable* harm: it is compensable and readily quantifiable. The court also found irreparable harm on the ground that transitioning patients from IR to XR risks health consequences. SA-55-56, SA-131. But non-economic harms are not grounds for an antitrust injunction. Moreover, the court's finding of risk to Alzheimer's patients is not just unsupported; it is at war with the FDA's judgment, the record, and extensive empirical experience confirming that switching to XR is safe, beneficial, and relieves patients and caregivers' pill burdens. That error is fatal, because "[i]n the absence of evidentiary support of irreparable harm, there [is] no basis for the entry of a preliminary injunction." *Faiveley*, 559 F.3d at 120. New York failed to show a substantial risk of irreparable harm—let alone the strong showing of irreparable harm required to obtain the mandatory injunction here. *Doe*, 666 F.2d at 773.

A. There Is No Irreparable Harm to Competition

The district court's finding of irreparable injury to "competition in the memantine market," SA-131, proves the impropriety of injunctive relief, not its necessity. Even if Forest's conduct were anticompetitive—which it is not, *infra* pp. 40-55—the district court found that any resulting harm to competition is *monetary*, because "[c]onsumers would bear approximately [redacted] in additional co-payment costs and [redacted] in third party payor costs." SA-95; *see* SA-132.

By definition, quantifiable financial harm is not irreparable harm. "[I]t has always been true that irreparable injury means injury for which a monetary award cannot be adequate compensation and that where money damages [are] adequate compensation a preliminary injunction will not issue." *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979). There can be no irreparable injury, and no injunction, when "there is an adequate remedy at law, such as an award of money damages," *Faiveley*, 559 F.3d at 118, or when the court can "'wait[] until the end of trial to resolve the harm,'" *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005). This rule is particularly applicable here, because a "triple-damage antitrust case" would provide "a very liberal rule for the proving of damages." *Jack Kahn Music Co., Inc. v. Baldwin Piano & Organ Co.*, 604 F.2d 755, 763 (2d Cir. 1979). Preliminary injunctions are reserved for

exceptional cases. *Salinger*, 607 F.3d at 79. The district court's ruling would open the floodgates to injunctive relief as a matter of course to any plaintiff claiming predicted monetary harm, and should be reversed.

B. Medical Harm Is Non-Cognizable and Nonexistent

The district court's other basis for finding irreparable harm—medical risk to patients—is neither legally cognizable nor remotely supported by the record. The court found that for some vulnerable patients, "the benefits of the change to Namenda XR are outweighed by the risks of changing the medical routine." SA-55; *see* SA-131.

But courts cannot find irreparable harm warranting an antitrust injunction based on harm that antitrust law does not recognize. *Cargill Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 109, 112 (1986). Medical risk is a grave charge against a pharmaceutical company—which is why Forest sought FDA approval and did clinical studies on the safety of switching from IR to XR, and introduced at trial expert opinion. Medical risk, however, is no basis for an antitrust injunction; antitrust law only remedies economic harms, and this antitrust lawsuit is not the appropriate vehicle for New York to raise health claims. *Infra* pp. 48-49.

In any event, not a shred of evidence supports the court's conclusion. New York did not bother to introduce a single medical expert. The court relied on a fact witness, Dr. Lah, who asserted that "[a]ny small change in medication raises the

risk of an adverse effect." SA-55-56, SA-92. New York made no effort to qualify Lah as an expert. Lah offered no basis for this assertion, knew of no examples of harm, and had not even reviewed the FDA label. JA__ (Lah Dep_73_142_225). He further admitted that he "ha[s] no foundation or basis on which to conclude that … an individual patient will have greater adverse effects going to XR from IR. It's a potential concern, *not a known concern*." JA__ (Lah Dep_289) (emphasis added). The court also cited Dr. Berndt's speculation that switching might be medically disruptive, SA-56, but Berndt is an economics PhD with zero basis for opining about medical risks.

In contrast to this speculation, there is the FDA: XR's FDA-approved label confirms that switching is safe and simple. Namenda XR Package Insert, *supra*, at 2. And there is widespread experience: Some 250,000 patients have already switched from IR to XR; New York identified no harm to any of them. And during XR supply shortages in summer 2014, patients who had switched from IR to XR had to switch from XR back to IR, then back to XR. JA__ (Reisberg_11/13/14_Hr'g_724-26); JA__ (Kohrman_11/13/14_Hr'g_737-42). New York identified no harm to these patients either. On top of that, Forest introduced *five* Alzheimer's experts; all confirm switching is safe. *Supra* p. 19.

There is more: the court's other findings confirm that patients, caregivers, and physicians have *no need* for Namenda IR because XR is an improvement. The

court credited testimony that reducing the pill burden produces an "exponential difference" for Alzheimer's patients and caregivers and that "[m]any controlled clinical trials have also shown that 'extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes.'" SA-35-36. Dr. Lah testified that there was no "market need" for IR once XR came on the market. JA__ (Lah_11/10/14_Hr'g_85). That only confirms that patients are *not* at risk from switching; otherwise, IR would still be needed.

There is no medical risk from switching—but even if there were, distribution through Foundation Care eliminates it. If there are any patients for whom switching presents a medical risk, they will never have to switch; their physicians can sign a one-page form confirming IR's medical necessity. Uncontroverted evidence shows doctors would not hesitate to do so. JA__ (Reisberg_11/13/14_Hr'g_729-30); JA__ (Kohrman_11/13/14_Hr'g_743-45). And there is no cap on how much Namenda IR Foundation Care can supply. JA__ (Saunders_11/11/14_Hr'g_242); JA__ (Kane_11/12/14_Hr'g_551-52). All the district court said on this point was that doctors who saw *no medical need for IR*

whatsoever would be reluctant to sign Foundation Care's form. SA-69. But that just proves Forest's point.[4]

The court's reasoning that "'[a]ny small change in medication'" might hurt certain patients also proves too much. SA-92 (quoting Lah). As New York's Dr. Berndt agreed, "a lot of Alzheimer's patients . . . are going to have a change in their routine when they get the generic memantine." JA__(Berndt_11/12/14 _Hr'g_442). Those generic versions could deliver memantine at a rate and extent that is anywhere between 80-125% of the memantine delivered by Namenda IR. *Supra* pp. 10-12. Generic IR will enter the market without the rigorous clinical safety and efficacy tests that Forest did for Namenda IR. *Id.* Patients could receive drugs from different generic manufacturers with every refill, without choosing this. In short, every refill, patients and caregivers could see drugs with different shapes, sizes, colors, taste, and preservatives that potentially deliver different memantine absorption rates. *Id.* This injunction ensures that cost concerns trump everything else—patient choice, caregiver convenience, and continuity in medication.[5]

[4] The court stated that only 2.4% of patients would be able to obtain the drug under the "'medical necessity' standard." SA-70. Again, no evidence suggests reluctance by doctors worried about medical harm from a change in dosage. Moreover, the 2.4% figure is not a limit on IR's availability for medically needy patients. It is a prediction reflecting the low number of patients who want to stay on IR. SA-67, 70.

[5] Of course state substitution laws allow physicians to write "Dispense as Written" on the prescription so that patients for whom switching could be potentially risky need not switch. But if (as the district court implausibly found) physicians are

Finally, the injunction will delay the launch of Forest's newest fixed-dose-combination innovation, Namzaric, which means two fewer pills for IR patients to take. Those patients, and their caregivers, will lose months of experiencing a beneficial therapy because the court is ordering Forest to instead produce outdated IR tablets. *Infra* pp. 35-40. Even if the district court's finding of irreparable medical harm were correct, the outcome the court ordered is indefensible.

C. The Court Ignored Irreparable Harm to Forest

In any event, the district court erred in holding that the balance of harms favors New York rather than Forest, which suffers demonstrable and significant irreparable harm from the injunction. SA-132-33; *see Random House, Inc. v. Rosetta Books LLC*, 283 F.3d 490, 492 (2d Cir. 2002). Patent law gives Forest an unqualified right to control how it makes, distributes, and sells IR. *Infra* pp. 34-38. The injunction obliterates that right to benefit Forest's future competitors. This infringement upon "the fundamental nature of patents" is alone irreparable harm. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011).

Just complying with the injunction irreparably harms Forest. Until the injunction, Forest no longer made IR. The FDA certified only one Forest plant in Dublin, Ireland to make Namzaric, XR, or IR. The same employees make each

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reluctant to sign a form indicating that Namenda IR is necessary, these same physicians would presumably be reluctant to stop generic substitution with a similar certification.

drug, and the same employees and equipment test them; making IR thus trades off against making XR and developing Namzaric. Obtaining FDA approval for a different factory would take years. JA__ (Stewart_12/14/14_Decl_2-3_). Until the injunction, that factory's Namenda production was exclusively dedicated to XR, and was to begin producing Namzaric, for which XR is a key ingredient. The injunction compels Forest to radically change course and quickly produce IR. Because XR production relies on the same operators and chemists, Forest must alter XR production drastically, which also delays Namzaric's launch. *Id.*; JA__ (Meury_12/12/14_Decl_7). The district court's finding that Forest would face no "hardship" complying with the injunction is inexplicable. SA-133.

Moreover, Forest's business plan is at a critical stage. The injunction compels Forest to abandon the distribution strategy Forest has been pursuing for months, and will force layoffs and retrenchments. New York's economist testified that Forest will lose [redacted] if Forest cannot transition patients to Namenda XR. JA__ (Berndt_11/12/14_Hr'g_425). Forest cannot recover that sum from the State should Forest later prevail. *United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983) (per curiam). And loss of good will, personnel layoffs, and abandonment of research devoted to developing other uses for a drug are irreparable harms. *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342 (S.D.N.Y. 2006), *aff'd*, 470 F.3d 1368, 1382-83 (Fed. Cir. 2006).

III. New York's Antitrust Claims Fail As a Matter of Law

A. Forest's Patent Rights Foreclose Antitrust Liability

1. Because Forest has merely exercised rights afforded by the Patent Act, its conduct does not violate antitrust law. It has been clear for a century that antitrust liability cannot be premised on the exercise of rights granted by the Patent Act. "The patent laws … are in *pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964). "[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market," *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945), and a patentee's decision "to exclude others from the use of the invention … is not an offense against the Anti-Trust Act," *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918).

The Patent Act defines the scope of the patent: it grants a "patentee … or [its] assigns … the right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. § 154. Patent rights are "the compensation which the law grants for the exercise of invention," and "exerti[ng]" those rights "within the field covered by the patent law is not an offense against the [Sherman] Act." *United Shoe*, 247 U.S. at 57. Thus, the "threshold question" in antitrust cases involving the exercise of a valid patent is whether the conduct "exceeds the

scope of the patent grant." *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327 (Fed. Cir. 2000) ("*ISO*").

Of course, conduct not authorized by the Patent Act (*e.g.*, tying or restrictive licensing terms) is subject to antitrust scrutiny.[6] Or if there are serious doubts about the patent's validity and parties collusively settle that litigation, patent law may yield to antitrust scrutiny. *See Actavis*, 133 S. Ct. at 2236. But if the defendant exercises core rights on a valid patent, the "inquiry is at an end." *ISO*, 203 F.3d at 1328. As this Court held, "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws *cannot trigger any liability under the antitrust laws*." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) (emphasis added).

2. The district court considered Forest's patent rights over Namenda IR and XR so irrelevant as to not even warrant mention, and treated this as a garden-variety antitrust case. SA-113-15. It is not. Forest's right to control or stop IR distribution falls in the heartland of its patent rights. The right not to use a patent encompasses the right not to produce, distribute, market, or sell the patented product. "The essential rights of a patentee … include[] the right to suppress the invention." *United States v. Studiengesellschaft Kohle, m.b.H*, 670 F.2d 1122,

[6] Tying arrangements can trigger antitrust liability because a patentee "may not condition the right to use his patent on the licensee's agreement to purchase, use, or sell, or not to purchase, use, or sell another article of commerce not within the scope of his patent monopoly." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 136 (1969).

1127 (D.C. Cir. 1981). It "has been settled doctrine since at least 1896" that "[a] patent owner … has no obligation either to use [the patent] or to grant its use to others." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432-33 (1945). A "court should not presume to determine how a patentee should maximize its reward for investing in innovation. … The market may well dictate that the best use of a patent is to exclude infringing products, rather than market the invention." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995).[7] The Patent Act, in short, gives Forest an unfettered right to make (or not make) and sell (or not sell) as much (or as little) IR as Forest chooses.

If the above precedents were not enough, Congress amended the Patent Act in 1988 to provide that "refus[ing] to … use any rights to the patent" cannot constitute "misuse or illegal extension of the patent right." 35 U.S.C. § 271(d)(4) (1988). That language insulates non-use of a patent from antitrust liability. *See ISO*, 203 F.3d at 1326. Congress knows how to create antitrust carve-outs: the very next subsection provides that certain tying agreements *could* be "misuse or illegal extension of the patent right" if the patentee has "market power in the relevant market." 35 U.S.C. § 271(d)(5). Congress's "use of explicit language" in

[7] *Special Equip. Co. v. Coe*, 324 U.S. 370, 378 (1945) (Congress "did not" "condition[] [patents] upon the use of the patented invention); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940) (patentees have "right to refuse to sell … patented products"); *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908) (patentees can "use or not use [their patents], without question of motive"); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) (en banc) (similar).

Section 271(d)(5) "confirm[s]" the lack of a comparable limitation in Section 271(d)(4). *Marx v. Gen. Revenue Corp.*, 133 S. Ct. 1166, 1177 (2013). And the legislative history demonstrates that Congress intended Section 271(d)(4) to codify this Court's holding in *SCM* that unilaterally refusing to use or license a patented product cannot violate antitrust law. 134 Cong. Rec. H10646, H10648-02 (Oct. 20, 1988) (statement by primary sponsor Rep. Kastenmeier).

Accordingly, New York's claims are barred, because antitrust law cannot proscribe "the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant." *ISO*, 203 F.3d at 1327; *see* 2 ABA Section of Antitrust Law, *Antitrust Law Developments* 1107 (7th ed. 2012) ("[U]nilateral refusal to use … a patent … cannot form the basis for an antitrust claim.").[8]

3. New York asserts that Forest cannot use its patent rights in a way that hampers generic competitors entering the market in July 2015. But the Patent Act confers patent rights for the *entire* patent term. Patents are not designed to ensure that competitors enter the market (much less succeed) the day a patent expires. No court has ever deemed conduct within the scope of the patent a violation of the antitrust laws merely because competitors will find competition tougher later. Instead, a patent includes the right to exclude others from engaging in R&D to

[8] New York does not challenge the IR or XR patents' validity, nor does it dispute that Forest is exercising rights within the scope of those patents. Moreover, "New York has never" argued that Forest engaged in "anticompetitive use of patents." NY Concl. of Law Reply ¶ 23.

develop competing products that would infringe on the patent—even when the result is to delay and impede competitors' market entry post-patent. *Roche Prods., Inc. v. Bolar Pharma. Co., Inc.*, 733 F.2d 858, 864 (Fed. Cir. 1984).[9] Likewise, a firm with a patent monopoly may replace an older product with a newer one during the patent exclusivity period, even if doing so impedes competitors' market entry after the old patent expires. *E.g., Cal. Computer Prods., Inc. v. IBM*, 613 F.2d 727, 744 (9th Cir. 1979) (IBM "had the right to redesign its products …. It was under no duty to help [competitors reliant on its older products] survive or expand.").

New York's contrary rule has no limiting principle, and would inject courts into impossible determinations of how soon into the patent term various patent rights should be curtailed to benefit competitors later. And this rule would allow courts to make basic business decisions about how companies should allocate resources and what products to make. Since the Founding, the federal government has guaranteed patent-holders a limited but absolute right to exclude competition within the scope of the patent. 35 U.S.C. § 154; U.S. Const. art. I, §8, cl. 8. This injunction renders that promise meaningless.

B. Forest's Conduct Would Not Violate Antitrust Law Irrespective of Patents

[9] The Hatch-Waxman Act responded to *Bolar* by authorizing generic drug companies to engage in otherwise infringing research prior to patent expiration. 35 U.S.C. §271(e)(1). Tellingly, Congress did not otherwise limit a patentee's right to affect post-patent competition through pre-expiration exercise of patent rights.

New York's suit would fail even if the Patent Act did not immunize Forest's conduct. Section 2 of the Sherman Act prohibits companies from obtaining or maintaining monopoly power through exclusionary, anticompetitive conduct. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). New York must show that Forest engaged in "the willful acquisition or maintenance of [monopoly] power" through exclusionary conduct, "as distinguished from … a superior product, business acumen, or historic accident." *Verizon Commc'ns, Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S. 398, 407 (2004). New York also must show that this conduct actually had anticompetitive effect. *Cargill*, 479 U.S. at 110-11.

New York's other claims all derive from its Section 2 claim. The court tied its Section 1 ruling—that Forest likely illegally contracted with Foundation Care to distribute IR—to its Section 2 analysis. SA-125. New York's Donnelly Act claim is entirely derivative of the Section 1 claim; that Act does not prohibit unilateral conduct under Section 2. SA-127-28; *Global Reins Corp.-U.S. Branch v. Equitas Ltd.*, 18 N.Y. 3d 722, 731 (N.Y. App. Div. 2012). New York's Executive Law Section 63(12) claim provides another state remedy for the federal claims. SA-128-29. New York is not likely to prevail on these claims, and cannot show a clear entitlement to relief.

1. Forest Did Not Engage in Any Exclusionary Conduct

a. Product Switches Are Not Exclusionary Conduct

Exclusionary conduct is the *sine qua non* of a Section 2 claim. *Trinko*, 540 U.S. at 407. "The antitrust laws … were enacted for the protection of competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (internal quotations omitted). Exclusionary conduct "comprehends at the most behavior that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 n.32 (1985) (internal quotations omitted).

Forest has done nothing to prevent "competition on the merits" by generics. Forest has not locked up generic suppliers or distributors through exclusive dealing contracts. Forest has not engaged in any tying arrangement. Nor has Forest refused to deal with its competitors, denying them the supply of some input or access to some facility necessary for them to compete. All Forest has done is reduce its competitors' ability to free-ride on prescriptions for an older version of Namenda. But preventing free-riding is not anticompetitive or exclusionary conduct and does not violate Section 2. *E.g.*, *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1295 (11th Cir. 2004) (rejecting Section 2 claim where

conduct was intended to prevent free-riding); *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 372-73, 377-78 (7th Cir. 1986) (Posner, J.) (same).

Before July 2015, Forest seeks to limit distribution of its older product so that consumers buy its newer product. That conduct cannot harm competition because, before July 2015, Forest is the only seller of memantine-based drugs. Competition between XR and IR is competition between Forest's own drugs. Such competition within the same firm raises no antitrust concern, as "implement[ing] a single, unitary firm's policies" does not "deprive[] the marketplace of the independent centers of decisionmaking that competition assumes and demands." *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 771 (1984). Even had Forest denied consumers any access to IR—which it will not—product withdrawal is not exclusionary conduct. Refusals to supply customers (like when Coke pulled Coke Classic from the market in favor of New Coke) do not raise antitrust concerns. *E.g.*, *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1358 (Fed. Cir. 1999). And New York's economist Dr. Berndt conceded that patients who switch from IR to XR before July 2015 get a "lower priced product" that is "good for the consumers." JA__ (Berndt_11/12/14_Hr'g_465). The district court confirmed this: the court found that XR substantially benefits patients and caregivers by reducing the pill burden and increasing convenience and compliance. SA-35-36.

After July 2015, Forest's conduct is not anticompetitive. If anything, there will be a surfeit of competition. Five generic manufacturers plan to enter the market in July alone and can compete vigorously. *Supra* p. 21. New York has not alleged that Forest blocked generic IR's approval. *Compare Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 424-28 (D. Del. 2006). Nor has Forest allegedly blocked access to the research and information needed to make generic IR. *Compare In re Suboxone Antitrust Litig.*, 2014 WL 6792663, at *3-4 (E.D. Pa. Dec. 3, 2014). Nor has Forest impeded access to product distribution channels. *Compare United States v. Microsoft Corp.*, 253 F.3d 34, 59-62 (D.C. Cir. 2001) (en banc). Quite the contrary: pharmacies have huge financial incentives to distribute generic IR. The end result: Physicians and patients can choose generic IR if they want it.[10]

[10] The district court's examples of when "[a] monopolist's decision to withdraw a product … constitutes exclusionary conduct," SA-114, reinforce that Forest's conduct is *not* exclusionary. *Glen Holly Entertainment v. Tektronix Inc.*, 352 F.3d 367, 372 (9th Cir. 2003), recognizes that "antitrust laws do not preclude any manufacturer from independently discontinuing a product line." In *Xerox Corp. v. Media Sciences International*, 511 F. Supp. 2d 372, 387-89 (S.D.N.Y. 2007), Xerox was a monopolist in both the color printer and printer ink cartridge markets; it redesigned color printers so that rivals' ink cartridges—which work only with a printer—could not be used. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 n.39 (2d Cir. 1979), similarly hypothesizes that a monopolist in film and camera markets could violate antitrust law if it stopped making film that fit rivals' cameras, rendering rivals' products unusable. But the Supreme Court has never endorsed an "essential facilities" theory, *Trinko*, 540 U.S. at 410-11, and consumers do not need to take Namenda IR for generic IR to work. In *Free Freehand Corp. v. Adobe Systems Inc.*, 852 F. Supp. 2d 1171, 1181 (N.D. Cal. 2012), plaintiffs claimed that conduct lawful in isolation became unlawful in combination. The district court misquoted the decision, which states: "it is reasonable to infer that Adobe's discontinuation of FreeHand, in aggregate with Adobe's other conduct, reduced competition." *Id.* at 1183.

b. Reducing Competitors' Profits from State Substitution Laws Is Not Exclusionary Conduct

The district court concluded that antitrust law "requires [Forest] to allow generic competitors a fair opportunity to compete using state substitution laws" by keeping IR on the market and selling it at significant levels past July 2015. SA-95-96, SA-137-38; *accord* SA-80 ("[S]tate substitution laws" create "the principal means by which generics are able to compete."). According to the court, by reducing the number of IR prescriptions outstanding in July 2015, Forest will violate Section 2 by preventing generic manufacturers from solely relying on state substitution laws to award them 80-90% of sales in July 2015. SA-48, SA-111-12.

Neither the Supreme Court nor this Court has endorsed this type of analysis, which vitiates settled antitrust principles. The injunction compels Forest to continue distributing IR so that its competitors can free-ride on that product to cannibalize its sales. Forest has no such obligation. The Seventh Circuit rejected a competitor's claim that a monopolist that had previously advertised for its rivals had to keep doing so once a competitor "could not survive without access" to this advertising. *Olympia Equip.*, 797 F.2d at 372-33, 377. The court held that "a firm with lawful monopoly power has no general duty to help its competitors, whether by holding a price umbrella over their heads or by otherwise pulling its competitive punches." *Id.* at 375. A competitor "ha[s] no right under antitrust law to take a free ride on its competitors' sales force …. Advertising a competitor's products

free of charge is not a form of cooperation commonly found in competitive markets; it is the antithesis of competition." *Id.* at 377-78; *see Pac. Bell Tel. Co. v. LinkLine Commc'ns, Inc.*, 555 U.S. 438, 449-51 (2009).

New York's theory would require Forest not merely to "help its competitors" through advertising or other indirect assistance, but literally to hand over sales. The more IR Forest produces and sells between now and July 2015, the more prescriptions state law will convert into sales for generic competitors. If a business has no antitrust duty to advertise for its competitors, it certainly has no duty to maximize its competitors' market share.

And the district court's contradictory opinion illustrates the absurdity of imposing such a duty. The court deemed Forest's conduct anticompetitive, yet concluded that Forest could use different means to achieve the *same* outcome of reducing IR sales now to reduce generic IR substitution later. The court stated that "soft switches"—*e.g.*, using marketing to get consumers to change products—were "the industry practice." SA-96-97. A soft switch, the court concluded, is *lawful*, because it "maintains consumer choice before and after generic entry." SA-130. New York's economist, Dr. Berndt, testified that it would *not* be anticompetitive for Forest to increase IR's price "ten fold," which would effectively end demand for IR. JA__ (Berndt_11/12/14_Hr'g_459-60). In other words, it is "a legitimate

soft switch tactic" for Forest to stop selling Namenda IR by eliminating demand, yet limiting IR distribution is somehow unlawful. *See id.*

This nonsensical distinction ignores basic laws of supply and demand and is inimical to antitrust law, which treats charging high prices for a product and refusing to supply it as identical. *E.g.*, *LinkLine*, 555 U.S. at 450 ("[F]or antitrust purposes, there is no reason to distinguish between price and nonprice components of a transaction."); *W.L. Gore & Assocs., Inc. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976) (similar). If a soft switch that prevents state substitution laws from converting Namenda IR prescriptions to generic IR is not exclusionary, *a fortiori* a so-called "hard switch" with the same effect is not either. Equally unclear is how much of a limit on distribution is too much. Would Forest violate antitrust law if only 30,000 of the 59,000 pharmacies that carry IR now would carry it in July? Could Forest announce tomorrow that it will withdraw Namenda IR from the market the day the injunction expires? Nor is it apparent why Forest must keep selling IR 30 days after generic entry, versus 15 or 45. All New York's economist, Dr. Berndt, offered was: "I'm not sure what the rationale" for requiring Forest to keep selling IR past July 2015 "would be other than punitive." JA__ (Berndt_11/12/14_Hr'g_489).

The imponderables and inconsistencies do not end there. New York suggests that the problem here was timing: Forest sought to withdraw IR as it

"fac[ed] imminent" generic entry. JA__ (Am. Compl. ¶ 2). So Forest presumably could have withdrawn IR one or two years before generic entry—yet that would have the same effect, if not greater, on generics. New York says that Forest's conduct is only anticompetitive if its new drug is not "better than the original," or "offer[s] little to no therapeutic advantage over the prior versions." JA__ (Am. Compl. ¶ 33.). So Forest presumably could withdraw IR if a sufficient consensus of scientists (or doctors? or FDA regulators?) rated XR's benefits highly enough over IR. Antitrust law cannot turn on such arbitrary and unworkable distinctions.

c. Antitrust Law Is Not a Vehicle For Enforcing the Spirit of Drug Laws

The district court found that Forest "attempt[s] to manipulate the regulatory system," SA-29, and "violat[e] the spirit of the Hatch-Waxman Act," SA-135. But even if Hatch-Waxman or state substitution laws imposed a duty on Forest to keep selling IR for generics' benefit (they do not), that would be irrelevant to New York's antitrust claims. The Supreme Court rejected a nearly identical argument in *Trinko*, finding that Verizon's duty under the Telecommunications Act to aid a competitor does "not automatically lead to the conclusion that [this duty] can be enforced by means of an antitrust claim." 540 U.S. at 406; *see In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014).

If antitrust law is unavailable to enforce actual regulatory obligations, it is not a vehicle for enforcing laws that *permit* the conduct at issue. Forest's conduct

violates neither Hatch-Waxman nor state substitution laws, and no one has suggested otherwise. (That is presumably why the district court (SA-135) invoked their "spirit.") And Congress passed Hatch-Waxman to encourage brand innovation and facilitate generic entry into the market, not to guarantee generic manufacturers total market dominance thereafter. *Supra* pp. 10-11.

Moreover, New York has a remedy that will not explode the reach of antitrust law. New York's claim stems from the fact that if patients in July 2015 are on XR rather than IR, New York's generic substitution law does not automatically convert those prescriptions into generic IR. But that is only because New York's law considers drugs of different dosages too different for pharmacists to automatically substitute them. No federal law imposes this rule. New York actually posits that drugs of different dosages—here, XR and IR—are "virtually identical." JA__ (Am. Compl. ¶ 4). If so, New York can amend its law and make pharmacists substitute generic IR for Namenda XR.

At bottom, the district court's approach makes it impossible to apply the Sherman Act on a uniform, nationwide basis. If changing the effect of generic substitution laws is an antitrust violation, it exists only in states where pharmacists can automatically substitute generic IR for Namenda IR but not XR. But in up to 20 other states, there is no violation; pharmacists can substitute generic IR for XR. *Supra* p. 13. Courts, however, must interpret antitrust law in ways that guarantee

"clear rules" that require minimal judicial supervision. *LinkLine*, 555 U.S. at 452-53. The Sherman Act's meaning cannot turn on the vicissitudes of state law.

2. Forest's Conduct Will Not Have Anticompetitive Effects

The anticompetitive harms that the district court predicted do not support liability. The court found that generics do not advertise, and if they must start instead of relying on state substitution laws, they will have to raise prices. SA-78-79. But the need to advertise is proof of effective competition, not its absence. When a company "obligate[s] [its competitor] to increase its own advertising, competition [is] only enhanced," because "advertising and promotion [are] essential to vigorous market rivalry." *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 674-75 (D.C. Cir. 2005). The court's finding also is clearly erroneous; New York's own competition expert testified that generics can use general marketing effectively to generate sales, and can form joint ventures to advertise. JA__ (Berndt_11/12/14_Hr'g_462-63).

The district court found that inducing physicians to switch patients to XR risks harming patients whose health could be jeopardized by "[a]ny small change in medication." SA-92 (quoting Lah). Even if this finding were supportable—it is not, *supra* pp. 28-32—antitrust law remedies only "injur[y] [to] business or property," *i.e.*, economic "loss or damage." 15 U.S.C. §§ 15(a), 26. The terms "'business or property' …. *exclude personal injuries suffered*." *Reiter v. Sonotone*

Corp., 442 U.S. 330, 339 (1979) (emphasis added). Concerns about "public safety" and health may be part of other statutes, but importing them into the Sherman Act "would be tantamount to a repeal of the statute" and "a frontal assault on [its] basic policy." *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 690 (1978). If New York sought to vindicate such concerns, it should have sued under another law.

The district court found that if patients are doing well on Namenda XR, physicians might not switch patients to generic IR come July 2015. SA-72, 90-91, 120-21. But the first firm in a market often enjoys an incumbency advantage by virtue of having had a lawful monopoly before new competitors enter, and new entrants always bear the burden of convincing customers to switch. The advantage of being first is precisely the type of reward for "superior skill, foresight and industry" that antitrust law encourages. *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945) (Hand, J.).

Undoubtedly, trying to persuade physicians and patients to switch to generic IR—*i.e.*, *competing*—takes greater effort from generic manufacturers than relying on the coercive effect of state substitution laws. But antitrust law encourages that additional effort, which in any event entails a single phone call from pharmacists to persuade physicians to switch the patient to generic IR. *See* SA-58. And the record belies the notion that such competitive efforts are doomed to fail. Were that

so, no slew of generic manufacturers would be expected to enter the market in July and October 2015. And once they enter, the wind will be at their sails, regardless of state substitution laws: using powerful incentives and leverage, third-party payors and pharmacists will pressure physicians, patients, and caregivers to switch to generic IR. *Supra* pp. 14-15.[11]

The district court found that Forest's conduct limits patients' choices, and patients and insurance companies may ultimately pay more. SA-91, SA-131-32. But as noted, before July 2015 this harm is illusory. The loss of choice among a single firm's products is not anticompetitive (even if that firm is a monopolist), and XR costs less than IR. *Supra* p. 41. After July 2015, patients lose no choice. They can choose among generic IR, XR, Namzaric (once it launches), and IR oral solution. New York's substitution law will work as intended: unless doctors specify otherwise, pharmacists will fill Namenda IR prescriptions with generic IR. If patients and insurance companies pay more for memantine-based drugs, that is the market's choice. Claims that conduct "has the effect of reducing consumers' choices or increasing prices to consumers do[] not sufficiently allege an injury to

[11] The only contrary evidence came from New York's witness David Stitt, who is employed by a minor regional healthcare provider and concedes he does not know how his company will act in July 2015, or know about state substitution laws or conditions outside New York. JA__(Stitt_11/10/14_Hr'g_137,152-53). The court erred in relying on Stitt for generalizations about the national market.

competition," because "[b]oth effects are fully consistent with a free, competitive market." *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012).[12]

3. Forest's Conduct Is Procompetitive

a. New York's claims independently fail because Forest's conduct is *pro*competitive. Forest's 2013 introduction of XR eliminated any market need for IR tablets. Forest then sought to maximize its return on its investment in XR. That is the kind of behavior antitrust law encourages. The Sherman Act must be interpreted in ways that "safeguard the incentive to innovate," *Trinko*, 540 U.S. at 407, and "any dampening of technological innovation would be at cross-purposes with antitrust law," *Microsoft*, 147 F.3d at 948. Launching a new product, like Forest did here, advances competition by adding a better product to the market and by paving the way for further innovation.

This is a case in point. The Patent and Trademark Office issued patents for Namenda IR and XR, and the FDA, through its arduous approval process, confirmed that both drugs are safe and therapeutically beneficial. That alone shows these products are not shams created just to thwart generics. Moreover, Forest worked to develop XR because the market demands once-daily drugs; every other Alzheimer's drug is once-daily. *See* SA-35. Extensive record evidence

[12] *Accord Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 867 (D.C. Cir. 2008); *Doctor's Hosp. of Jefferson, Inc. v. S.E. Med. Alliance, Inc.*, 123 F.3d 301, 310 (5th Cir. 1997).

confirms that XR offers significant benefits over twice-daily IR. Once-daily dosing reduces risk of a missed dose; alleviates burdens on caregivers who manage complex pill schedules; helps patients suffering dementia who resist pills; and makes it easier for patients to stay with their families for longer. *Supra* pp. 17-18.

Unrebutted testimony from Forest's five expert medical witnesses confirms these conclusions. *Supra* pp. 19-20. New York's fact witness Dr. Lah agreed that with XR, there is no "market need" for IR tablets. (Lah_11/10/14_Hr'g_85). While the district court castigated follow-on drugs that "offer little to no therapeutic advantage over the prior formulation," SA-29, the court *credited* testimony about XR's benefits. SA-35. It would have been impossible for Forest to develop Namzaric without including the XR formulation. JA__ (Stewart_12/14/14_Decl_2-5). And empirical evidence confirms that much of the market prefers XR to IR. JA__ (Meury_11/13/14_Hr'g_607-08). As Actavis's CEO explained, "[W]hat we hoped for and what we'll have to see what plays out when generic competitors enter the market in 2015 is do patients and physicians and caregivers, you know, view the innovation of XR important enough to pay for it … [P]eople will have that chance to vote with their wallets." JA__ (Saunders_11/11/14_Hr'g_203); *see* JA__ (Hausman_10/21/14_Decl_8-9).

Withdrawing an old drug while promoting a new one is also procompetitive. Preventing "free-riding" by competitors is a legitimate business purpose. *See*

Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 55 (1977). And Forest's conduct is common in the pharmaceutical industry. In 2002, Allergan withdrew its older glaucoma treatment to favor a new version with a different preservative; generics entered a year later and still captured a 50% market share. JA__ (Kolassa_10/20/14_Decl_App'x-1_2-3). In 2011, ISTA Pharmaceuticals stopped selling its twice-daily anti-inflammatory drug, and promoted a once-daily version. Again, generics captured significant sales after entering the market months later. Other examples abound. JA__ (Kolassa_10/20/14_Decl_2-5,Appx-1).

The district court also found that Forest's conduct would cost Forest short-term profits from IR sales. SA-123. But short-term costs do "not distinguish anticompetitive from procompetitive uses of innovation." Areeda & Hovenkamp, Antitrust Law, ¶ 651 (2014). The court ignored the above procompetitive justifications, and discounted the more than [redacted] in additional XR sales that Forest stood to earn.

The court also found that "[c]ontinuing to keep IR tablets available is highly unlikely to have any impact on [Forest's] incentive to innovate," because Forest previously "launched 8-9 new drugs" without limiting distribution. SA-76. But this injunction compels Forest to produce a first-generation, 10-year-old drug with no market need. And Forest must do so at the expense of selling new and improved XR or launching Namzaric because of its production constraints. The

injunction thus impedes Forest's ability to bring newer innovations to the marketplace *at this very moment*. *See* JA__ (Meury_12/12/14_Decl_10-11), JA__ (Stewart_12/14/14_Decl_2-5).

b. New York contends that Forest's conduct cannot be procompetitive because XR is not "truly" innovative. *E.g.*, JA__ (Am. Compl. ¶ 33). Overwhelming evidence refutes that position. *Supra* pp. 19-20, 31-32. But the dangers of this position bear emphasis. Under this theory, courts—not scientists, regulators, or markets—decide when a new version of a drug is sufficiently ingenious to avoid antitrust liability. If changing dosage form halted all patient deterioration, Forest could presumably pull IR from the market with impunity. Yet any benefits short of this—including, apparently, XR's conceded benefits of convenience and patient compliance—are not innovative enough. Courts are not equipped to make these kinds of medical and scientific judgments, let alone to second-guess the judgments the PTO and FDA already made.

4. New York's Section 1 Claim Independently Fails

New York's Section 1 (and Donnelly Act) claims rest on the counterintuitive theory that Forest violated antitrust law by agreeing to distribute IR through Foundation Care, rather than pulling IR entirely. Rather than looking at the effects of this distribution agreement, the district court reasoned that Forest's conduct was

anticompetitive under Section 2; thus, any agreements that advanced this conduct violated Section 1 also. SA-125-26.

That was the wrong inquiry under Section 1, which only prohibits agreements that "unreasonabl[y] restrain … trade." *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006). To hold that Section 1 is violated just because of the predicted (not actual) impact Forest's change in distribution would have on the market, New York had to identify collusive conduct that is *per se* anticompetitive. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885-86 (2007). It did not.

Forest's agreement with Foundation Care is subject to the rule of reason, because "[a] manufacturer of course generally has the right to deal, or refuse to deal, with whomever it likes." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984). An "exclusive distributorship arrangement[]" thus is "presumptively legal" under Section 1. *E & L Consulting*, 472 F.3d at 30 (internal quotations omitted). Alleging that customers had less choice in suppliers, or even paid higher prices, "is not a sufficient allegation of harm to competition caused by the exclusive distributorship." *Id*. Rather, such agreements violate Section 1 only if they "will have an actual adverse effect on competition in the relevant market," which requires more than a reduction in the number of firms that distribute Forest's products. *Elecs. Commc'ns Corp. v. Toshiba Am. Consumer Prods., Inc.*, 129 F.3d

240, 244 (2d Cir. 1997). Because Forest's agreement to distribute IR solely through Foundation Care does not harm generic competition, it is of no concern to antitrust law. *E.g.*, *Cowley v. Braden Indus., Inc.*, 613 F.2d 751, 755 (9th Cir. 1980). That is especially true because there is zero evidence that Forest agreed with Foundation Care to cap IR sales. Undisputed evidence shows the contrary. JA__ (Saunders_11/11/14_Hr'g_242); JA__ (Kane_11/12/14_Hr'g_551-52).

The district court's reasoning would open the floodgates to antitrust liability. Any subsidiary agreement a Section 2 defendant entered into would trigger separate Section 1 liability. And all counterparties to these subsidiary agreements could face Section 1 liability as well.

IV. The Injunction Is Vague and Overbroad

Independent of anything else, this Court must vacate the injunction as impermissibly vague and overbroad. An injunction must "state its terms specifically" and "describe in reasonable detail … [the] acts sought to be restrained." Fed. R. Civ. P. 65(d). Any order that fails to do so "will not withstand appellate scrutiny," because of "the dangers inherent in the threat of a contempt citation for violation of an order so vague that an enjoined party may unwittingly and unintentionally transcend its bounds." *Corning*, 365 F.3d at 158. Likewise, "courts must take care to ensure that injunctive relief is not overbroad," because "a court is only empowered to grant relief no broader than necessary to cure the

effects of the harm caused by the violation." *City of New York v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d Cir. 2011) (internal quotations omitted). The district court ignored these maxims.

1. The injunction orders Forest to "make" IR "available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)." SA-137. Given how terms and conditions have shifted over the past 17 months, that is an unintelligible command. IR's price fluctuated both in absolute terms and relative to XR. Adding to the confusion, XR entered the market in June 2013, not July. *Supra* p. 19. The only conduct the injunction specifically prohibits is for Forest to "impose a 'medical necessity' requirement or form for the filling of prescriptions of Namenda IR." SA-138. It is simply "not possible to ascertain from the four corners of the order precisely what acts are forbidden." *Corning*, 365 F.3d at 158 (internal quotation marks omitted).

At the injunction hearing, Forest's counsel sought clarification of what the "same terms and conditions" means. JA__ (12/15/14_Hr'g_47). No clarification came. The court responded, "Let's stop right there. … You have been negotiating with distributors over this entire period. If you do it consistent with what you have been doing, I don't see why it isn't consistent … but I am not going to give you any absolution absent the facts." *Id.* The court elaborated: "I am not unaware of the difficulties that this creates for the parties," but "I am not going to interpret the

language any more than you all. You will have to see what you think it means. I think I know what it means, but we will see." JA__ (12/15/14_Hr'g_47-48). Forest's counsel followed up: "[O]ne question we have … is whether [the order] freezes the price exactly at the price as of that date." JA__ (12/15/14_Hr'g_48). The court replied: "[Y]ou will have to make your own conclusion," and added, "I am not going to change the words. Good luck." *Id.*

Understanding what an injunction means should not require luck. The injunction must "state its terms specifically." Fed. R. Civ. P. 65(d). But this injunction's ambiguity places "the entire conduct of [Forest's] business under the jeopardy of punishment for contempt for violating the injunction." *Sanders v. Air Line Pilots Assoc., Int'l*, 473 F.2d 244, 248 (2d Cir. 1972). The Supreme Court has vacated injunctions that vaguely enjoined defendants from "enforc[ing] 'the[ir] present [] scheme.'" *Schmidt v. Lessard*, 414 U.S. 473, 476-77 (1974). This Court has similarly vacated injunctions that compel defendants to take "appropriate prophylactic measures" without specifying particular conduct. *Mickalis Pawn*, 645 F.3d at 144. Ordering Forest to conform its conduct to undefined, shifting conditions over a 17-month period likewise deprives Forest of "explicit notice of precisely what conduct is outlawed." *Schmidt*, 414 U.S. at 476. On pain of contempt, Forest must apply to the court to approve decisions concerning IR going

forward—exactly the kind of economic micromanagement that the Supreme Court rejects in antitrust cases. *E.g.*, *Linkline*, 555 U.S. at 452-54.

2. The nationwide injunction (*see* SA-137-38) is also fatally overbroad. Under New York's theory, there is no antitrust harm in the up to 20 states whose generic substitution laws allow pharmacists to automatically substitute generic IR for Namenda XR. In those states, generics can still capture 80-90% of sales, averting all alleged antitrust harms. *Supra* pp. 15-16. This alone was an abuse of discretion. *E.g.*, *Emergency One, Inc. v. Am. Fire Eagle Engine Co., Inc.*, 332 F.3d 264, 274 (4th Cir. 2003) (vacating "nationwide injunction" absent "factual basis" for finding nationwide violation). Nor is this defect easily remedied. On remand, the court would have to parse states' varying generic substitution laws to determine which states allow this type of substitution. Some states, for instance, leave substitutability up to pharmacists' professional judgments. *E.g.*, Minn. Stat. Ann. § 151.21. Determining what that means, and whether generic IR can be substituted for Namenda XR, is a state-by-state task. This is why state laws should not control what the Sherman Act means.

The injunction is also overbroad because it forces Forest to offer IR tablets to *new* patients until 30 days after generic entry on July 11. SA-137-38. The district court's reasoning did not remotely justify this. Patients whose doctors decide to prescribe them a memantine-based drug after generic entry start from

scratch. They have no prescriptions for state substitution laws to convert into generic IR prescriptions. Yet the injunction compels Forest to offer new patients an old prescription drug. And the complexity of distinguishing between new and existing patients would require additional fact-finding. This is why courts should not seize control and supervision of day-to-day business operations.

CONCLUSION

The district court's injunction breaks dangerous new ground. No court before has nullified a manufacturer's valid patent rights and commandeered its factory to aid future competitors. No federal agency has this power. Even the FDA, with its extraordinary control over the pharmaceutical industry, cannot "require a company to manufacture a drug, maintain a certain level of inventory … or reverse a business decision to cease manufacturing." FDA, *Strategic Plan for Preventing and Mitigating Drug Shortages*, at 6 (Oct. 2013), http://1.usa.gov/1xEUBAC. Allowing courts to assume these powers is unprecedented, dangerous, and unwarranted. The decision and injunction below should be reversed.

Dated: January 8, 2015

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

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14-4624

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General

Plaintiffs-Appellees,

v.

ACTAVIS plc AND FOREST LABORATORIES, LLC

Defendants-Appellants.

FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
CASE NO. 14-CV-7473 (RWS)

SPECIAL APPENDIX (UNDER SEAL)

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

14 Civ. 7473

-against-

REDACTED OPINION*

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

----------X

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* The initial opinion was filed under seal to protect any confidential information asserted by the parties. Redactions have been made as determined by the prior opinion of the Court, dated October 24, 2014.

Sweet, D.J.

The plaintiff, the People of the State of New York (the "State" or the "Plaintiff"), has moved pursuant to Rule 65 of the Federal Rules of Civil Procedure to preliminarily enjoin the defendants, Actavis, PLC ("Actavis") and Forest Laboratories, LLC ("Forest") (collectively, the "Defendants"), from engaging in antitrust violations by discontinuing the current sales of the Forest drug Namenda IR, used in the treatment of Alzheimer's disease, currently scheduled to take effect on January 1, 2015. Based on the findings of fact and conclusions of law set forth below, the motion is granted, and a preliminary injunction will issue.

This motion involves one piece of the complicated mosaic that is the health care sector in the United States. At issue is the competition between Forest, a manufacturer of branded and patented drugs to treat Alzheimer's disease, and manufacturers that produce generic equivalents, as well as the effect of that competition on consumers. This competition has been the subject of federal and state legislation and is of great importance to pharmaceutical companies, patients, physicians, pharmacists, insurers, health plans, and regulators.

The issue is significant because of the particular needs of patients afflicted by Alzheimer's, the process by which prescription drugs are created and sold, and the economic significance of Forest's Namenda drugs, which had annual sales of over $1.5 billion in last year.

The idiosyncrasies of competition in this market were captured by the State's expert, Dr. Ernst Berndt:

> I think the phrase goes, he who consumes doesn't pay, and he who buys is not held accountable. . . . So we have this multiplicity of prices. We have the price received by the manufacturer and we have the total revenues received by the pharmacy. And we have the reimbursement to the pharmacy and a copayment by the patient. Who the consumer is ultimately a bit ambiguous.

Tr. 368:1-7 (Berndt).

Able and skilled counsel have assisted the court with their presentations of the complicated and significant issues raised by the State's antitrust and state law violation claims. In addition, this excellent performance has been rendered under the difficult conditions imposed by the march of time and the controlling external events.[1]

[1] The calendar has also dictated the timing of the issuance of this opinion. While the issues are deserving of an exhaustive treatment, their significance requires resolution in time to permit the possibility of appellate review.

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing Special Appendix (Under Seal) for Defendants-Appellants Actavis PLC and Forest Laboratories, LLC to be served on counsel for Plaintiff-Appellee via Hand Delivery:

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I certify that six hard copies of the foregoing Special Appendix (Under Seal) for Defendants-Appellants Actavis PLC and Forest Laboratories, LLC were sent via Hand Delivery to:

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January 8, 2014

/s/ Lisa S. Blatt
Lisa S. Blatt

Prior Proceedings

On February 28, 2014, the Antitrust Bureau of the Office of the Attorney General of the State of New York (the "Bureau") opened an investigation into Forest's business plans regarding the pharmaceutical product Namenda, a therapy approved to treat Alzheimer's disease by the Food and Drug Administration ("FDA").

The State filed an initial complaint on September 15, 2014, followed by an Amended Complaint ("AC") on November 5, 2014, alleging that Defendants violated federal and state antitrust laws by attempting to improperly maintain and extend a monopoly over the Namenda drug. The AC sought injunctive relief requiring Defendants to keep the original form of the drug, Namenda IR, available on the market and to prevent the Defendants from in effect requiring patients to switch a new patent-protected form, Namenda XR.

The AC contains allegations describing: the parties (AC ¶¶ 12-15); the regulatory framework and relevant federal regulations, including the Food Drug and Cosmetic Act, 21 USC § 301 et seq., the Drug Price Competition and Patent Term

Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (AC ¶¶ 16-20); state generic substitution laws (AC ¶¶ 21-27); and the effect of generic competition and brand name manufacturers' tactics to evade them (AC ¶¶ 28-43).

The AC also contains allegations with respect to: Alzheimer's disease and the relevant products (AC ¶¶ 44-45); and the relevant market (AC ¶¶ 46-63), including memantine that is branded and marketed as Namenda by Defendants; Namenda's recent annual sales in excess of $1.5 billion in the United States; the extension of the Namenda patent; and the anticipated entry of generic competition in July 2015. The AC further alleges that the Defendants have made efforts to stall the effects of generic entry in the market (AC ¶¶ 64-97), including the launch of Namenda XR in June 2013 and the effort to convert patients from Namenda IR to Namenda XR and the implementation and subsequent modification of a scheme to force patients to switch to the new formulation. The AC alleges the anticompetitive effect of the conduct of the Defendants (AC ¶¶ 98-104) and their conduct in exaggerating the imminence of the plan to force switches (AC ¶¶ 105-119).

Six causes of action are alleged: (1) monopolization in violation of Section 2 of the Sherman Act; (2) attempted monopolization in violation of Section 2 of the Sherman Act; (3) unreasonable restraint of trade in violation of Section 1 of the Sherman Act; (4) violation of the Donnelly Act, New York General Business Law Section 340 et seq.; (5) repeated or persistent illegality in violation of Section 63(12) of the New York Executive Law; and (6) repeated or persistent fraud, in violation of Section 63(12) of New York Executive Law.

The AC seeks: (i) a decree that Defendants violated the statutory provisions in the six causes of action outlined above; (ii) disgorgement of proceeds from illegal activity, repayment of monies gained from unjust enrichment, and payment of restitution and damages to injured parties; (iii) preliminary and permanent injunctive relief barring Defendants from discontinuing Namenda IR until generic memantine becomes available, barring Defendants from other violations of law and other equitable relief necessary to redress Defendants' purported violations of law; (iv) civil penalties, damages and restitution for violations of state laws, including the Donnelly Act; and (v) attorneys' fees.

The State moved pursuant to Rule 65 of the Federal Rules of Civil Procedure for a preliminary injunction. The motion was heard and evidence adduced from November 10 to November 14, 2014, and final arguments were heard and the motion was marked fully submitted on November 24, 2014.

Certain materials submitted to the Court have been designated confidential. In order to protect that confidentiality, a public version of this opinion will not be filed for twenty-four hours to give the parties an opportunity to request redactions.

Evidence

The following witnesses provided live or written testimony with respect to these proceedings:

Dr. Ernst Berndt ("Dr. Berndt")	Louis E. Seley Professor of Applied Economics at the Massachusetts Institute of Technology
Mr. Dan Blakely, R.Ph. ("Blakely")	Chief Executive Office of Foundation Care (an Actavis Vendor)
Mr. Napoleon Clark ("Clark")	Executive Director for Marketing - U.S. Generics at Actavis
Dr. Pierre Y. Cremieux ("Dr. Cremieux")	Managing Principal at Analysis Group
Mr. Mark Devlin ("Devlin")	Senior Vice President Managed Markets at Actavis
Ms. Babette Edgar ("Edgar")	Principal at BluePeak Advisors
Dr. Steven Ferris ("Dr. Ferris")	Gerald D. and Dorothy R. Friedman Professor of New York University's Alzheimer's Disease Center
Mr. Jason Harper ("Harper")	Director of Marketing at Mylan Pharms.
Dr. Jerry Hausman ("Hausman")	McDonald Professor of Economics at Massachusetts Institute of Technology
Dr. Alan Jacobs ("Dr. Jacobs")	Neurologist in private practice
Mr. William Kane ("Kane")	Vice President of Marketing Internal Medicine at Actavis
Dr. Bruce Kohrman ("Kohrman")	Neurologist in private practice
Dr. E. Mick Kolassa ("Dr. Kolassa")	Chairman and Managing Partner of Medical Marketing Economics
Dr. James J. Lah, MD, PhD ("Dr. Lah")	Associate Professor of Neurology at Emory University Medical Center Director of Emory Cognitive Neurology Program Associate Director of Alzheimer's Disease Research Center
Mr. William Meury ("Meury")	Executive Vice-President of Commercial Operations for the North American Brands Division at Actavis
Ms. LuMarie Polivka-West ("Polivka-West")	Vice-President and Senior Director of Policy and Program Development for the Florida Health Care Association
Dr. Barry Reisberg ("Dr. Reisberg")	Psychiatrist, Alzheimer's Disease Center of the New York University Langone Medical Center
Dr. Barry Rovner ("Dr. Rovner")	Professor of Psychiatry and Neurology at the Signey Kimmel Medical College of Thomas Jefferson University

Mr. Brenton Saunders ("Saunders")	Chief Executive Officer of Actavis (former Chief Executive Officer of Forest Labs.)
Mr. David F. Solomon ("Solomon")	Partner at Hildred Capital Partners, LLC (former Senior Vice President of Corporate Development and Strategy of Forest Labs.)
Mr. Robert Stewart ("Stewart")	Chief Operating Officer of Actavis
Mr. David F. Stitt, R. Ph. ("Stitt")	Director of Pharmacy at a New York-based health plan (MVP Health Care)
Dr. Marco Taglietti ("Dr. Taglietti")	Senior Vice President for Research & Development at Actavis
Mr. Kevin Walsh ("Walsh")	Senior Vice-President of Operations at Actavis

In addition to live witness testimony, the State presented 581 exhibits and the Defendants presented 835. One hundred fifty-one exhibits were referenced during the testimony of the witnesses.

Findings of Fact

I. The Parties

1. The State, by its Attorney General, brought this action in its capacity as parens patriae and also as an "indirect purchaser of Namenda." Amended Complaint ("AC") ¶ 9.

2. Defendant Actavis is a public limited company registered in Ireland and headquartered at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. It manufactures and sells generic drugs. In July 2014, Actavis acquired Forest. Tr. 192:8-10 (Saunders). Forest is a Delaware limited liability company with an office at Morris Corporate Center, 400 Interpace Parkway, Parsippany, New Jersey and at various New York locations. It manufactures and sells a number of branded pharmaceutical products including memantine hydrochloride (HCL) drugs in the form of Namenda IR tablets, Namenda IR oral solution, and Namenda XR capsules. See Press Release, Forest Labs., Forest Laboratories to Discontinue NAMENDA Tablets, Focus on Once-Daily NAMENDA XR (DX499) (Feb. 14, 2014). Defendants' United States revenues from Namenda were approximately $1.6 billion in Forest's 2014 fiscal year, and total sales stand to grow

consistent with the epidemiological projection that the number of Americans living with Alzheimers will triple by 2050. Tr. 612:16-22 (Meury); Forest 10-K (PX48) at 56; Rovner (PX358) ¶ 20.

II. Background

A. Alzheimer's Disease

3. As Dr. Ferris testified, "Alzheimer's disease is a progressive, irreversible, incurable disease of the brain that is the most common cause of dementia worldwide." Ferris Decl. ¶ 11. "Current pharmacotherapies offer only symptomatic benefits." Ferris Decl. (PX276) ¶ 13. The disease afflicts more than five million people in the United States and is the sixth leading cause of death in United States. Ferris Decl. ¶ 11; see also Rovner Decl. (PX358) ¶ 20. As the population continues to live longer, the number of people living with Alzheimer's is expected to triple by 2050. Rovner Decl. (PX358) ¶ 20. The visible signs of Alzheimer's include problems with memory and other cognitive functions, social skills, planning, and judgment. Ferris Decl. (PX276) ¶ 11. Patients also develop neuropsychiatric problems including apathy, depression, agitation, and delusions. Ferris Decl. (PX276) ¶ 11; see also

Reisberg Dep. 173:16-24. As the disease progresses, patients become completely dependent on their caregivers as they gradually lose the ability to perform routine activities of daily living. Ferris Decl. (PX276) ¶ 11; Kohrman Dep. 130:25-131:10; Reisberg Hr'g 728:18:729:4. In the final stages of the disease, patients require skilled nursing and intensive supportive care. Ferris Decl. (PX276) ¶ 11; Reisberg Dep. 176:2-177:17.

4. New York in 2014 has about 380,000 people living with Alzheimer's disease, and 1 million non-professional caregivers who provide 1.1 billion hours of care at an unpaid value of $14.3 billion each year. See Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, 10 J. Alzheimer's Assoc. e47 (2014) (DX360); Rovner Decl. (PX358) ¶ 21. This caregiving is draining emotionally and physically and becomes more difficult and prolonged because patients with advanced disability can survive many years. Rovner Decl. (PX358) ¶ 21. Most persons with Alzheimer's are cared for at home by spouses and adult children or by professional caregivers in long-term care-facilities. Rovner Decl. (PX358) ¶ 21. About one in seven people with Alzheimer's live alone. Rovner Decl. (PX358) ¶ 23.

5. In 2013, caregivers provided unpaid care valued at more than $220 billion and the burden of providing that care imposed more than $9 billion in additional health care costs on the caregivers themselves. Cremieux ¶ 19 (PX229); Polivka-West Hr'g 621:7-9, 24-25.

B. Number of Prescriptions

6. Although the record does not establish the total number of Namenda prescriptions, the latest estimates are that Namenda IR and Namenda XR each have 50% of the market, as defined below. Defendants' CEO has stated that there are hundreds of thousands of Namenda IR prescriptions. Tr. 242:7-12 (Saunders). A fair approximation of the number of prescriptions is in the neighborhood of 500,000. See Tr. 165:15-21 (Stitt).

C. Available Drugs

7. The FDA has approved five drugs to treat Alzheimer's disease: Aricept, Cognex, Exelon, Razadyne, and Namenda, four of which currently are on the market. Lah Decl. (PX85) ¶ 5. Cognex was withdrawn from the market in 2012 because it was toxic. Rovner Dep. 50:23-51:3; Ferris Dep.

96:20-98:14. All these drugs except Namenda are acetylcholinesterase inhibitors ("CIs") and work in the same basic manner. Tr. 53:1-5 (Lah); Lah Decl. (PX85) ¶ 6. CIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. Jacobs Dep. 92:14-93:10; 102:6-19.

8. Namenda is an N-Methyl D-Aspartate ("NMDA") receptor antagonist and works differently from CIs. AC ¶ 47; Tr. 53:10-12; 63:18-64:1 (Lah); Lah Decl. (PX85) ¶ 7; Namenda Franchise Business Plan (PX24) at FRX-NY-01686843 ("CIs work on the acetylcholine pathway while Namenda works on the glutamate pathway."). As Dr. Jacobs explained:

> Neurons in the brain communicate by signaling each other. Some of these signals are transmitted through an influx of calcium into a molecule on the surface of neurons called the NMDA receptor. This influx of calcium is triggered when glutamate, an excitatory neurotransmitter, docks at the NMDA receptor, causing the calcium influx. When patients enter the moderate stage of Alzheimer's disease, there can be overexcitation of the NMDA receptor by glutamate.

Jacobs ¶ 24 (CD Ex. 11); see also Ferris Dep. 99:14-16 (CD Ex. 27). Namenda works by "partially blocking the NMDA receptor to

prevent overexcitation, which can cause toxicity to neurons in the brain." Jacobs ¶ 24 (CD Ex. 11).

9. Currently, the two forms of Namenda produced and sold by Forest, Namenda IR tablets and liquid solution, and Namenda XR capsules, are the only available NMDA receptor antagonists approved to treat Alzheimer's disease. Lah Decl. (PX85) ¶ 7. The active ingredient in both Namenda formulations is memantine HCL. Jacobs ¶ 24 (CD Ex. 11); AC ¶ 47.

D. Stakeholders in the U.S. Healthcare Industry

10. Defendants are one of the complex array of stakeholders comprising the healthcare industry in the United States. See Tr. 368:1-7 (Berndt).

11. Suppliers in this industry include academics and relatively small start-up companies that conduct the initial research necessary to develop medically-promising chemical compounds; large branded pharmaceutical companies such as Forest whose business focuses on developing the medically-promising chemical compounds into saleable patent-protected and FDA-approved medicines, and generic pharmaceutical companies such as Actavis and third-party witness Mylan Pharmaceutical ("Mylan")

whose business focuses on low-cost production of the branded companies' drugs once those medicines have lost patent-exclusivity. See Tr. 236:20-237:20, 246:12-247:06 (Saunders).

12. Depending on the nature of the drug being considered, several intermediaries stand between a supplier and the ultimate end-user, i.e., the patient.

13. One intermediary is the FDA. As the main federal regulator in the industry, the FDA determines which medications can be marketed, whether a drug requires a physician's prescription to be dispensed, and how that drug may be marketed.

14. Another set of intermediaries are physicians and other medical professionals. If the medication is a prescription drug, this group determines which drugs to prescribe, in consultation with their patients. See Tr. 727:3-17 (Reisberg). Pharmacists, either working in traditional brick-and-mortar or mail-order pharmacies, dispense the medications and process payment for the medications. See Kolassa Decl. (DX821) ¶¶ 33, 52.

15. Depending on a patient's morbidity, caregivers comprise yet another group of intermediaries. Caregivers,

whether family members, friends or professional caregivers, may administer or assist the patient in taking the medication.

16. The final group of intermediaries are the third party payors, entities that pay all or part of the costs of a prescription drug on behalf of patients. Kolassa Decl. (DX821) ¶ 31. These include insurance companies and health plans, such as third party witness MVP Health Care ("MVP"). Kolassa Decl. (DX821) ¶ 31; Stitt (PX122) ¶ 4.

17. Typically, third party payors employ several strategies to manage costs. They generate a drug formulary, a list of approved drugs that will be paid for by the health plan (in whole or in part) when an insured patient fills a prescription. Kolassa Decl. (DX821) ¶ 34. A health insurer's drug formulary typically explains what drugs are covered, as well as the level of cost sharing the health plan requires the patient to bear. Kolassa Decl. (DX821) ¶ 34. Pharmacies enjoy larger profit margins on generic versus branded medications. Kolassa Decl. (DX821) ¶ 26.

18. Third party payors sometimes engage pharmacy benefit management companies (PBMs) to assist them in managing

their prescription drug costs. Kolassa Decl. (DX821) ¶ 31 and fn. 27.

19. Third party payors may also require patients to pay a portion of the costs of a drug as a "co-payment" or "co-pay." Kolassa Dep. 156:7-12; Kolassa Decl. (DX821) ¶ 34. This is often accomplished through a tiered co-pay system imposed in conjunction with the formulary file. Kolassa Decl. (DX821) ¶ 37. A typical three-tiered system has tier 1 reserved for generic drugs, tier 2 for preferred branded drugs, and tier 3 for non-preferred branded drugs. Kolassa Decl. (DX821) ¶ 37. The co-pays increase with each tier. Kolassa Decl. (DX821) ¶ 37. Tier 1 co-pays for generic drugs are commonly $10 or less and are sometimes $0. Kolassa Decl. (DX821) ¶ 37. By contrast, tier 3 co-pays for non-preferred brands are commonly between $50 and $90. Kolassa Decl. (DX821) ¶ 37.

20. Step therapy is another third party payor cost savings tool that rejects insurance coverage for a drug until the patient attempts unsuccessfully to take a preferred, usually less costly, alternative for that drug. Kolassa Decl. (DX821) ¶ 41.

21. Finally, third party payors attempt to educate patients and doctors about low-cost alternatives to branded medications, and occasionally implement programs to incentivize doctors and pharmacists to prescribe low-cost drugs. Kolassa Decl. (DX821) ¶¶ 20-21, 28-28.

E. Competition and Regulation

22. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), governs the manufacturing, sale and marketing of pharmaceuticals in the United States. Pursuant to the FDCA, a company seeking to bring a new drug to market must submit a New Drug Application ("NDA") with FDA and provide scientific data demonstrating that the drug is safe and effective. 21 U.S.C. 355(b)(1). The process for obtaining FDA approval of an NDA can be costly and time consuming. Berndt Decl. (PX64) ¶¶ 11-12; Tr. 339:13-18 (Berndt).

23. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Act"), which was intended to facilitate competition from lower-priced generic drugs while also providing further incentives for pharmaceutical companies by extending

patent protection. Tr. 338:22-340:18 (Berndt); Berndt Decl. (PX64) ¶ 12.

24. By creating benefits, limits, and incentives for both generic and branded pharmaceutical manufacturers, the Hatch-Waxman Act attempted to balance the competing policy goals of encouraging innovation and expediting patient access to less expensive versions of branded drugs. Tr. 338:22-340:18 (Berndt); Berndt Decl. (PX64) ¶ 12; H.R. Rep. No. 98-857, Pt. 1, 14-17 (1984). The Act has been variously characterized as the "grand compromise" between pharmaceutical companies with patent exclusivity and generic manufacturers and as the "thumb on the scales" in favor of generics. Tr. 228:1-12 (Saunders); Tr. 339:19-22 (Berndt).

25. Under the Hatch-Waxman Act, a company seeking to market a generic version of a drug that has an NDA may obtain FDA approval by filing an Abbreviated New Drug Application ("ANDA"), and demonstrating that its generic version is "bioequivalent" to the drug that has an NDA. Tr. 338:19-340:9 (Berndt). By permitting the generic to rely on studies submitted by the NDA applicant (the branded drug manufacturer),

the Act reduces development cost and speeds up FDA approval for generics. Tr. 339:19-340:9 (Berndt).

26. As part of the legislative compromise underlying the Hatch-Waxman Act and its amendments, the Hatch-Waxman Act includes several provisions that grant branded drug manufacturers opportunities to lengthen their exclusivity period beyond the twenty-year term of a patent. The Act allows a branded drug manufacturer to seek up to a five-year patent extension to compensate for time lost during the FDA regulatory process. 35 U.S.C. § 156; Tr. 340:15-340:18 (Berndt); Berndt Decl. (PX64) ¶ 92. In addition, a branded manufacturer may obtain an additional six months of "pediatric exclusivity" after the expiration of the life of its patent, if the manufacturer conducts pediatric studies of its drug that meet certain requirements. 35 U.S.C. § 156; 21 U.S.C. § 355a; Berndt Decl. (PX64) ¶ 92. The Hatch-Waxman Act has twin goals: (i) to encourage generic entry when a branded firm's patent is invalid or not infringed; and (ii) to ensure that the branded firm's patent exclusivity, as well as the branded product's market exclusivity, are appropriately protected. The Hatch-Waxman Act, like the patent laws, incentivizes research by helping to preserve lawful patent and regulatory monopolies, which allows

branded firms to better recover the upfront costs of their innovations, including for drug research and development. AC ¶ 17; Cremieux Decl. (PX229) ¶ 12.

27. State generic substitution laws aim to encourage generic drug sales. New York, prior to the Hatch-Waxman Act enactment in 1984, enacted drug substitution laws that require a pharmacist filling a prescription for a branded drug to substitute a less-expensive, therapeutically equivalent generic drug, unless a physician directs otherwise. See N.Y. Educ. Law § 6816-a; Tr. 115:8-117:4 (Stitt); Tr. 342:13-343:14 (Berndt); Berndt Decl. (PX64) ¶¶ 45-47; Tr. 222:12-222:25 (Saunders). Eleven other states enacted similar legislation. See Tr. 467:16-20 (Berndt); Jesse C. Vivian, Generic-Substitution Laws, U.S. Pharmacist (DX731) (June 19, 2008) at 3 tbl. 2. There are 40 additional states that permit generic substitutions. Id.

28. State substitution laws operate to facilitate lower cost generics because they allow or require a pharmacist to provide a patient with a lower-cost generic drug without contacting the doctor to change the prescription. Tr. 797:19-798:20 (Kolassa). Generics compete on price at the pharmacy and take business from higher-priced brands. Tr. 115:8-117:4

(Stitt); Stitt Decl. (PX122) ¶ 21; Tr. 342:13-343:24 (Berndt); Tr. 897:13-22 (Cremieux). This competition results in reduced drug costs for patients and health plans after generic entry and still provides patients with the same therapeutic benefits as the brand. Tr. 113:16-114:20 (Stitt). An important limitation of generic substitution laws is that they generally permit a pharmacist to dispense a less-expensive generic drug instead of the branded drug only if the FDA approves the generic drug as "AB-rated" to the branded drug. Berndt Decl. (PX64) ¶¶ 45-47; Tr. 342:18-22 (Berndt); Stitt Decl. (PX122) ¶ 21. To be "AB-rated" to a branded drug, the generic drug must not only have the same active ingredient, but also the same form, dosage, strength, and safety and efficacy profile. Zain Decl. Ex. 5 (U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations, Preface (32d ed. 2012)); Tr. 342:2-12 (Berndt).

29. In permissive substitution jurisdictions, managed care organizations and other third party payors encourage generic substitution at the pharmacy, such that any heterogeneity between mandatory and permissive states is negated in practice. Berndt Hr'g 343:11-14 ("And so even though there is variability across states in the specifics of state

substitution laws, in practice there is relatively little heterogeneity.").

30. Price competition at the pharmacy, facilitated by state generic substitution laws, is the principal means by which generics are able to compete in the United States. Tr. 409:6-11 (Berndt); Stitt Decl. (PX122) ¶ 22 ("[T]he substitution of AB-rated generic drugs for the branded equivalents, through the applicability of state generic substitution laws, is the only method by which generic drugs achieve significant sales.");

[redacted]; Tr. 351:10-14; 353:1-8; 376:12-17 (Berndt).

31. Generic drugs are usually priced substantially below their brand-name drug equivalents. According to an FDA study using average retail drug prices between 1999 and 2004, entry of multiple generic competitors can reduce prices to as little as 20% of the branded price—in other words, an 80% discount. Tr. 376:12-17 (Berndt).

32. When the branded manufacturer's exclusivity ends and multiple generics enter the market, a branded drug often loses more than 80-90% of its market share within six months. Saunders Dep. 44:8-21; Tr. 802:5-8 (Kolassa), 376:12-17 (Berndt). Defendants' CEO saw this result of the statutory scheme as stacking the deck against Forest. Tr. 202:18-21 (Saunders) ("[T]he entire healthcare system is designed to benefit the generic companies and put up barriers and obstacles to the innovative companies, and so that's why you generally see the market shift 90/99 percent towards the generics."). This tradeoff of longer exclusivity rights for branded manufacturers like Forest, in return for quick and effective generic entry after loss of exclusivity, is the fundamental premise behind the policies and procedures that Congress enacted in the Hatch-Waxman Act, and which New York and other states embraced in their substitution laws. Berndt Decl. (PX64) ¶ 12-19; Tr. 339:19-340:18 (Berndt).

33. According to a 2013 study commissioned by the Generic Pharmaceutical Association, over the 10-year period from 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the U.S. health care system by reduction in price over the branded drug. Generic Pharm. Ass'n, Generic

Drug Savings in the U.S. (PX8) at 1 (2013). In 2012, generic drugs saved the health system $217 billion. Id. Once patent exclusivity is lost, and generic entry occurs, the brand name manufacturer can expect a sharp drop in revenue, as it must choose between either competing by significantly lowering prices or accepting dramatically lower sales volume. This sharp drop in revenue has been referred to in this litigation and in the industry as the "patent cliff." Tr. 192:18-193:1 (Saunders), 386:2-11 (Berndt).

34. This AB-rated requirement, while intended to ensure therapeutic equivalence to the branded drug, provides an opportunity for branded manufacturers to game the system through a practice termed "product hopping." Tr. 453:19-454:12 (Berndt). For a drug that is about to go-off the "patent cliff," the drug manufacturer develops a "follow-on" version of the drug with a later patent expiration, and encourages patients and their physicians to switch to the new version. See Berndt Decl. (PX64) ¶ 41. As found above, the generic of the original version of the drug will not be "AB-rated" to the follow-on branded drug. Thus, if physicians write prescriptions for the follow-on version instead of the original, the generic entry is not dispensed even if, in practice, the cost savings offered by

the generic may outweigh any advantage offered by the new version of the branded drug.

35. Sometimes, these follow-on drugs may be better than the original version. Tr. 456:19-457:12 (Berndt). In other instances, the new drugs offer little to no therapeutic advantage over the prior formulation, and the reformulation is merely an attempt to manipulate the regulatory system and interfere with effective price competition between branded and generic drugs at the pharmacy. Tr. 453:19-454:12 (Berndt).

36. A branded manufacturer may use various tactics to encourage physicians and patients to switch to its new follow-on drug. Typically, the company will aggressively promote the follow-on drug and remove marketing effort behind the original drug, what has been termed a "soft switch." Berndt Decl. (PX64) ¶ 41; Tr. 221:5-9 (Saunders). A brand manufacturer that has successfully achieved a switch to a follow-on product can expect that most "switched" patients will not make a second switch back to the original product. Tr. 374:1-22 (Berndt).

III. The Development of the Namenda Franchise

A. The Success of Namenda IR

37. In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 held by Germany's Merz Pharma GmbH & Co. KGaA. In December 2002, Forest submitted an NDA to the FDA, seeking approval to market memantine HCL tablets (5mg and 10mg) branded as "Namenda" for the treatment of Alzheimer's. U.S. Food & Drug Admin., NDA 21-487 Approval Letter (DX782) (Oct. 16, 2003).

38. On October 16, 2003, the FDA approved Namenda Instant Release Tablets ("Namenda" or "Namenda IR") for the treatment of moderate-to-severe Alzheimer's disease. FDA Approval Letter, Application No. 21-487 from Robert Temple, Dir., Office of Drug Evaluation I, Ctr. for Drug Evaluation & Research, to Doreen V. Morgan, Forest Labs., Inc. (PX10) (Oct. 16, 2003). Forest brought Namenda IR to market in January of 2004. Press Release, Forest Labs., Inc., Namenda(TM) (memantine HCl), First Drug Approved For Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (PX11) (Jan. 13, 2004). Forest sought and received a five-year patent extension as compensation for the time spent obtaining FDA approval for Namenda tablets. 35 U.S.C. § 156; Tr. 340:15-340:18 (Berndt); Berndt Decl. (PX64) ¶ 92. As a result, Forest's main patent for

Namenda IR, the '703 patent, expires on April 11, 2015. U.S. Patent and Trademark Office, Patent Term Extensions (PX12).

39. At the time of the launch of Namenda IR tablets in January 2004, Namenda IR was the first and only medication approved for patients with moderate-to-severe Alzheimer's disease. See Tr. 124:21-125:09 (Stitt). Clinical trials established that Namenda IR is both safe and efficacious as a monotherapy. Reisberg Dep. 156:19-157:19, 196:12-199:20 (discussing the studies); Press Release, Forest Labs., Namenda(TM) (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (DX484) (Jan. 13, 2004). Leading Alzheimer's experts confirm the salutary effect Namenda has made in the everyday lives of Alzheimer's patients. See Reisberg Decl. (PX352) ¶ 24; Rovner Decl. (PX358) ¶ 39. Alzheimer's patients taking Namenda more easily perform "common activities of daily living such as eating, walking, toileting, bathing, and dressing." Press Release, Forest Labs., Namenda(TM) (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (DX484) (Jan. 13, 2004). Namenda IR is administered twice a day. Lah Dep. 191:4-6.

40. In 2005, Forest introduced a liquid form of Namenda IR (often referred to as an "oral solution") for patients who have difficulty swallowing tablets, although any Namenda patient can take it. Meury Decl. (DX720) ¶ 7; Lah Decl. (PX85) ¶ 13; Lah Dep. (DX487) 192:10-13; see also Jacobs Dep. 104:23-105:9 (CD Ex. 41); Rovner Dep. 210:2-13 (CD Ex. 28); Reisberg Dep. 117:5-118:6; Solomon Decl. (DX718) ¶ 6. Namenda IR oral solution is an immediate-release product that has the same active ingredient as Namenda IR tablets and is as effective as the tablets. See Lah Dep. (DX487) 186:16-25, 191:4-23, 284:8:14. The oral solution originally was covered by the same FDA-approved label as the tablets. Namenda Package Insert (DX456) (Oct. 2013); Lah Dep. (DX487) 284:15-22. As of August 2014, the tablets and the oral solution are covered under separate labels. See Namenda Oral Solution Package Insert (Aug. 2014) (CD Ex. 47). Like Namenda IR tablets, the oral solution should be administered twice a day. Lah Dep. (DX487) 191:4-6; Jacobs Decl. (CD Ex. 11) ¶ 25; Ferris Decl. (CD Ex. 20) ¶ 15; Kohrman Decl. (CD Ex. 15) ¶ 21; Reisberg Decl. (CD Ex. 13) ¶ 25; Rovner Decl. (CD Ex. 18) ¶ 31; Meury Decl. (DX720) ¶ 9; Solomon Decl. (CD Ex. 16) ¶ 7.

41. In 2009 and 2010, Forest, as a resolution of patent litigation, entered into licensing agreements with ten generic competitors allowing for the sale of generic memantine ("generic Namenda" or "generic IR") tablets on July 11, 2015, three months before Forest's exclusivity ends, or earlier in certain circumstances. See also Solomon Decl. (DX718) ¶¶ 13-14; Press Release, Forest Labs., Forest and Merz Pharma GmbH & Co. KGaA Settle Namenda IR Patent Litigation (DX781) (July 22, 2010). Five generic manufacturers have obtained and currently maintain tentative approval from the FDA to market their generic versions of Namenda IR tablets as early as July 11, 2015. Solomon Decl. (DX718) ¶ 14. Seven more generic competitors may begin selling their generic versions of generic Namenda IR tablets as early as October 11, 2015. Solomon Decl. (DX718) ¶ 16.

42. In 2009, Forest began a large program to evaluate whether memantine could be approved to treat pediatric autism at the FDA's "official request," known as a "Pediatric Written Request" ("PWR"). Taglietti Decl. ¶¶ 25-26; Taglietti Dep. (CD Ex. 42) 235:8-236:19; Solomon Dep. (CD Ex. 39) 227:20-237:8 (explaining full background of autism studies). On June 18, 2014, Forest announced that FDA had granted its request for

pediatric exclusivity, extending Forest's exclusivity rights for another six months. Press Release, Forest Labs., Inc., Forest Obtains Six Months U.S. Pediatric Exclusivity for Namenda R and Namenda XR (PX13) (June 18, 2014). This extended the patent exclusivity to October 11, 2015. Solomon Decl. (DX16) ¶ 15.

43. Forest invested almost $70 million in support of clinical studies for the treatment of pediatric autism. Taglietti Decl. (DX303) ¶ 25; Saunders Dep. (CD Ex. 38) 318:13-17. At that time, it was the "largest study ever done on autistic patients." Taglietti Dep. (CD Ex. 42) 237:3-7. In designing and running these clinical studies for pediatric autism, Forest "developed for the first time a network of over 185 clinical study sites for autism that had never existed before." Taglietti Decl. (DX303) ¶ 28.

44. Sales of Namenda IR for 2013 have exceeded $1.5 billion and 2012 had similar results. Kolassa Decl. (DX821) ¶ 5; Nikhil Nayak email re: FW: Namenda Manager's Meeting Draft Script (PX70) at FRX-NY-01634297.

B. Introduction of Namenda XR And Its Place In The Franchise

45. Between 2006 and 2014, Forest invested approximately [redacted] in R&D for an improved version of Namenda: a once-daily extended release capsule called Namenda XR. Meury Decl. (DX720) ¶¶ 5, 8. All currently marketed symptomatic treatments for Alzheimer's disease had already moved to once-a-day treatments before the introduction of Namenda XR. Ferris Dep. 107:16-109:9; Reisberg Dep. 165:23-166:8.

46. As Dr. Reisberg testified:

> [T]here is an exponential difference between being able to take a medicine once daily versus twice daily. And I think all of us have taken medications know this, that it's much easier to take a medicine once a day than twice a day. But these differences become very much compounded for my patients. So persons with Alzheimer's disease are frequently older, and older people take more medications than younger people. And persons with memory problems have difficulty taking medication.

Reisberg Hr'g 727:6-728:8; Reisberg Dep. 136:5-137:8. All Defendants' medical experts echoed Dr. Reisberg's statements. Kohrman Hr'g 740:1-9; Rovner Dep. 271:16-25; Ferris Dep. 317:17-318:11; Jacobs Dep. 217:20-219:15. Fewer pills generally lead to greater compliance with treatment. Lah Hr'g 95:5-7; Lah Dep. 137:13-138:24; Kohrman Decl. (PX315) ¶¶ 3, 24-28 (once-daily dosing increases compliance); Reisberg Decl. (PX352) ¶¶ 30-31;

Rovner Decl. (PX358) ¶ 37; Ferris Dep. 112:8-10; Jacobs Dep. 218:24-220:16.

47. "Many controlled clinical trials have also shown that 'extended-release agents are associated with improved tolerability, greater patient adherence to treatment, reduced total treatment costs, and better long-term clinical outcomes.'" Cremieux (PX229) ¶ 18. Some Alzheimer's disease patients experience "sundowning," which is the "tendency for some patients with Alzheimer's disease to become more confused, anxious, paranoid, [and] restless later in the day than earlier in the day." Rovner Dep. 245:8-14; Kohrman Hr'g 740:3-9; Polivka-West Dep. 120:10-121:6. As Dr. Lah testified, "sundowning may lead to agitation" which "may make it more difficult to get the patient the medication they need." Lah Hr'g 98:18-99:2; Lah Dep. 173:16-18; see also Rovner Dep. 247:21-248:2 (reporting that half of his sundowning patients have trouble taking medication at night); Rovner Decl. (PX358) ¶¶ 41-42; Ferris Decl. (PX276) ¶ 41; Hausman Hr'g 714:13-15 (acknowledging caregiver burden and difficulties associated with getting patients to take a drug in the afternoon).

48. Forest is the sole owner (through its subsidiary) or exclusive licensee of all patents covering Namenda XR listed in the Orange Book. See Food & Drug Admin., Orange Book: Approved Drug Products with Therapeutic Equivalence Functions (DX388) (2014). The FDA approved once-daily Namenda XR in June 2010. Meury IH Tr. (DX488) 160:22-24; Taglietti Dep. 166:20-22 (CD Ex. 42). The patents that cover Namenda XR expire in 2029, several years after those covering the original Namenda IR. Tr. 598:21-599:1 (Meury); U.S. Food & Drug Admin., Orange Book: Approve Drug Products with Therapeutic Equivalence Evaluations (PX18). Forest is in litigation with potential generic competitors over these patents [redacted]. Tr. 203:8-23 (Saunders).

49. In the summer of 2011, Forest worked with market research firm GfK Healthcare to learn more about caregiver burdens and preferences and obtain caregiver feedback regarding Namenda and a potential Namenda XR combination therapy. GfK Healthcare, 2011 Alzheimer's Disease Caregiver Study (CD Ex. 4) (Aug. 15, 2011). In late 2012, GfK surveyed physicians on behalf of Forest, in part, to gauge awareness of the upcoming Namenda XR. GfK Healthcare, 2012 Alzheimer's Disease Physician

Study (CD Ex. 3) (Dec. 20, 2012). Forest conducted further research in the spring of 2013. GfK Healthcare, Namenda Caregiver Research, Final Presentation (DX496) (May 2013).

50. In the 2013 survey, caregivers reported that they viewed Namenda XR as a "meaningful and welcome improvement" over the twice-a-day Namenda IR tablets. Id. at 6, 33 (emphasis added). Eighty percent of caregivers interviewed responded that they were likely to ask the patients' physicians about Namenda XR. Id. at 33.

51. Defendants obtained survey results that 90% of physicians support the switch from Namenda IR to Namenda XR. Tr. 34:18-22 (showing slide and citing 93% approval for discontinuation plan in opening statement). However, the 90% figure is based on a single question that sought a rating from 1 to 10, but first instructed the physicians to assume caregiver and patient satisfaction. Tr. 505:7-506:17. Other open-ended questions indicate that some doctors were outraged by the forced switch scheme. Tr. 513:17-18.

52. Forest did not bring Namenda XR to market until July 21, 2013. FDA Approval Letter, Application No. 22-525 from Russell Katz Dir., Div. of Neurology Prods., Office of Drug

Evaluation I, Ctr. for Drug Evaluation & Research, to Michael P. Niebo, Forest Labs., Inc. (PX20) (June 21, 2010); Press Release, Forest Labs., Inc., Forest Announces U.S. Availability of New Once-Daily NAMENDA XR (PX21) (June 13, 2013). At that time, generic competition for Namenda IR was imminent, and Namenda XR was needed to accomplish the product extension strategy to protect its share of the market.

53. Forest spent approximately [redacted] educating patients, caregivers, health care providers, and pharmacists about Namenda XR, including Namenda XR's benefits and FDA-approved instructions for transitioning from Namenda IR to Namenda XR. Namenda XR Package Insert § 2.2 (Sept. 2014) (DX368); Meury Decl. ¶ 10 (DX720); Hausman Decl. ¶ 22 (PX287). After launching Namenda XR, Forest sold Namenda IR tablets, IR oral solution, and Namenda XR capsules concurrently. Taglietti Decl. ¶ 29 (DX303).

54. Namenda XR has the same therapeutic effect as Namenda IR but because of its one-a-day dosage it can reduce costs based on the number of pills administered by a caregiver, the time expended in pill administration. Tr. 59:12-13 (Lah).

55. Defendants are in the process of developing and/or marketing another future product, a Fixed Dose Combination ("FDC"), that combines Namenda XR with donepezil, the once-a-day CI, in one pill. Meury Decl. (DX720) ¶ 9; see Taglietti Decl. (DX303) ¶¶ 17-20; Meury Dep. 26:24-27:2. Defendants are currently seeking FDA approval for the FDC product. Saunders Hr'g 272:23-273:3.

IV. Defendants Have Monopoly Power

A. Medical Practice Demonstrates Memantine Is Its Own Market

56. In practice, doctors commonly prescribe a CI in the early stage of the disease. Tr. 54:12-18 (Lah); Tr. 732:21-733:4 (Reisberg). Namenda is prescribed in the moderate-to-severe stages, in addition to the CI, or alone if CIs cannot be tolerated due to side effects. Lah Decl. (PX85) ¶ 9; Tr. 54:19-55:1 (Lah); Tr. 732:21-733:4 (Reisberg); Tr. 760:1-6, 760:16-24 (Kohrman); Jacobs Dep. 92:14-93:10; 102:6-19 (explaining that all patients who clinically qualify to take a CI are prescribed one unless they have side effects, and explaining the differences between the functions of memantine and CIs); Jacobs

Dep. 102:6-19 ("[T]he cholinesterase inhibitor will be most effective when there is cholinergic deficiency at the same time that there is neurons around to utilize the return of acetylcholine and . . . memantine will be more effective any time the brain cells are leaking calcium"); Rovner Dep. 68:25-69:11 ("Q. They complement one another, would you say? A. They work in different ways, and tackle the problem from different directions, but they all have the same focus. Q. So they work with differing mechanisms? A. That's right."); see also "Namenda Franchise Business Plan" (PX68) at FRX-NY-01648216 ("As Aricept is indicated for mild patients it is usually initiated first. Namenda is usually added when the patient progresses to the moderate stage of the disease . . . .").

57. Namenda IR is not indicated for use with mild-stage Alzheimer's Disease patients. FDA "Highlights of Prescribing Information (PX109) (Sept. 2014). Using Namenda for early Alzheimer's patients has little clinical support. Press Release, Forest Labs., Inc., Forest Laboratories Announces FDA Decision on Supplemental New Drug Application for Namenda® (PX43) (Jul. 25, 2005).

58. Doctors do not consider CIs to be reasonable substitutes for Namenda. Tr. 63:18-64:1 (Lah); Lah Decl. (PX85) ¶ 7 ("To the best of my knowledge, there are not therapeutic substitutes for Namenda currently on the market"), ¶ 10 ("Almost all of my patients who take Namenda also take a CI. The two drugs are not interchangeable; rather, they seem to have the greatest beneficial effect when they are used together"); Tr. 760:15-24 (Kohrman) ("[I]n the mild stage of the disease the typical way of approaching this is that . . . I will prescribe a cholinesterase inhibitor, calling it a CI . . . and if they progress into the moderate or moderate to severe stage, at that point continuing the cholinesterase inhibitor, I will add Namenda to that regimen"); Jacobs Dep. 106:7-23 ("I . . . start with a cholinesterase inhibitor, because I am usually seeing them earlier in the phase of their dementia syndrome, and then try to get them on both drugs because that's two different types of good band-aids to help them think better.").

59. Doctors do not switch patients from Namenda to a more affordable CI because they are not substitutes for one another. Tr. 63:18-64:1 (Lah) ("Q. Did you consider switching your patients on Namenda IR to a cholinesterase inhibitor? A. No. Q. Why not? A. That wouldn't make any sense. Q. Why not?

A. The drugs very different. So Namenda works by an entirely different mechanism than any of the cholinesterase inhibitors, so they're not equivalent drugs.")

60. Instead, the two classes of drugs are complements: 70% of Namenda patients also take an ACI. Tr. 609:9-19 (Meury); Namenda Franchise Business Plan (PX24) at FRX-NY-01686842; Forest Laboratories Management Discusses Q2 2014 Results, Earnings Call Transcript at 4 (PX485); Jennifer Rinaldo email re: Namenda and Carip Business Reviews (PX68) at FRX-NY-01648216; Tr. 883:11-14 (Cremieux).

61. Even in instances where memantine is prescribed without a CI, i.e., as a monotherapy, it is the severity of the CIs' side-effects that eliminates that class of drugs altogether as a viable therapy. Lah Decl. (PX85) ¶ 9; Tr. 54:19-55:1 (Lah); Tr. 732:21-733:4 (Reisberg); Tr. 760:1-6, 760:16-24 (Kohrman); Jacobs Dep. 92:14-93:10, 102:6-19.

62. Thus, whether prescribed alongside CIs or as a monotherapy, medical practice establishes that memantine is not a substitute for CIs.

B. Empirical Analysis Demonstrates Memantine Is Its Own Market

63. The economic evidence also establishes that CIs are not reasonable substitutes for Namenda. Tr. 346:16-348:8; 351:17-20: 352:3-5; Tr. 358:16-20 (Berndt); Berndt Decl. (PX64) ¶¶ 23-28; Tr. 359:15-361:2 (Berndt) (discussing PX331).

64. Dr. Berndt's study of the cross elasticity of demand between Namenda IR and a generic form of one of the CIs, donepezil, demonstrated little to no switching from Namenda to donepezil when the relative price of donepezil fell. Tr. 351:3-20 (Berndt); Tr. 346:16-351:15; 351:25-6; 352:7-22 (Berndt); Berndt Decl. ¶¶ 29-32. This pattern continued for a number of years after the relative drop in donepezil's price, in fact memantine's demand slightly increased following the donepezil relative price reduction, suggesting the two medications are complements rather than substitutes. Tr. 355:14-356:4 (Berndt). This finding establishes a low cross elasticity of demand between the two drugs, and supports the State's contention that memantine and CIs do not comprise one market of competing Alzheimer's drugs.

65. Dr. Cremieux's, Defendants' expert's, conclusion that cross elasticity of demand between memantine and donepezil

was substantial is not as persuasive as Dr. Berndt's. Dr. Cremieux's conclusions were based on a data sample of approximately less than 600 prescriptions from one employer. Tr. 362:11-363:11 (Berndt). By contrast, Dr. Berndt's conclusion was based upon the behavior of multiple payors, representing over one million prescriptions pulled from the entire U.S. market. Tr. 362:11-363:11 (Berndt). Moreover, Dr. Cremieux's dataset reflected changes to patients' copayments alone, while Dr. Berndt's data included both health plan and patient costs. Tr. 367:10-9 (Berndt).

66. Dr. Cremieux's other principal analysis is based upon a 2013 Forest study documenting "reversals," i.e., where a Namenda XR patient does not fill his prescription, and "rejections," i.e., where a Namenda XR patient's insurance company refuses to pay for Namenda XR. See DX093; Cremieux Dep. 165:15-168. Patient reversals are not useful proxies for substitutability. Substitutability assumes that changes in relative price result in changes in demand. Reversals in this data set, on the other hand, do not control for other non-price factors that may affect a patient's decision to refuse XR, such as an increase in negative side-effects when switching from CIs to memantine. Payor rejections are likewise ill-suited to a substitutability analysis. Defendants study shows that [redacted] of

those Namenda XR prescriptions that were rejected by payors were filled with another product. DX093 at slides 2, 6. Of this [redacted] group, about [redacted] were filled with Namenda IR, and roughly the remaining [redacted] were filled with a CI. [redacted] But an insurer refusal to pay for the Namenda XR is equivalent to a highly significant price increase on that drug since the patient sees his effective price shift from the co-payment to the full retail price of the drug. Therefore, the ratio of the two, the cross-elasticity, is too small to demonstrate substitutability.

67. To the extent that Dr. Berndt's and Dr. Cremieux's cross elasticity of demand analyses conflict, Dr. Berndt's relatively data-rich analysis is more credible.

C. Defendants' Business Strategy Demonstrates Memantine Is Its Own Market

68. In addition to medical practice and empirical evidence, Defendants' own withdrawal strategy illustrates that CIs are not substitutes for NMDA receptor antagonists such as Namenda IR. If they were, Forest's withdrawal of Namenda IR

from the market would drive Namenda patients to CIs, many of which are much less expensive than Namenda XR. Indeed, it is the complementary nature of CIs and memantine that gives Defendants' FDC product a comparative advantage. Meury Hr'g 566:4-23; see also Hausman Hr'g 664:11-665:6. Meury Decl. ¶ 9 (DX720); see Taglietti ¶¶ 17-20 (DX303); Meury Dep. 26:24-27:2. Defendants are experienced producers in the market that have premised their Namenda IR strategy on the absence of substitutes for memantine. Defendants' studies predict that approximately [redacted] or more of Namenda IR patients will switch to Namenda XR as a result of the intended discontinuation. Presentation titled "Namenda IR & XR Conversion Plan" (PX31). In January 2013, a Forest employee expressed confidence that discontinuing Namenda would likely be successful because, unlike other attempts to pursue similar product extension strategies, "there are no alternatives" to Namenda—"although of course patients could simply stop taking the drug." Presentation titled "Namenda IR & XR Conversion Plan" (PX31) at FRX-NY-01575875. This was so, even though donepezil (the generic version of Aricept) has been and continues to be priced significantly lower than Namenda XR. Tr. 892:8-25 (Cremieux).

69. Accordingly, NMDA receptor antagonists, including Namenda IR, Namenda XR, and any future AB-rated generics that may enter constitute the relevant product market ("memantine market"). Tr. 336:14-16 (Berndt). Defendants currently have all of the sales in that market. Tr. 344:9-19 (Berndt). Patents and other regulatory requirements presently prevent potential competitors from entering that market.

70. There is no dispute that the relevant geographic market is the United States.

V. Forest's Anti-Competitive Conduct

A. Defendants Strategies to Avoid the Patent Cliff

71. If Defendants maintain the status quo with respect to IR sales and distribution, generic memantine will have about 80% of the total memantine market within three months and 90% after twelve. Berndt Decl. (PX064) ¶ 63.

72. By Fall 2012, Forest was considering ways to convert patients from IR to XR prior to the availability of generic memantine. PX14-PX17. Forest emphasized the importance

of switching patients from Namenda IR to Namenda XR in internal documents, sales training, and public statements. In June of 2013, for example, an executive made a speech at a Namenda XR launch event:

> Our mission is to convert to Namenda XR and lift the franchise as a result of increased sales calls and combination therapy usage . . . . Make no mistake about it, this is a sprint. We need to convert as much IR business to Namenda XR as quickly as possible.

PX22 (Speech from Namenda XR launch event, June 2013) at FRX-NY-01573603-04. Another executive wrote in a draft speech:

> [T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.

PX23 at FRX-NY-01574212.

73. In June 2013, Forest's senior marketing executives considered two alternatives to the typical soft switch approach described above: completely discontinuing Namenda IR; or "technically" leaving the drug on the market, but severely restricting patient access with "limited distribution." Presentation titled "Namenda IR & XR Conversion Plan" (PX31).

74. In a presentation attached to a June 26, 2013 email between two of Defendants' executives dated, the author notes that, with respect to Forest's conversion strategy, "[e]ither [a withdrawal or limited distribution] approach is unprecedented . . . [we] would be operating in uncharted territory." Namenda IR + XR Conversion Project (PX32) at slide 4. The presentation also notes that "Prescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment." Namenda IR + XR Conversion Project (PX32) at slide 4; see also PX14; Tr. 183:22-184:17 (Stitt) (describing differences between the Namenda IR hard switch and prior situations where there were substitutes for the discontinued drug: "So the unique thing here I think is that there's really no place for prescribers to, to go with a drug to treat that condition.").

75. On October 18, 2013, a Forest executive emailed his colleagues, announcing the decision to withdraw Namenda from the market: "Dear all: Forest has made the decision to discontinue sales of Namenda IR and transition all patients to Namenda XR." Saunders testified that he made the decision. Tr.

262:18-23 (Saunders). By doing the hard switch, Forest hoped to hold on to a large share of its base instead of losing them to competition. Tr. 219:12-16 (Saunders).

76. In a January earnings call, Saunders explained that the purpose of the hard switch was to protect the company's Namenda revenues from declining too quickly after generic entry and the ensuing "patent cliff":

> [I]f we do the hard switch and we convert patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force. They don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult and is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff.

Tr. Of Jan. 21, 2014 earnings call, annexed to Zain Decl. as Ex. 1.

77. On February 14, 2014, Forest began the "forced switch" by publicly announcing that Namenda IR tablets would be discontinued on August 15, 2014. Press Release, Forest Labs., Inc., Forest Laboratories to Discontinue Namenda Tablets, Focus on Once-Daily Namenda XR (Feb. 14, 2014), annexed to Zain Decl. as Ex. 33. That same day, Forest notified the FDA that it would

"be discontinuing the sale of Namenda Tablets effective August 15, 2014." Zain Decl. Ex. 34. Forest also published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR and urging caregivers to speak with their loved ones' "healthcare provider[s] as soon as possible to discuss switching to Namenda XR." Patrick Boen letter to healthcare providers (PX37).

78. Forest's announcements of its plans for discontinuance were made to alert physicians and patients that Forest would be discontinuing IR so they could take appropriate actions. Tr. 616: 18-20 (Meury). Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR. Tr. 61:8-19 (Lah) (viewing the announcement as forcing a "wholesale switch" of patients from Namenda IR to Namenda XR).

79. In its Form 10-K filing with the Securities and Exchange Commission for fiscal year 2013 (ending March 31, 2014), Forest made representations that it would discontinue Namenda IR on August 15, 2014. In Item 7, which relates to "Management's Discussion and Analysis of Financial Condition and Results of Operations," Forest's 10-K reads: "In February 2014,

the Company announced that it would discontinue the sale of Namenda tablets effective August 15, 2014."

80. Forest sought to convert the drug's largest customer base, Medicare patients, from XR to IR by having the CMS remove IR from its FRF. On Feb. 5, 2014, a Forest employee wrote an email to the Defendants' Executive Vice President for Sales stating:

> I propose that we have a letter to CMS and also place a call to the agency. We need to ask CMS to REMOVE [Namenda] IR from the Formulary Reference File. That way, the plans won't see it when they create their own formularies.

Decl. Ex. 39 at FRX-NY-01596407. The letter was approved and sent. Amanda Seef-Charny email re: FW: Forest Laboratories to Discontinue Namenda® Tablets, Focus Once-Daily Namenda XR® (PX39). Defendants' expert pharmaceutical consultant witness testified that she has never in her consulting experience heard of a company sending such a letter. Edgar Hr'g 63:24-25. If the drug is not on the FRF, health plans are less likely to include it in their formularies and, thus, health plans may not cover Namenda tablets starting in January 2015. Stitt Decl. (PX122) ¶¶ 29-31.

81. As Forest sought to accomplish the switch from IR to XR, Forest executives began to express concerns that their efforts would be insufficient to switch a high enough number of patients from Namenda IR to Namenda XR prior to the market entry of generic memantine. William Meury email re: Namenda XR Weekly Performance Tracker - WE 8-9-13 (PX28) at FRX-NY-01618169-70.

82. Patients and their physicians are reluctant to switch from Namenda IR to Namenda XR. Lah Decl. (PX85) ¶¶ 11, 22, 25. The benefits of a switch from Namenda IR to Namenda XR are often marginal. Tr. 58:5-15 (Lah); Lah Decl. (PX85) ¶ 15 ("In my experience, compliance has not been a problem. A twice-daily regimen is easy to follow . . . ."). No studies have been done to show that Namenda XR is more effective than Namenda IR. Taglietti Dep. 181:7-16, 211:22-212:7. Being able to take Namenda once a day instead of twice, is not a significant benefit for patients already taking other twice-daily medications. Lah Decl. (PX85) ¶¶ 15, 22.

83. According to Polivka-West, most Alzheimer's patients are in a long-term care facility (Tr. 626:6-13)

(Polivka-West), and that the average patient in a long-term care facility takes nine pills per day. Tr. 641:5-22 (Polivka-West). She also testified that long-term care facilities generally dispense pills three times a day. Tr. 640:4-6 (Polivka-West). Thus, a patient that switches from Namenda IR to Namenda XR might go from nine pills a day to eight pills a day, Tr. 642:5-8 (Polivka-West), and given that pills are dispensed three times a day, it is possible that the patient is still going to have to take pills multiple times per day. Tr. 642:9-12 (Polivka-West).

84. Only half of all patients are willing to pay more money out-of-pocket to reduce their pill burden by half (e.g. going from eight pills per day to four). Tr. 642:13-643:17 (Polivka-West) & Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy: An Observational Study (PX349) at 414.

85. For some patients (and their physicians), the benefits of the change to Namenda XR are outweighed by the risks of changing the medical routine of a highly vulnerable patient. As Dr. Lah explained:

> For Alzheimer's patients, stability is key: this is a very vulnerable group of patients. Any small change

> in medication raises the risk of an adverse effect. As Namenda is typically prescribed in the mid to later phases of Alzheimer's disease, the patients taking Namenda are at a stage in the disease when they are especially vulnerable. Even a small change in a patient's condition can require him or her to be moved to a care facility.

PX85 (Lah Decl.) ¶ 24; PX64 (Berndt Decl.) ¶ 84 (discussing reasons why twice-daily Namenda may be preferred by some patients).

86. Given the potential risks, without studies that show that a new medication has meaningful benefits over a patient's current medication, physicians frequently will not switch an Alzheimer's patient from a medicine on which the patient is doing well. Tr. 58:5-15 (Lah); Lah Decl. (PX85) ¶ 25; Rovner Dep. 106:18-25, Oct. 29, 2014 ("Q. And if the caregiver said I would rather just keep my husband or wife on the medication they're taking, they seem to be doing fine, what would you do? A. I would go along with that.").

87. As a result, despite aggressive marketing and pricing practices typical of a soft switch, Forest forecasted in late 2013 that only about [redacted] of patients using Namenda IR tablets could be voluntarily converted to Namenda XR prior to availability of generic Namenda IR. William Meury email re:

Namenda Financials (PX29) at FRX-NY-01566763. If physicians and patients had the choice, many would stay on the original formulation. As one Forest executive stated, "I could see doctors just being apathetic about it and if patient is fine and not complaining of any issues, why switch?" William Meury email re: Namenda XR Weekly Performance Tracker - WE 8-9-13 (PX28) at FRX-NY-01618168.

88. For Forest's plan to avoid the "patent cliff" to be successful Forest had to switch large numbers of patients from Namenda IR to Namenda XR. Tr. 412:15-20 (Berndt); Berndt Decl. (PX64) ¶¶ 76, 79. Forest also realized that, to be successful, its product switch had to be accomplished before less expensive generic versions of Namenda IR tablets became available in the market. Transcript of Forest Earnings Call, January 17, 2014 (PX3) at FRX-NY-01642564 (Saunders: "IR will go generic in July of 2015. And so the sweet spot for a [Namenda] switch would be in the fall [of 2014]"). Once generic memantine became available, generic and branded Namenda IR would be AB substitutable at the pharmacy, and most patients with prescriptions for Namenda IR would likely switch to generic memantine instead of Namenda XR. Tr. 375:21-376:5 (Berndt).

89. If, however, Forest could get patients, physicians, and insurers to switch to Namenda XR before the entry of generic memantine, Forest would be able to prevent manufacturers of generic Namenda IR from effectively competing for those patients. Generic memantine tablets would not be AB-substitutable for Namenda XR under state substitution laws. A pharmacist would have to call the prescribing physician in order to substitute lower-priced generic memantine for branded Namenda XR. Stitt Decl. (PX122) ¶ 38; Tr. 409:9-23 (Berndt).

90. Forest gave priority to converting patients from Namenda IR to Namenda XR as quickly as possible. In Defendants' CEO's words, "I think our view is that what we're trying to do is make a cliff disappear." Tr. 197:5-22. It was one of the three key elements in its strategy to protect the Namenda franchise sales stream. Tr. 201:9-18 (Saunders); Transcript of Forest Earnings Call, January 17, 2014 (PX3) at 8; Namenda Transition PowerPoint presentation, Dec. 2013 (PX363).

91. Forest's CEO stated during a January analyst call: "We're very focused on our Namenda conversion . . . if you kind of look at the timing of IR, IR will go generic in July of 2015. And so the sweet spot for a switch would be in the fall,

and so that's kind of how we're thinking about it." Transcript of Forest Earnings Call, January 17, 2014 (PX3) at 2. A document titled "Namenda Franchise Business Plan" dated September 2013 specifically explains that the sales target for "converting" Namenda patients must be achieved "prior to the Namenda LOE [loss of exclusivity] in 2015." FRX-NY-01686842 (PX24).

92. A separate presentation lists "Maximize XR Conversion leading up to IR LOE [loss of exclusivity]" as a key part of Forest's strategy for convincing health plans to pay for Namenda XR. Namenda XR FY15 Business Plan Managed Care (PX25) at 4. Forest agreed to pay [redacted] rebates to health plans to make sure they put Namenda XR on the same tier as Namenda IR so that members would not have an incentive to choose Namenda IR. Carolyn Myers email re: FW: Namenda (PX15).

93. The total promotional budget for the Namenda franchise in fiscal year 2014 was [redacted], with "[a]ll funds . . . allocated to drive conversion from Namenda to Namenda XR." Namenda Franchise Plan (PX24) at FRX-NY-01686845. Last year, Forest spent hundreds of millions of dollars detailing, i.e., visiting doctors to promote, Namenda XR. Tr.

231:14-17 (Saunders). Forest knew that once generic Namenda IR entered the market, it would be even more difficult and expensive to promote Namenda XR. Tr. 218:21-23 (Saunders).

94. Since 2013, Forest has undertaken an aggressive marketing campaign aimed at converting as many IR patients to XR as quickly as possible prior to Namenda IR losing exclusivity.

[redacted]

95. As found above, third party payors use formularies to influence the drugs doctors prescribe and patients take. To achieve formulary coverage for Namenda XR, Forest negotiated with health plans to obtain "preferred brand" status with top Part D plans nationally. See Hausman Decl. (PX287) ¶ 13, tbl. 1; Meury Dep. 22:3-25; Kane Dep. 276:25-277:4; Meury Decl. (DX720) ¶ 12; Devlin Dep. 118:25-119:5 (Forest negotiated to get XR on formularies after launch). The lower co-pay associated with "preferred brand" status lowers the

price to patients and can be crucial to a new drug's success because better formulary positioning results in substantially higher demand. See Hausman ¶ 12 (PX287); Hausman Hr'g 659:23-662:3 (testifying that formulary tier status can result in $350 to $1000 a year savings to a patient and provide "an incentive to switch"). For patients, because "nonpreferred" brands have higher co-pays, the negotiated "preferred brand" formulary position can result in patient savings of up to $40 per prescription, depending on the plan. Tr. 111:23-112:5 (Stitt). For other plans with three rather than four tiers, Forest achieved a tier status identical to Namenda IR in most cases. Devlin Dep. 127:19-148:10; PX242-PX251 (formularies for several health plans).

96. Forest discounted Namenda XR at a minimum of 5% discount from the wholesale acquisition cost ("WAC") of the Namenda IR tablets. Meury Decl. (DX720) ¶ 12; Kane Dep. 275:23-276:10. On average, the discount of XR is [redacted] off the average selling price of Namenda IR. See Meury Dep. 23:3-7. Where additional discounts apply, Forest positioned Namenda XR to be over [redacted] less expensive for health plans than Namenda IR tablets. Meury Decl. (DX720) ¶ 12.

97. Discounts that Forest offered ranged "anywhere from [redacted] percent." Devlin Dep. 120:10-18; Meury Hr'g 593:24-594:1 ("We have to negotiate . . . in some cases [redacted] discounts with health plans . . . ."). For example, one of the [redacted] providers "of the Medicare Part D benefit in the country" secured a discount of over [redacted]. Meury Hr'g 579:9-14. In 2014, managed care organizations paid approximately [redacted] less for Namenda XR than for Namenda IR. Meury Dep. 22:21-25. Meury testified that when the "tidal wave" of generics comes in 2015, [redacted] Meury Hr'g 594:6-9. The total discounts given by Forest exceed [redacted]. See Meury Hr'g 580:20-581:5.

98. During the same period, executives at Forest became aware that problems in the manufacturing and supply of Namenda XR presented a substantial risk that they would be unable to discontinue Namenda IR and effectively implement the proposed forced switch by August 15, 2014 because it would be unable to supply the market with sufficient Namenda XR. Stewart Decl. (DX717) ¶ 10; Meury Decl. (DX720) ¶¶ 22-23; Press Release, Forest Labs., Forest Laboratories Announces Intention to

Continue Marketing Both NAMENDA® TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (DX371) (June 10, 2014).

99. In June 2014, in light of manufacturing issues affecting the yield of production batches of Namenda XR, higher than expected demand, and other factors, Forest announced that it would continue selling Namenda IR tablets through Fall 2014. Press Release, Forest Labs., Forest Laboratories Announces Intention to Continue Marketing Both NAMENDA TABLETS and Once-Daily NAMENDA XR® Into the Fall of 2014 (DX371) (June 10, 2014); see Stewart Decl. (DX717) ¶ 10; Meury Decl. (DX720) ¶¶ 22-23.

100. Following improvements to the XR manufacturing process, Forest regained the ability to supply the market. Stewart Dep. (CD Ex. 37) 87:6-23; Stewart Decl. (DX717) ¶ 13. On November 5, 2014, in the Actavis 3rd Quarter Earnings Press Release the company confirmed: "The Company continues to enhance manufacturing efficiencies related to its once-daily dosing of Namenda XR, and is now producing product at capacities sufficient to support transitioning all Namenda IR twice daily tablet patients to its Namenda XR® once-daily product." See Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion

in Third Quarter 2014; Non-GAAP EPS Increases 53% to $3.19 (Nov. 5, 2014).

B. Distribution through Foundation Care

101. Forest actively considered alternative plans to outright discontinuance of IR, including after the State began investigating the planned withdrawal in February 2014. According to Meury, Forest's plan for limited distribution was "on the table" in February 2014 when Forest announced its plan to discontinue Namenda IR as of August 15, 2014; he also testified that it was still "on the table" when Forest announced in June 2014 that the August date was extended to the Fall. Tr. 615:1-14 (Meury). However, neither the February nor June announcements mentioned any alternative plan. See Pill Burden in Hypertensive Patients Treated with Single-Pill Combination Therapy: An Observational Study (PX34); Press Release, Forest Labs., Inc., "Forest Laboratories Announces Intention to Continue Marketing both NAMENDA® Tablets and Once-Daily NAMENDA XR® into the Fall of 2014" (PX41) (June 10, 2014).

102. Forest began speaking with Foundation Care LLC ("Foundation Care") about a limited distribution plan [redacted]

[redacted]. Tr. 616:21-25. Established in 2004, Foundation Care is accredited by the Accreditation Commission for Health Care (ACHC) as a specialty pharmacy and by National Association of Boards of Pharmacy as a Verified-Accredited Wholesale Distributor (VAWD) through July 22, 2017. Master Service Agreement ("MSA") (DX607); Foundation Care Verified-Accredited Wholesale Distributors Accreditation (DX97). It is also recorded with the New York State Board of Pharmacy as a Non-Resident Establishment Registered Wholesaler of Drugs and/or Devices, valid through May 2017, DX101-DX103, and holds a controlled substance license from the New York Department of Health, valid through November 2015, N.Y. State Dept. of Health Controlled Substance License (DX99). Foundation Care is a "full-service retail pharmacy, so any product that's available from any store in the country can be made available through Foundation Care." Blakeley Dep. 17:18-24, 38:15-18 (CD Ex. 45). Foundation Care provides reimbursement coverage for most all commercial health care plans as well as Medicaid (Pharmacy and DEME) and Medicare (Part B & D). Foundation Care Overview and Capabilities Presentation (DX87) (Oct. 21, 2014).

103. [redacted] after the State filed its initial complaint in this action, Defendants signed a Master

Services Agreement ("MSA") and Work Order with Foundation Care, to distribute Namenda IR tablets directly to patients whose physician decides it is medically necessary. MSA (DX88) [redacted]; Blakeley Dep. 46:1-6, 29:13-15. On November 5, 2014, Forest publicly announced its distribution arrangement with Foundation Care ("limited distribution"). Press Release, Actavis, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014; Non-GAAP EPS Increases 53% to $3.19 (DX721) (Nov. 11, 2014); Kane Hr'g 500:22-501:2.

104. Under the MSA, Defendants remain the sole supplier, or "vendor," and Foundation Care becomes the sole distributor, [redacted] of IR tablets. See MSA (DX88) [redacted]. Foundation Care will ship the Namenda IR tablets within two business days of receipt of a valid prescription and Medical Necessity Order Form [redacted] MSA, Work Order No. 1 § 2.7(a) (DX88); see also Stitt Hr'g 129:12-14.

105. Foundation Care is expected to dispense Namenda IR tablets to patients on the basis of a prescription and a

Medical Necessity Form from physicians. The Work Order's Medical Necessity Form requires basic information: patient information, physician information, and a prescription; as well as a physician certification that the "Namenda [IR] tablets are medically necessary." MSA, Work Order No. 1, Medical Necessity Form (DX607); Kane Dep. 295:1619 (CD Ex. 30).

106. Though there are currently "millions" of IR prescriptions in the market, Saunders Dep. 346:19-20, [redacted] Defendants' economics expert agrees. Cremieux Dep. 91:4-15 (referring to Forest's limited distribution plan as "largely eliminating the use of that product"). Defendants predict that less than 3% of patients will take advantage of the Foundation Care program. Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014 dated November 5, 2014 (PX501) (stating "for select groups of patients, perhaps less than 3 percent, the continued utilization of the twice-a-day tablet dosing of Namenda® might be necessary for treatment").

107. Limited distribution could impose an undue burden on physicians and their staffs, who would have to fill out more paperwork to obtain the drug for their patients, with no financial incentive to do so.

108. Like discontinuance, limited distribution would create artificial roadblocks to patient access to Namenda IR. Tr. 61:8-19 (Lah). Defendants have instructed their specialty pharmacy distributor not to dispense Namenda IR to patients unless a physician has signed a form stating that the patient has a "medical necessity" for Namenda IR. Tr. 549:2-10 (Kane). Defendants designed those roadblocks to protect their profits. Tr. 244:23-245:2 (Saunders) ("Q. The reason that you are requiring the medical necessity form is a competitive reason; it's not a medical reason, right? A. I guess you could lump it into a competitive reason.")

109. Because Namenda IR and XR are pharmacologically the same drug, doctors may not be willing to sign such a form. PX85 (Lah Decl.) ¶¶ 29-31. Dr. Lah explained the reluctance that he and other physicians may feel as follows:

> Q. Would you be uncomfortable signing this form for most of your patients even though they might, even

> though you might prefer that they continue on IR instead of switching to XR? A. Yes.

Tr. 70:14-17. He continued:

> So I'm not sure I would be comfortable continuing to prescribe Namenda IR if it were required me to declare that it was medically necessary for an individual to stay on that drug, when another perfectly good drug, Namenda XR, which may also be perfectly safe and effective may also be available for that patient.

Tr. 72:11-16 (Lah).

110. A prescription does not indicate medical necessity for Namenda IR tablets given the availability of Namenda XR:

> And so when I prescribe a medication and indicate a specific version should be dispensed, then I am indeed declaring that it is medically necessary for that individual to have that version of the drug. But as a general matter, prescribing medications in my mind does not imply that level of medical necessity.

Tr. 106:2-7 (Lah); see also Tr. 733:17-23 (Reisberg) ("Q. And I believe you testified before that you don't see a medical need for Namenda IR tablets on the market, is that correct? A. What I said was that for some of my patients, finances are a concern. At the moment—two different issues here. Yes, at the present

time, I do not—right, I do not see any—any medical need for the IR tablets, that's correct.").

111. Defendants' survey data and testimony indicate that only 2.4% of patients would be able to obtain the drug under the "medical necessity" standard, consistent with the State's contention that physicians will be reluctant to certify that Namenda IR tablets are medically necessary for their patients. Tr. 535:14-16 (Kane) ("So based on the surveys, we have quantified that approximately 2.5% or so of patients would require Namenda [IR] tablets based on medical necessity"); Kane Decl. (PX282) Ex. A; Press Release, Actavis Net Revenue Increases 83% to $3.7 Billion in Third Quarter 2014 dated November 5, 2014 (PX501) (stating "for select groups of patients, perhaps less than 3 percent, the continued utilization of the twice-a-day tablet dosing of Namenda® might be necessary for treatment.").

112. The limited distribution of Namenda IR does not materially alter the nature and impact of the earlier hard switch strategy. Tr. 336:9-337:8 (Berndt). Both discontinuance and the limited distribution are functionally hard switches.

C. The Absence of Business Purpose

113. Defendants have not established a legitimate pro-competitive justification for their plan to limit IR distribution until generic entry. Tr. 337:2-4, 411:24-412:20, 415:12-416:20 (Berndt).

114. Defendants have stated that the very purpose of the limited distribution is to blunt generic competition and prevent the operation of state generic substitution laws. Tr. 228:13-15 (Saunders) ("Q. But you intend to fight back and try to blunt the force of those laws, right? A. That's the definition of competition.").

115. According to Saunders, generic substitution laws cause the deck to be "stacked against" Defendants, and "put the thumb on the scale for the generics." Tr. 227:5-9.

> [T]he market isn't designed for generics as a standalone versus innovator. It is the innovator, the generic, the pharmacy, the PBM, the managed care company all working against the innovator. The decks are stacked incredibly the other way. That's why we refer to it as a dog fight.

Tr. 223:25-224:4.

116. Defendants have stated that the company is fighting back against the state substitution laws by seeking to convert patients from Namenda IR to Namenda XR prior to generic entry, which would allow Forest to evade the application of these laws and thus have a better chance of protecting its sales. Tr. 223:25-224:4 (Saunders); Forest Laboratories F3Q 2014 Earnings Call Transcript (PX2) (Saunders: "if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing [prescriptions]. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff."). While Saunders discussed contemplated discontinuation of Namenda IR on numerous earnings calls with investors, he never suggested that this business tactic would result in any cost savings or other efficiencies. See generally April 29, 2014 transcript of earnings call (PX366); Forest Laboratories F4Q 2014 Earnings Call Transcript (PX82); Tr. of Jan. 21, 2014 earnings call (PX2); Forest Laboratories Management Discusses Q2 2014 Results, Earnings Call

Transcript at 4 (PX485); Tr. Of Jan. 21, 2014 earnings call, annexed to Zain Decl. as Ex. 1.

117. Under a conventional scenario, i.e., leaving the older drug on the market while competing on the merits to convince physicians that the newer one is better, it would take years to convince patients and physicians to switch to Namenda XR. Tr. 694:17—20 (Hausman). The forced switch limits access to Namenda IR in order to overcome what Saunders called the "inertia" that causes most patients and physicians to resist changing medicines, with the goal of impeding lower-cost competition and the result of driving up the average price for memantine. See Tr. 286:18-287:9 (Saunders), 376:3-17 (Berndt). This conflicts with the notion that patients should not be switched off of a drug that is working. Tr. 58:5-15 (Lah); Lah Decl. (PX85) ¶ 25; Polivka-West Dep. 90:2-7.

118. [redacted] Tr. 232:21-233:20 (Saunders); Tr. 411:24-412:5; 413:23-414:23; 415:12-416:5 (Berndt). Forest seeks [redacted] greater retention of sales after generic entry than it would have had absent a forced switch. TR:

233:21-23 (Saunders). As Dr. Berndt testified, [redacted] Tr. 411:12-412:20 (Berndt).

119. Defendants have referenced several pro-competitive for the limited distribution in conjunction with this litigation: [redacted] savings in inventory costs; savings due to greater "focus" and a reduction in manufacturing costs; benefits from "focus" on newer innovations; and distribution and other supply chain-related savings. Meury Hr'g 570:12-20; Meury Decl. (DX720) ¶ 14; Saunders Dep. 222:10-21; Saunders Dep. 66:13-17; Solomon Dep. 64:4-13, 203:7-17, 203:17-204:2; Meury Hr'g 569:17-21; Meury IH Tr. 270:11-272:24.

120. However, Defendants have not quantified most of the savings resulting from limiting distribution of Namenda IR. Tr. 234:25-235:4 (Saunders); Tr. 416:10-20 (Berndt). Defendants' economic expert has also not quantified any savings from discontinuing the widespread availability of Namenda IR. Cremieux Dep. 238:14-241:21.

121. Defendants' two senior management witnesses, Saunders and Meury, did not testify that the purported savings from the hard switch were considered when the strategy was adopted, nor do these explanations appear elsewhere in the documents produced by Defendants.

122. [redacted] Tr. 416:6-20 (Berndt); Berndt Decl. (PX64) ¶ 80-82 (pro-competitive rationales proffered by Defendants, including "focus," are not credible).

123. Presumably in part because of its announced discontinuance, [redacted] which addresses any concern that selling multiple drugs for the same indication reduces "focus." Tr. 221:5-9 (Saunders). While the oral solution is nominally on the market, Defendants do not promote it, and physicians do not prescribe it. Tr. 245:13-14 (Saunders); Tr. 58:16-59:1 (Lah); Tr. 732:9-12 (Reisberg); Jacobs Dep. 104:9-15; Rovner Dep. 102:18-20.

124. Since the launch of Namenda XR in mid-2013, [redacted] Tr. 605:16-606:4 (Meury). [redacted] Tr. 606:14-22 (Meury). Sales reps are told to promote Namenda XR, not IR. Tr. 606:14-22 (Meury). [redacted] Tr. 606:10-13 (Meury) [redacted].

125. Continuing to keep IR tablets available is highly unlikely to have any impact on Defendants incentive to innovate. Forest launched 8-9 new drugs in new therapeutic areas in the last five years without discontinuing or limiting distribution of any other drug. Tr. 894:3-895:5 (Cremieux).

VI. Effect of the Anti-Competitive Conduct

A. Damage to Competition

126. As found above, Namenda IR, Namenda XR, and in the future any AB-rated generics that may enter constitute the relevant product market, i.e., the memantine market. Tr.336:14-16 (Berndt). As found above, Defendants currently have all of the sales in that market. Patents and other regulatory requirements prevent potential competitors from entering that market. The first generic versions of Namenda IR are expected to enter the market in July 2015.

127. By implementing the limited distribution, Defendants game the generic substitution laws and prevent pharmacists from offering patients taking Namenda a lower-priced generic. As a result of the hard switch strategy, the pharmacist would need to contact the doctor in order to obtain approval for generic substitution. Tr. 409:12-23 (Berndt); Berndt Decl. (PX64) ¶ 50. If pharmacists are not permitted to dispense a lower-priced generic instead of the brand without needing to get a new prescription from a doctor, generics are unlikely to be able to make substantial sales. Stitt Decl. (PX122) ¶ 22; Lah Decl. (PX85) ¶ 32; Berndt Decl. (PX64) ¶ 50; Tr. 380:19-381:7, 381:11-15 (Berndt).

128. Generic products are typically not marketed to physicians or patients. Harper Decl. (PX496) ¶ 11; Tr. 62:24-63:1 (Lah); Jacobs Dep. 203:7-18 ("Q. What about from generic drug companies, do you get any marketing information or pens from those firms? . . . A. I don't remember ever getting—I don't know anything about generic companies honestly, never heard of one. Q. You can't name a single generic company? A. Not at all."); Tr. 759:8-25 (Kohrman) (no sales calls from generic manufacturers other than branded generics several years after entry).

129. For example, Mylan does not have any direct relationship with patients, does not talk to doctors, and does not do direct-to-consumer advertising. Moreover, "generic products . . . most efficiently will achieve sales through AB-rated substitution for the branded product at the pharmacy level." Tr. 327:1-14 (Harper). Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete. Tr. 299:24-300:3, 327:15-328:4 (Harper). In addition, "because the generic [firm] promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one

of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter." Tr. 328:5-11 (Harper).

130. Generic manufacturers do not generally market to health plans. As MVP's representative testified:

> Q. In your experience, do generic drug manufacturers engage in marketing?
>
> A. Not to the—I'm going to just answer no. But they may in journals put [advertisements] out. But I have never had a generic manufacturer call on me at the health plan. And I could have brand manufacturers coming in every day to sell their drugs.
>
> So I would say generic manufacturers don't market, and the—probably the most—I mean, the reason for that would be simple. Because if you're one of three and you get somebody to write a prescription and you didn't—and not indicate dispense as written, the benefit isn't necessarily going to accrue to you. You're only going to get, if there's three people out there, maybe a third of that business. So just the motivation behind marketing a generic product is limited when compared to a brand product.

Tr.117:5-19 (Stitt).

131. Generic manufacturers compete by selling products at a significant discount relative to their branded equivalents, and that discount typically increases as additional generic versions of a branded product enter the market. Tr. 376:12-17

(Berndt); Harper Decl. (PX496) ¶ 5; see Berndt Decl. (PX64) ¶ 17.

132. Price competition at the pharmacy, facilitated by state substitution laws, is the principal means by which generics are able to compete in the United States. See Berndt Decl. (PX64) ¶¶ 10, 22, 44-46; Stitt Decl. (PX122) ¶¶ 21-22; Tr. 116:4-117:4 (Stitt); Harper Decl. (PX496) ¶ 10; Tr. 299:12-23 (Harper); see also Tr. 409:6-11 (Berndt); Tr. 114:21-115:3 (Stitt); Tr. 897:3-22 (Cremieux); Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 14, Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., 2:12-cv-03824 (E.D. Pa. May 7, 2014) (PX5) ("Under Hatch-Waxman and state substitution laws, generics can only compete cost-effectively through substitution on the new or old branded-drug version."). Generic Namenda will not be AB-rated to Namenda XR and generics will not be automatically substituted for Namenda XR (after entry in 2015) under New York's mandatory substitution laws. Tr. 115:19-25 (Stitt).

133. Non-AB-rated generic drugs, such as generic memantine, cannot compete effectively for sales of a branded drug in the same class, such as Namenda XR, even if the price of

the generics is much lower than the brand. For example, imposing utilization plans to shift people from Lipitor—the "biggest [drug] in history"—to generic simvastatin, a non-AB-rated generic in the same statin class, only resulted in 30% of patients switching from Lipitor to simvastatin. Tr. 815:13-817:5 (Kolassa).

134. If Defendants are permitted to execute the limited distribution, they would achieve significantly higher levels of conversion from Namenda IR to Namenda XR than they would have achieved absent the forced switch. Tr. 218:12-16 (Saunders). Before October 2013, Forest predicted that it could switch approximately [redacted] of Namenda IR patients to Namenda XR without a hard switch, but Defendants' hard switch strategy is expected to result in [redacted] of Namenda IR patients switching to XR prior to generic entry. Tr. 217:25-219:3 (Saunders); Presentation titled "Namenda IR & XR Conversion Plan" (PX31) at 31; Presentation discussing "Namenda Disruption Scenarios" (PX45) at 1; Meury email with subject line reading "Re: Namenda Financials" (PX46) at FRX-NY-01565787.

135. Forest has predicted that forcing a hard switch from Namenda IR to XR will generate over [redacted] in

additional sales of Namenda XR than it would have absent a hard switch. Tr. 221:10-15 (Saunders).

136. The limited distribution "is likely to have a significant impact on potential generic competition," in that "[d]iscontinuing Namenda [IR] in late 2014 and shifting the market to Namenda XR ensures that by the time generic entry occurs in July 2015, there will be few to no prescriptions of Namenda left in the market." Tr. 326:3-16 (Harper); Tr. 124:21-125:9 (Stitt) (because Namenda is the only drug in the "particular cascade" of drugs used to treat Alzheimer's, "prescribers will be forced essentially to switch to the XR product."). This decreases the sales opportunities available to generic manufacturers because few patients are left on Namenda IR who can switch to generics under state substitution laws. Tr. 380:15-381:10; 409:12-23 (Berndt).

137. Forest internally predicted that, absent the forced switch, it would only be able to switch [redacted] of Namenda IR prescriptions to Namenda XR prior to generic entry. Tr. 217:25-218:5 (Saunders). If [redacted] of patients switched to Namenda XR, then generic substitution laws would cause about 90% of the remaining [redacted] of patients still taking Namenda IR to be switched

to generics within a few months of generic entry. Tr. 217:25-218:16 (Saunders).

138. Meury stated to investors that perhaps 5-30% or more of patients taking Namenda XR might switch back from Namenda XR to generic memantine at some point after generic entry, a process occasionally referred to as "erosion" or a "reverse commute." April 29, 2014 transcript of earnings call (PX366) at 12-13; Tr. 88:2-8 (Lah), 223:13-22 (Saunders), 390:9-392:17 (Berndt), discussing PX366 ("Q. Okay. Now what did you take way from this exchange? A. I take it that by April of this year, Forest had conducted a fair bit of research, its marketing folks had done that; that they came up with a wide range of estimates, and that Meury and Saunders believed the range of 5-30 percent is a reasonable range. But notably it's much, much less than 100 percent or the 90 percent you would get from a conventional launch."). Meury represented to investors in the April call that generic erosion would not be on the high side of that estimate. April 29, 2014 transcript of earnings call (PX366) at 13. That is, 63% of the market would typically be generic.

139. As a result of the limited distribution, Defendants will be able to maintain their monopoly share of the market for memantine for longer than they would have otherwise. Defendants predicted that they would have had a [redacted] share of the market and generics would have had a [redacted] share but for the hard switch. Instead, under the hard switch scenario, the results are essentially inverted. In 2016, Defendants are likely to achieve an [redacted] share of the market and generics are likely to achieve a [redacted] share. The following graphic, PX580, prepared by the State, is based on data from Defendants' files and reflects this market effect:

140. Dr. Hausman, Defendants' economic expert, corroborated [redacted] that as a result of the hard switch, market shares would dramatically change. Tr. 688:7-11 (Hausman). He did not dispute that with the hard switch, a large number of the patients that would have gone on to generics would instead end up on Namenda XR. Tr. 692:12-16 (Hausman).

141. Mylan predicted, in early January 2014, that prescriptions being written for XR would reduce the market for IR by [redacted]. Tr. 300:6-303:17 (Harper); Mylan Namenda sales forecast, January 2014 (PX142). Following Forest's announcement that it would discontinue IR in August, the generic manufacturer revised its estimate of IR market share loss to [redacted]. Tr. 303:18-304:23, 305:7-11 (Harper); Mylan Namenda sales forecast, (PX145) (April 2014). After doing a "deeper dive" in the summer of 2014, the generic manufacturer further revised its estimate, estimating that the forced switch would reduce the Namenda IR market by [redacted]. Tr. 310:14-25 (Harper); Mylan Namenda sales forecast (PX148) (July 2014). Mylan's January forecasts predict that Mylan's revenue from generic Namenda IR will stabilize around [redacted] per quarter. Mylan Namenda sales forecast, (PX142) (Jan. 2014). By contrast, Mylan's July forecasts predict that Mylan's revenue from generic Namenda IR will stabilize at [redacted] per quarter. Mylan Namenda sales forecast, July 2014 (PX148). Defendants' CEO made a similar projection as to the effectiveness of the forced switch. Saunders Dep. 117:16-118:2; Tr. 117:5-25 (Saunders).

142. To date, about 50% of existing patients have converted from Namenda IR to Namenda XR in anticipation of the

lack of availability of Namenda IR. Press Release, Forest Labs., Inc., "Forest Laboratories Announces Intention to Continue Marketing both NAMENDA® Tablets and Once-Daily Namenda XR into the Fall of 2014" (PX41) (June 10, 2014).

143. As found above, several factors are likely to inhibit switching from Namenda XR to generic memantine once it becomes available in the market. Physicians and caregivers are reluctant to disrupt patients' medical routines without a medical reason to do so. Tr. 131:8-133:22 (Stitt), 508:1-3, 541:21-542:4 (Kane).

144. In addition, health plans are reluctant to pressure patients to switch from a drug that they are already taking, a rule that applies especially powerfully in the case of vulnerable patients such as those with Alzheimer's. Stitt Decl. (PX122) ¶¶ 45, 47; April 28, 2014 earnings call (PX82) at 13.

145. MVP, the New York health plan, for example, is unlikely to try to move patients taking Namenda XR to Namenda IR because of the challenges of moving a patient off a drug when he is doing well on the drug he is taking. Tr. 134:12-139:16 (Stitt); Stitt Decl. (PX122) ¶ 45.

146. This reduction in the market opportunity for generics, from an estimated [redacted] prescriptions down to [redacted] within a few months, and further to [redacted] in six to eight months, is a substantial harm to competition. Tr. 380:15-381:15 (Berndt).

147. The Defendants' expert and fact witness predict that third party payors and the other intermediaries discussed at length above will intervene to thwart Defendants' attempts to limit generic memantine's drive into the market. See generally Kolassa Decl. (DX821) and this Opinion's Findings of Fact ("FOF") § II, E. [redacted] First, as sophisticated market participants with extensive experience as both branded and generic manufacturers of drugs, Defendants are unlikely to have adopted the limited distribution strategy, [redacted] and incurring the legal expense and reputational costs associated with this action, [redacted] Second, Dr. Kolassa's exhaustive analysis of the cost pressures faced by manufacturers generalized across

different drug markets. Neither he nor the Defendants analogized between the memantine market and the drug markets in which the eight other examples of "hard switches" occurred. As found above, this market features a unique unsubstitutable product and patients that are extremely sensitive to changes in routine. It is these specific characteristics that make limited distribution so harmful to patients and to competition, and therefore so enticing a strategy upon which Defendants hope to profit.

B. Damage to Consumers

148. Consumers benefit from the lower prices of generic drugs. Tr. 803:6-8 (Kolassa).

149. Once patients have switched to Namenda XR, it is very unlikely that most of them will switch to generic Namenda IR. In April 2014, Forest's head of sales told investors that perhaps 5-30% of patients taking Namenda XR might switch from Namenda XR to generic Namenda at some point after generic entry. Yoon Decl. Ex. 5 at 13.

150. This reduction in the market opportunity for generics, [redacted] of the market going to

generics without the forced switch, to only about 5-30% with the forced switch, not only substantially harms competition but affects the cost of memantine to consumers. Tr. 336:9-337:8 (Berndt). Based on Defendants' own data, Dr. Berndt testified that health plans will pay at least [redacted] more and patients will pay [redacted] more for memantine because of the actions challenged in this litigation. Berndt Decl. ¶¶ 61-64. Dr. Berndt's testimony was credible and substantially not impeached.

151. Physicians are reluctant to disrupt patients' medical routines without a medical reason to do so. Lah Decl. (PX85) ¶ 25 (won't switch a patient who is stable and doing well). One of Defendants' medical experts testified that he continues his patients' current prescription even when he would not prescribe the drug himself to patients not already taking it. Jacobs Dep. 81:14-82:11 ("[I]f they are on a drug and it is working for them and there was no reason to change it, I wouldn't change it."). After patients have been forced to bear a change in routine by switching to Namenda XR, physicians are reluctant to have their patients switch again. Lah Decl. (PX85) ¶ 11; Stitt Decl. (PX122) ¶ 47 ("[P]hysicians are also reluctant

to switch patients to a different drug when the patient is already doing well on the current drug they are taking.").

152. According to Saunders, this "behavioral change" inhibits switching from Namenda XR back to generic memantine. Declaration of Saami Zain, dated September 24, 2014 Ex. 1; Saunders Dep. at 204-05, annexed to Yoon Decl. as Ex. 12.

153. Defendants' forced switch will also result in dramatically higher drug costs for insurers and patients, who might otherwise have chosen the less expensive generic. Stitt Decl. (PX122) ¶ 36 (Defendants' forced switch will lead MVP to "incur substantially higher costs for its member[s]" and hurt patients, who would have higher co-pays for the brand); Tr. 411:24-412:20 (Berndt); William Meury email and attachment re: Namenda Transition Plan 1.ppt (PX339) (showing increased profits); Tr. 405:16-406:1 (Berndt); Berndt Decl. Figure 4 and accompanying text (showing harm to patients and plans). As Stitt, an executive at MVP, explained:

> I believe that if Actavis is permitted to accomplish the "forced switch" of patients from Namenda to Namenda XR, it will hurt patients, impose significant costs on MVP, and harm the economics of the health care delivery system.

PX122 (Stitt Decl.) ¶ 56.

154. Alzheimer's patients who are Namenda's users (those with moderate to late stages of the disease) are an especially vulnerable group of patients. Lah Decl. (PX85) ¶ 24; Stitt Decl. (PX122) ¶ 45; Tr. 379:8-14; 383:12-14 (Berndt); Forest Laboratories F4Q 2014 Earnings Call Transcript (PX82). Given Alzheimer's patients' vulnerability, "[a]ny small change in medication raises the risk of an adverse event" and "[e]ven a small change in a patient's condition can require him or her to be moved to a care facility." Lah Decl. (PX85) ¶ 24; Tr. 58:5-15 (Lah).

155. Physicians can also be reluctant to switch medications because the patients and others, such as their caretakers, must be educated on how the new medication is taken. Stitt Decl. ¶ 47; Polivka-West Dep. 72:23-73:4.

156. Further, the forced switch could actually result in a portion of these vulnerable Alzheimer's patients having to switch medications (and face the risks of adverse events) twice: once because Namenda XR will be the only product available to

patients; and again because some small number of patients may switch back to the generic Namenda IR once it is available.

157. Defendants' surveys show that many physicians, caregivers, and pharmacists are concerned about potential harm to patients from the forced switch. When presented with the possibility that Defendants would restrict the availability of Namenda IR, physician responses to the survey included statements like "terrible," "how awful," "horrible," "what kind of game is the drug company playing?," "It puts an undue burden on us and would anger me," and "Is this legal?" Physician survey responses concerning limited distribution plan (PX311) at 1; Physician survey responses concerning limited distribution plan (PX298) at 5, 14. Other physicians specifically complained of the reduction in choice, stating that they "would be frustrated that a good therapy is no longer available" (Physician survey responses concerning limited distribution plan (PX311) at 3; Physician survey responses concerning discontinuation plan (PX299) at 4; Physician survey responses concerning limited distribution plan (PX298) at 22, that they "would like the choice to be decided between myself and my patients," (Physician survey responses concerning limited distribution plan (PX311) at 3) and that they suspect Forest "is

manipulating the market to shift to XR product in anticipation of generic availability." Physician survey responses concerning limited distribution plan (PX298) at 22.

158. Defendants' economic expert testified that, based on actual decisions made in the market, approximately [redacted] of physicians prefer Namenda IR and approximately [redacted] prefer Namenda XR. Tr. 716: 19-25 (Hausman).

159. Defendants' surveys also asked doctors and caregivers whether the discontinuation of Namenda IR would be "acceptable," as opposed to a word with a more positive connotation, such as "desirable." Tr. 503:10-16 ("To be acceptable, they would accept it. They wouldn't challenge it."). Even using Defendants own surveys and methodology, 21% of the caregivers surveyed by the Defendants did not find discontinuation of Namenda IR to be acceptable. The reasons provided by such caregivers include "patient used to it," "keep things the same for now," "he likes having his schedule stay the same," "doing well [with] it, no reason [to] change," and "I prefer not to change up her medication at this point." Caregiver survey responses concerning preference for IR versus XR (PX304) at 2, 3, 9, 10, 15.

160. Defendants' documents reflect their expectation that "[p]rescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment." Zain Decl. Ex. 31 at 4. Consequently, Forest projected that somewhere between [redacted] of all Namenda patients would not switch to Namenda XR and instead cease memantine treatment entirely. Zain Decl. Ex. 30 at 31; Zain Decl. Ex. 44 at 1; Zain Decl. Ex. 45 at FRX-NY-01565787.

161. If Defendants are allowed to implement their hard switch strategy, harm to consumers, and the corresponding gain to Forest, would be approximately [redacted] based on Defendants' expert's data. Tr. 405:5-406:6 (Berndt). Consumers would bear approximately [redacted] in additional co-payment costs and [redacted] in third party payor costs. Tr. 405:5-406:6 (Berndt).

162. Based upon the facts found above, the public interest would be served by an injunction. Defendants are entitled to a just return on their investment in Namenda IR, but having enjoyed that return for over a decade, the law now requires them to allow generic competitors a fair opportunity to

compete using state substitution laws. Tr. 417:17-418:14 (Berndt) (rejecting Defendant's "free-riding" argument, and explaining quid-pro-quo of patent exclusivity followed by generic entry).

163. The facts with respect to the harm to competition, to the consumers and consequently the state, the ultimate payor of certain costs, have been found above.

164. Aside from the effect resulting from federal and state legislation, the Hatch-Waxman Act and the state substitution laws, the Defendants have not established any harm resulting from the continued sale of Namenda IR.

165. [redacted]

166. The continuation of sales of Namenda IR adds choice to physicians, patients' health plans and insurers and

constitutes a soft switch which has been the industry practice when introducing a new drug.

167. The Defendants have not presented any evidence to establish material economic harm resulting from the continued sale of Namenda IR after the introduction of Namenda XR, other than that which is anticipated upon the entry of generic competition resulting from the relevant legislation.

Conclusions of Law

VII. The Preliminary Injunction Standard

The general purpose of a preliminary injunction is to avoid irreparable injury to the movant and to preserve the court's power to render a meaningful decision after a trial on the merits. See WarnerVision Entm't Inc. v. Empire of Carolina, Inc., 101 F.3d 259, 261 (2d Cir. 1996); see also 11A Charles A. Wright & Arthur R. Miller, Fed. Prac. & Proc. Civ., § 2947 (3d ed.).

A party seeking a preliminary injunction must establish: (1) either (a) a likelihood of success on the merits, or (b) sufficiently serious questions going to the merits of its claims to make them fair ground for litigation, plus a balance of the hardships tipping decidedly in favor of the moving party; (2) irreparable harm; and (3) that issuance of the injunction would be in the public interest. See Oneida Nation of N.Y. v. Cuomo, 645 F.3d 154, 164 (2d Cir. 2011) (internal quotations and citations omitted); Red Earth LLC v. United States, 657 F.3d 138, 143 (2d Cir. 2011).

With respect to the likelihood of success element, a movant must satisfy a higher standard where: "(i) an injunction will alter, rather than maintain, the status quo, or (ii) an injunction will provide the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." Id. at 33-34. Under this higher standard, a movant must show a "clear" or "substantial" likelihood of success on the merits or make a "clear or substantial showing of sufficiently serious questions of merits in their favor." See Wright v. New York State Dep't of Corr. & Cmty. Supervision, 568 F. App'x 53, 55 (2d Cir. 2014) quoting Tom Doherty, 60 F.3d at 33-34 (discussing the heighted standard with respect to likelihood of success on the merits); Jolly v. Coughlin, 76 F.3d 468, 473 (2d Cir. 1996) (same); Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 425 (S.D.N.Y. 2005) (discussing the heighted standard with respect to substantial question analysis); Shred-It Am., Inc. v. Haley Sales Inc., 01-cv-0041E, 2001 WL 209906, at *1 (W.D.N.Y. Feb. 26, 2001) (same). The movant must also make a "strong" showing of irreparable harm. Doe v. New York University, 666 F.2d 761, 773 (2d Cir. 1981). Defendants urge that the heightened standard as described in Tom Doherty be applied in this case. Defs.' Mem. in Opp'n 13-15.

The instant motion does not require the heightened standard set out in Tom Doherty. While, "[t]he distinction between mandatory and prohibitory injunctions is not without ambiguities or critics . . . [a] preliminary injunction is usually prohibitory, [i.e., forbids or restrains an act,] and seeks generally only to maintain the status quo pending a trial on the merits." Louis Vuitton Malletier v. Dooney & Bourke, Inc., 454 F.3d 108, 114 (2d Cir. 2006) (internal quotations omitted) citing Tom Doherty, 60 F.3d at 34 and Black's Law Dictionary 788 (7th ed.1999). The State is seeking an injunction barring Defendants from altering their current Namenda IR sales and distribution strategy pending a final resolution of this case. AC ¶ d. The requested interim relief would maintain the status quo, i.e., continue Defendants' current Namenda IR sales and distribution activities in order to preserve the Court's power to make a final determination regarding the legality of Defendants' proposed new course of action. The authorities Defendants cite in support of the higher standard are inapposite, as those pertain to injunctions that would alter rather than perpetuate the status quo. See e.g., Lincoln Cercpac v. Health and Hospitals Corp., 920 F.Supp. 488, 494 (S.D.N.Y. 1996) (holding that an injunction to re-open

an already-closed hospital would be mandatory rather than prohibitive, since it would upset the status quo); Cacchillo v. Insmed, Inc., 638 F.3d 401, 405 (2d Cir. 2011) (holding that an injunction requiring a company to provide a document that it had, up to that point, refused to provide is mandatory rather than prohibitive); SEC v. Unifund SAL, 910 F.2d 1028, 1039 (2d Cir. 1990) (holding that a prohibition against violating securities laws in the future is mandatory rather than prohibitive); Union Cosmetic Castle, Inc. v. Amorepacific Cosmetics USA, Inc., 454 F. Supp. 2d 62, 68 (E.D.N.Y. 2006) (holding that an injunction requiring a company to re-establish a severed business relationship is mandatory rather than prohibitive); Vantico Holdings v. Apollo Mgmt., LP, 247 F. Supp. 2d 437, 451 (S.D.N.Y. 2003) (holding that an injunction requiring a party to alter the way it votes is mandatory rather than prohibitive).

The second aspect of the Tom Doherty heightened standard is also inapplicable. A preliminary injunction would not provide the State with substantially all of the final relief it seeks in this case. The State seeks a permanent injunction and civil penalties for current violations of New York law and seeks to recover damages caused by Defendants' "misleading

announcements of the timing and scope of their discontinuation of Namenda IR." Pl.'s Mem. in Supp't 20; AC ¶ c. Moreover, the preliminary injunction would only bar Defendants from altering current Namenda IR distribution until a final adjudication of this case is completed.

Since a heightened mandatory injunction standard does not apply in this case, the State may show the following to succeed on its motion for a preliminary injunction: (1) a sufficiently serious question going to the merits of its claims to make them fair ground for litigation; (2) irreparable harm in the absence of the preliminary injunction; (3) a balance of the hardships tipping decidedly in its favor; and (4) that issuance of the injunction would be in the public interest. See Oneida, 645 F.3d at 164.

VIII. Substantial Questions of Antitrust Violations Exist

The State has presented facts as set forth above to support its claims of violations of Sections 1 and 2 of the Sherman Act, and of New York State's Donnelly Act.

A. The Appropriate Market is the U.S. Memantine Drug Market

An initial step in antitrust claim analysis requires identification of the market, which consists of a relevant product and geographic market. PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 105 (2d Cir. 2002) (components of market definition); Geneva Pharm. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004) (market definition is the initial step to both Section 1 and Section 2 claims). A relevant geographic market is the area "in which the seller operates and where consumers can turn, as a practical matter, for supply of the relevant product." United States v. Eastman Kodak Co., 63 F.3d 95, 104 (2d Cir. 1995). A relevant product market "is composed of products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." United States v. E. I. Du Pont de Nemours & Co., 351 U.S. 377, 404 (1956). As the geographic market is not in dispute here, definition of the product market is the relevant inquiry. FOF ¶ 70.

In defining the market, courts consider the choices available to consumers in the market. See Eastman Kodak Co. v. Image Tech. Servs., 504 U.S. 451, 482 (1992) citing United States v. Grinnell Corp., 384 U.S., at 572. Courts consider

"practical indicia [such as] industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price change, and specialized vendors." See Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962). Cross-elasticity of demand is a common empirical methodology used to determine whether two or more products comprise the same market. See e.g. Bogan v. Hodgkins, 166 F.3d 509, 516 (2d Cir. 1999) citing Brown Shoe, 370 U.S. at 325; Chapman v. New York State Div. for Youth, 546 F.3d 230, 238 (2d Cir. 2008); Hayden Pub. Co. v. Cox Broad. Corp., 730 F.2d 64, 71 (2d Cir. 1984). The cross-elasticity of demand calculation measures change in sales of a product to price changes of a potential substitute. E. I. du Pont, 351 U.S. at 400. A high cross-elasticity of demand suggests substitutability, while a low one does not; consumers will respond to an increase in the price of one product by purchasing the relatively inexpensive second product only if the two products are substitutes. See id. As a result, two products with high cross-elasticity of demand are properly grouped into the same market since they are substitutes. Id.

A single product may constitute a relevant market where there are no reasonably interchangeable substitutes. See Image Tech., 504 U.S. at 481-82. To be a substitute product for purposes of product market definition, customers must be willing to switch to a competitive product as a result of a price change. United States v. H&R Block, Inc., 833 F. Supp. 2d 36 (D.D.C. 2011).

As in this instance, courts have found a single brand-name drug and its generic equivalents to be a relevant product market in cases where the challenged conduct involves a branded drug manufacturer's effort to exclude generic competition. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 377-88 (D. Mass. 2013) ("The fact that other drugs may be used to treat heartburn and related conditions is immaterial to the present inquiry."); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fl. 2005).

The facts found above establish the State's contention that the appropriate product market in this case is the nationwide memantine market. See generally FOF § IV. CIs and memantine are not considered substitutes nor are they prescribed

as such by physicians. FOF ¶¶ 58, 62. CIs are used to treat patients with mild-stage Alzheimer's while memantine is not indicated for such patients, and the two types of drugs are predominantly complements rather than supplements. FOF ¶ 57.

Defendants' contention that the appropriate product market should include CIs is not well supported by the evidence. As found above, Defendants' cross elasticity of demand analysis was less convincing than the State's. FOF ¶ 67. Industry categorizations of memantine and CIs as part of the "Alzheimers' Drug Market" or an "anti-dementia" category do not alter the observable behavior of patients and physicians, as reflected in the cross elasticity of demand analyses summarized above. See FOF § IV.B. Categorizations in this instance may not be based on substitutability, but rather serve as umbrella terms encompassing distinct product markets: akin to, perhaps, categorizing two distinct non-substitutable products such as a sponge and soap under the umbrella of cleaning supplies. Similarly, the fact that both CIs and memantine tablets can be produced using the same machinery and sold along the same distribution channels does not establish substitutability. Adopting Defendants' contention, tablet forms of dissimilar medicines, for example heart medication and statins, may be

considered substitutes because they can be made on the same machines and distributed along the same sales channels.

The appropriate geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States.

B. The Defendant's Monopoly Power

To establish a claim of unlawful monopolization under Section 2 of the Sherman Act, the State must show that Defendants: (a) have monopoly power in a relevant market and; (b) acquired or maintained such monopoly power through anticompetitive exclusionary conduct. See Grinnell, 384 U.S. at 570-71. To establish a claim of unlawful attempted monopolization under Section 2 of the Sherman Act, the State must show that Defendants: (1) engaged in anticompetitive behavior; (2) with specific intent to monopolize; and (3) with a dangerous probability of achieving monopoly power. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993); PepsiCo, 315 F.3d at 105 (2d Cir. 2002). The two claims are substantially identical, with the exception that attempted monopolization requires a showing of specific intent to

monopolize. The remaining elements can be addressed jointly. Exclusionary behavior under the monopolization claim and anticompetitive conduct under the attempted monopolization claim overlap. The first monopolization and the third attempted monopolization elements vary only by degree. See Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 100 (2d Cir. 1998) ("the same concept of market power as that used in a completed monopolization claim [applies] . . . [though] a lesser degree of market power may establish an attempted monopolization claim than that necessary to establish a completed monopolization claim").

Having established that the relevant market is the nationwide memantine market, the issue is whether Defendants have monopoly power in the relevant market, i.e., "the ability to control prices or exclude competition." United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956); PepsiCo, 315 F.3d at 107. While a "patent does not of itself establish a presumption of market power in the antitrust sense," In re Indep. Serv. Organizations Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000), a high market share is an indication of monopoly power. Tops Markets, 142 F.3d at 98 (quoting Broadway Delivery Corp. v. United Parcel Serv. of

America, Inc., 651 F.2d 122, 129 (2d Cir.1981) ("the higher a market share, the stronger is the inference of monopoly power"). A complete market power analysis considers market share in light of the relevant market's particular characteristics, including "strength of the competition, the probable development of the industry, the barriers to entry, the nature of the anticompetitive conduct and the elasticity of consumer demand." Id. citing Int'l Distribution Centers, Inc. v. Walsh Trucking Co., 812 F.2d 786, 792 (2d Cir. 1987); see also Hayden, 730 F.2d at 69 citing United States v. Columbia Steel Co., 334 U.S. 495, 527 (1948). Market power may also be established by considering evidence of anticompetitive effects of the challenged conduct. FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 460-61 (1986) ("proof of actual detrimental effects . . . can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects."); Geneva Pharms, 386 F.3d at 509; Tops Markets, 142 F.3d at 98 (market power may be proven by direct evidence of anticompetitive effects); Todd v. Exxon Corp., 275 F.3d 191, 206 (2d Cir. 2001) ("If a plaintiff can show that a defendant's conduct exerted an actual adverse effect on competition, this is a strong indicator of market power.").

As established by the facts found above, prior to generic entry into the market, Defendants are the exclusive producers of all forms of memantine. FOF ¶ 41. Until that time, Defendants control price and distribution for memantine, and have a patent-protected right to exclude all competition. FOF ¶ 126. As CIs are not indicated for moderate to severe Alzheimer's patients, most patients in that group have no alternative to memantine. FOF ¶ 57. Prior to July 2015, Defendants have 100% of the market, there is no competition, development is controlled by Defendants, Defendants' patent are absolute barriers to entry, and demand is inelastic: Defendants have monopoly power. See generally FOF § IV.

Starting in July 2015, however, several generic manufacturers enter the memantine market and Defendants' memantine market share is projected to drop below 100%. See FOF ¶¶ 126-27, 136. Determining whether Defendants will continue to enjoy monopoly power following generic entry requires projections of future conditions in the memantine market. [redacted] FOF ¶ 147. At minimum, this conflict establishes that a serious question exists as to whether

Defendants will control sufficient market share to qualify as strong evidence of monopoly power. As found above, Defendants projected control of [redacted] of the memantine market ([redacted] with XR and [redacted] with the upcoming fixed dose combination) in 2016. FOF ¶ 139. This is a considerable market share, indeed "a share above 70% is usually strong evidence of monopoly power." Broadway Delivery Corp. v. United Parcel Serv. of Am., Inc., 651 F.2d 122, 129 (2d Cir. 1981).

Moreover, depending on other market factors, courts in the Second Circuit have permitted findings of market power with shares less than 50%. See United States v. Visa USA, Inc., 344 F.3d 229, 240 (2d Cir. 2003) (MasterCard found to have market power with 26% market share); Broadway Delivery, 651 F.2d at 129 ("the jury should not be told that it must find monopoly power lacking below a specified share or existing above a specified share"); In re Payment Card Interchange Fee & Merchant Discount Antitrust Litig., 562 F. Supp. 2d 392, 400 (E.D.N.Y. 2008) (a finding of market share less than 30% would not foreclose the possibility of proving monopoly power).

In the hard switch scenario, Defendants' generic competitors will be limited to the [redacted] of the memantine market

not controlled by XR and the anticipated FDC Namenda product. FOF ¶ 139. The switch-resistant Namenda users already taking XR, i.e., the majority of all memantine users at the time of generic entry, will likely exhibit the same resistance to adopting generic IR as exhibited by current IR patients resisting XR. FOF ¶¶ 85, 154. Physician and health plan hesitations to change their patients' medications will exacerbate this inertia. FOF ¶¶ 143-45, 155.

Defendants' dominance in the memantine market creates an adverse effect on memantine pricing and competition. FOF ¶ 117. Non-AB-rated generic drugs are not able to compete effectively for sales of a branded drug in the same class, even if the price of the generics is much lower than the brand. FOF ¶ 133. The Lipitor example, where the absence of AB-substitution limited a generic to only 30% of the market, is illustrative. FOF ¶ 133. Furthermore, generic drugs are typically not marketed to physicians or patients. FOF ¶ 128. Defendants' conduct, by emphasizing the more expensive patent-protected formulations of memantine and eliminating distribution of the Namenda IR formulation subject to generic substitution laws, may therefore significantly alter the average price of memantine in the market. FOF ¶ 117.

The evidence found above, while not definitive, adequately establishes a substantial question as to whether Defendants have monopoly power over the relevant market.

C. Anticompetitive Conduct by Defendants

While the mere possession of monopoly power is not unlawful, monopolists cannot run their businesses in an anticompetitive manner. See e.g., Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); United States v. Microsoft, 253 F.3d 34, 64 (D.C. Cir. 2001); C.R. Bard, Inc. v. M3 Sys., 157 F.3d 1340 (Fed. Cir. 1998); United States v. Dentsply Int'l, 399 F.3d 181 (3d Cir. 2005).

The central inquiry is whether "a monopoly [is] engaging in exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Microsoft Corp., 253 F.3d at 58 quoting Grinnell, 384 U.S. at 571; see also Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 274 (2d Cir. 1979); Port Dock & Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 124 (2d Cir. 2007); In re Adderall XR Antitrust Litig., 754 F.3d 128,

133 (2d Cir. 2014), as corrected (June 19, 2014); cf. United States v. Colgate & Co., 250 U.S. 300, 307 (1919) ("In the absence of any purpose to create or maintain a monopoly, the [Sherman] act does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal) (emphasis added).

A monopolist's decision to withdraw a product from customers may violate antitrust laws if done for the sole purpose of harming competition, i.e., if it constitutes exclusionary conduct. See e.g., Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 424 (D. Del. 2006) (defendant's decision to withdraw a prior drug formulation of TriCor in an effort to shift patients to a new one and exclude generic competition may be exclusionary); Xerox Corp. v. Media Scis. Int'l., 511 F. Supp. 2d 372, 388 (S.D.N.Y. 2007) (discontinued and redesigned printer models to "foreclose all other competition, and not to improve the product" may be exclusionary); Glen Holly Entm't v. Tektronix Inc., 352 F.3d 367, 374 (9th Cir. 2003) (reversing dismissal of plaintiff's antitrust claims when "discontinuation of the only competing product on the market [left consumers with no] viable choice

between market alternatives") (internal citation omitted)); Free Freehand Corp. v. Adobe Sys., 852 F. Supp. 2d 1171, 1182 (N.D. Cal. 2012) ("[I]t is reasonable to infer that Adobe's discontinuation of FreeHand and channeling of FreeHand users to Illustrator made it more difficult for potential competitors of Illustrator . . . to enter the market"); see also Berkey Photo, 603 F.2d at 287 n.39 ("the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera").

The D.C. Circuit case United States v. Microsoft lays out a useful framework for determining whether Defendants have engaged in anticompetitive conduct. 253 F.3d at 58. The plaintiff must demonstrate that the defendant's conduct had an anticompetitive effect. Id. If the plaintiff establishes an anticompetitive effect, then the monopolist may proffer a procompetitive justification for its conduct - "a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." Id. at 58-59. If the monopolist succeeds, then the plaintiff must rebut that justification or

demonstrate that the anticompetitive harm of the conduct outweighs its procompetitive effect. Id. at 59.

The Microsoft case has been widely cited by courts in this circuit, and its framework is frequently employed. See e.g., Meredith Corp. v. Sesac, LLC, 1 F. Supp. 3d 180, 222 (S.D.N.Y. 2014) (citing Microsoft, 253 F.3d at 59, for the proposition that "the determination of § 2 liability calls for a weighing of the exclusionary conduct against any 'valid business reasons' for it."); IHS Dialysis v. Davita, Inc., 2013 U.S. Dist. LEXIS 47532, *24 (S.D.N.Y. Mar. 31, 2013) (citing Microsoft, 253 F.3d at 58 for the proposition "[w]hether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern: the means of illicit exclusion, like the means of legitimate competition, are myriad."); In re Fresh Del Monte Pineapples Antitrust Litig., 2009 U.S. Dist. LEXIS 97289, *21, 55, 69 (S.D.N.Y. Sept. 30, 2009) (utilizing the Microsoft test to determine a § 2 violation). This framework has also more recently been applied in another forced switch antitrust decision, In Re Suboxone Antitrust Litigation, MDL No. 2445 (E.D. Pa. Dec. 3, 2014).

As explained below, anticompetitive effect is adequately demonstrated under the Microsoft framework and Defendants' procompetitive justifications are either not plausible or outweighed by the anticipated anticompetitive effects of the limited distribution strategy.

1. The State Demonstrated Anticompetitive Effect

The State demonstrated a substantial risk that Defendants' limited distribution strategy would harm competition in the memantine market, as found above. See generally FOF § VI. Both regulators and commentators recognize the substantial anticompetitive effect that circumvention of state substation laws can have. See Brief for Federal Trade Commission as Amicus Curiae at 9, Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., No. 2:12-CV-03824-PD (E.D. Pa. Dec. 13, 2012) (PX4) ("As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears."); Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 14, Mylan (PX5) ("Under Hatch-Waxman and state substitution laws, generics can only compete cost-effectively through substitution on the new or old branded drug version."); cf. FTC v. Actavis, 133 S.Ct. 2223, 2228 (2013) ("The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speed[s] the

introduction of low-cost generic drugs to market . . . thereby furthering drug competition.") (internal quotations and citations omitted).

Defendants undertook to achieve significantly higher levels of conversion from IR to XR precisely by reducing generic competition, putting in place a limited distribution strategy to serve as an "obstacle" to generic switching, thwarting state substitution laws. The result of the forced switch, as found above, is inflation of XR's share of the memantine market. FOF ¶¶ 134, 137. Most patients are effectively denied access to IR for the six months prior to generic entry.

That the limited distribution does not ban all competition does not demonstrate absence of exclusionary behavior. Exclusionary behavior need not result in "total foreclosure" of competition, but rather is found where "the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Dentsply, 399 F.3d at 191; LePage's Inc. v. 3M, 324 F.3d 141, 159 (3d Cir. 2003); Microsoft, 253 F.3d at 69; In re Fresh Del Monte Pineapples Antitrust Litig., 04-MD-1628, 2009 WL 3241401, at *16 (S.D.N.Y. Sept. 30, 2009) aff'd sub nom. Am. Banana Co. v. J. Bonafede

Co., 407 F. App'x 520 (2d Cir. 2010). "Where a course of action is ambiguous, 'consideration of intent may play an important role in divining the actual nature and effect of the alleged anticompetitive conduct.'" Berkey Photo, 603 F.2d at 288 quoting United States v. United States Gypsum Co., 438 U.S. 422, 436 n.13 (1978).

The State has met its burden under the first prong of Microsoft.

2. Defendants' Procompetitive Justifications Are Pretextual

In evaluating a monopolization claim, the trier of fact must distinguish "between conduct that defeats a competitor because of efficiency and consumer satisfaction, and conduct that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." Trans Sport, Inc. v. Starter Sportswear, Inc., 964 F.2d 186, 188-89 (2d Cir. 1992) (internal quotations and citations omitted); see also Microsoft, 253 F.3d at 59, 65.

The Supreme Court has held that where consumer choices are made as a result of "forcing" customers to purchase a product, then that is not competition on the merits. Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 27 (1984) (condemning tying as anticompetitive where it "restrain[s] competition on the merits by forcing purchases that would not otherwise be made"). Where "the conduct has no rational business purpose other than its adverse effects on competitors, an inference that it is exclusionary is supported." Stearns Airport Equip. Co. v. FMC Corp., 170 F.3d 518, 522 (5th Cir. 1999).

Saunders stated, contemporaneously with the adoption of the hard switch by Forest, that the purpose of the switch was anticompetitive: to put barriers obstacles in the path of producers of generic memantine and thereby protect Namenda's revenues from a precipitous decline following generic entry. FOF ¶ 116. He further stated: "if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing [prescriptions]. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it

can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff."). FOF ¶ 116.

Saunders's motivation for the hard switch, expressed at the hearing, that his team could better "focus" on XR and FDC if IR was no longer sold by Defendants, was not as specific, or as persuasive, as his earlier representations to shareholders, quoted above. Compare FOF ¶ 78 with ¶ 116; see also FOF ¶ 122.

As found above, Defendants' and Defendants' experts' rationalizations for the hard switch strategy are not only later-in-time but also not as persuasive. The only quantified savings from the limited distribution are roughly [redacted] of the loss of IR revenue within the first six months. FOF ¶ 119. Defendants did not quantify the remaining pro-competitive justifications identified in conjunction with this case. FOF ¶¶ 116, 120. Nor did Saunders elaborate on how the hard switch strategy would allow for greater focus. FOF ¶¶ 116, 120. There is no indication that these ancillary benefits were the basis for Defendants' hard switch strategy. FOF ¶ 121.

Finally, by contending at the hearing that a preliminary injunction against the forced switch would require significant changes to Defendants' operations as a result of the potential loss of [redacted] in sales, Defendants have essentially conceded that it is this expectation of [redacted] increased sales of Namenda XR that is driving thei[redacted] decision to engage in the forced switch. No other non-pretexual pro-competitive purpose has been established, either at the hearing or by any contemporary Forest analysis.

3. Any Procompetitive Justifications Are Outweighed by the Anticompetitive Impact of the Conduct

To avoid liability, Defendant may offer legitimate business justifications for their exclusionary conduct that outweigh the anticompetitive effects. Microsoft, 253 F.3d at 59; Xerox, 511 F. Supp. 2d at 389. Since these legitimate business justifications must outweigh the anticompetitive effect of the conduct to avoid liability, proffering a minor, immaterial efficiency justification for conduct, the principal purpose and effect of which is to harm competition, will not render such conduct lawful. Microsoft, 253 F.3d at 58-59, 64-66; Xerox, 511 F. Supp. 2d at 388-89; Abbott Labs., 432 F. Supp. 2d at 422. Rather, in such cases, the procompetitive benefits

of the business justification must outweigh the anticompetitive effects.

As discussed above, Defendants have not identified how the limited distribution efficiencies would outweigh [redacted]. The savings from the limited distribution are dwarfed by the loss of IR revenue within the first six months. FOF ¶ 119. The remaining justifications were not quantified. FOF ¶¶ 119-120. More to the point, these cost savings are dwarfed by the considerable anticompetitive harm: both to patients, who will pay [redacted] in higher co-payments or have to switch medications twice, and to third party payors, who will pay more than [redacted]. FOF ¶ 161.

On the basis of these factual findings, Defendants' justifications are outweighed by the anticompetitive effects of the limited distribution. Therefore, there is a serious question as to whether Defendants' limited distribution strategy constitutes competitive conduct.

D. Sherman Act Section 1 Claim

To establish a claim under Section 1 of the Sherman Act, the State must demonstrate: (a) concerted action between Defendants and Foundation Care; (b) resulting in an unreasonable restraint of trade affecting the United States. See Tops Markets, 142 F.3d at 95-96; 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal"); see also Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 885 (2007) (noting that Section 1 is properly construed to bar only unreasonable restraints, not all restraints).

Concerted action within the meaning of Section 1 exists when an agreement between "separate economic actors pursuing separate economic interests . . . deprives the marketplace of independent centers of decisionmaking." Am. Needle, Inc. v. Nat'l Football League, 560 U.S. 183, 195 (2010) (internal quotations and citations omitted). Foundation Care and Defendants are separate economic actors, occupying differing roles in the memantine supply chain: under the hard switch strategy, Defendants remain the sole supplier, or "vendor," and Foundation Care becomes the sole distributor, termed the "independent contractor." FOF ¶ 104. This is sufficient to

establish concerted action. See Anderson News, LLC v. Am. Media, Inc., 680 F.3d 162, 182 (2d Cir. 2012).

Allegations of restraints that are not per se unlawful are analyzed under the rule of reason test, where "the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Leegin, 551 U.S. at 885 (2007) (internal citations and quotations omitted). "When applying the rule of reason, courts weigh all of the circumstances surrounding the challenged acts to determine whether the alleged restraint is unreasonable, taking into account factors such as specific information about the relevant business, the restraint's history, nature, and effect, and whether the businesses involved have market power." Gatt Commc'ns, Inc. v. PMC Associates, L.L.C., 711 F.3d 68, 75 (2d Cir. 2013) (internal quotations omitted) citing Leegin, 551 U.S. at 885).

The Section 2 analysis above satisfies the unreasonable restraint prong. Defendants have monopoly power in the memantine market. See generally FOF § IV. The hard switch strategy will likely have an anticompetitive effect on that

market, denying current memantine patients access to IR tablets and driving up the average price of memantine following generic entry. See generally FOF § VI. In sum, the hard switch strategy constitutes an unreasonable restrain on trade without a pro-competitive justification, as discussed above.

The cases Defendants cite in opposition to this claim do not alter this conclusion. While it is true that manufacturers generally have control over distribution, E & L Consulting, Ltd. v. Doman Indus. Ltd., 472 F.3d 23, 30 (2d Cir. 2006), they are not permitted to exert that control in a manner that violates the antitrust laws. See Leegin, 551 U.S. at 892 (discussing the illegality of vertical restraints).

In E & L Consulting, the Second Circuit affirmed dismissal of a Section 1 claim for failure to plead that the concerted action would yield an adverse effect on the market. 472 F.3d at 31. The facts in that case established that the defendant-monopolist would continue to enjoy monopoly power with or without the agreement in question. Id. at 29 (the monopolist held 95% of the market). Since the defendant in E & L Consulting did not need the agreement to further its monopoly, the Second Circuit concluded that the agreement was not a proper

basis for Section 1 liability. Id. at 30. By contrast, Defendants in this case face potential competition from numerous generic manufacturers in summer of 2015, and are relying on the MSA to maintain their market power. This is also not a case where the vertical agreement is made for a pro-competitive reason. Compare the anticompetitive effect in this case with that in Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36 (1977) ("[v]ertical restrictions promote interbrand competition by allowing the manufacturer to achieve certain efficiencies in the distribution of his products").

As with the Section 2 claims, the State has demonstrated a substantial question exists as to the legality of the MSA as governed by Section 1 of the Sherman Act.

E. State Law Violations by Defendants

The Donnelly Act makes illegal and void any contract, arrangement, or agreement that restrains competition in any business, or unlawfully interferes with the free exercise of any activity in the conduct of any business, and is generally construed in accordance with the Sherman Act. See N.Y. Gen.

Bus. Law § 340; Anheuser-Busch, Inc. v. Abrams, 71 N.Y.2d 327, 334 (N.Y. 1988).

"A plaintiff alleging a claim under the Donnelly Act must identify the relevant product market, allege a conspiracy between two or more entities, and allege that the economic impact of that conspiracy was to restrain trade in the relevant market." Thome v. Alexander & Louisa Calder Found., 890 N.Y.S.2d 16, 32 (App. Div. 2009); see also, Benjamin of Forest Hills Realty, Inc. v. Austin Sheppard Realty, Inc., 823 N.Y.S.2d 79 (App. Div. 2006); Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp., 224 F. Supp. 2d 657, 678 (S.D.N.Y. 2002).

The Donnelly Act analysis tracks the Section 1 of the Sherman Act claim, as analyzed above. As with the Section 1 claim, the State has met its burden of demonstrating a substantial question going to the merits of this claim.

Under Section 63(12), the New York State Attorney General may sue defendants for violations of state or federal law, including Sherman Act or Donnelly Act violations, affecting more than one person within New York State. N.Y. Exec. L. §

63(12); State v. Feldman, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002) (antitrust violations are predicate offenses); State v. Stevens, 497 N.Y.S.2d 812, 813 (N.Y. Sup. Ct. 1985); People v. Wilco Energy Corp., 728 N.Y.S.2d 471, 471 (2d Dep't 2001) (the Attorney General can show repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person to satisfy the "repetition" requirement under the law).

As discussed above, the State has established a substantial question on the merits of its Sherman and Donnelly Act antitrust claims, and therefore adequately established these claims as well.

IX. A Preliminary Injunction Is Appropriate

Upon the establishment of serious questions of antitrust violations as concluded above, the standard questions for preliminary injunction relief remain and are concluded in favor of the State. The irreparable injury has been established, the balance of hardships tips markedly in the favor of the State, and the public interest is best served by preliminary relief maintaining the status quo.

Since the introduction of Namenda XR in 2013, Forest has successfully marketed and sold both XR and IR products. FOF ¶ 53. Namenda IR has been in the market since 2004 and its yearly sales have exceeded $1.5 billion, as found above. FOF ¶ 44. The present Forest sales program is consistent with an accepted industry practice of a soft switch when a new product is introduced, a practice that maintains consumer choice before and after generic entry into the market. FOF ¶ 36. To maintain the status quo is appropriate relief under the circumstances here presented.

A. Irreparable Harm Has Been Established

Although the State has maintained otherwise, see Pl.'s Mem. in Supp't 40, it is not entitled to a presumption of irreparable harm. See 15 U.S.C. § 26 (authorizing injunction "when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity . . . and a showing that the danger of irreparable loss or damage is immediate"); Salinger v. Colting, 607 F.3d 68, 78 n.7 (2d Cir. 2010) (noting that eBay Inc. v. MercExchange, LLC, 547 U.S. 388, (2006), eliminated all

presumptions of irreparable harm absent contrary explicit congressional intent); see also Weinberger v. Romero-Barcelo, 456 U.S. 305, 313 (1982) (statute should not be read lightly to replace traditional equity test). Therefore, the State "must demonstrate that absent a preliminary injunction [it] will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." Grand River Enter. Six Nations, Ltd. v. Pryor, 481 F.3d 60, 66 (2d Cir. 2007) (internal quotations and citations omitted). Consequently, the State must show that there is a "substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." Brenntag Int'l Chemicals, Inc. v. Bank of India, 175 F.3d 245, 249 (2d Cir. 1999).

The facts found above established that that patients, caregivers, and physicians will be constrained in obtaining Namenda IR in the absence of a preliminary injunction. FOF ¶ 112. Permanent damage to competition in the memantine market can also result from Defendants' planned hard switch strategy. See generally FOF § VI.A.

In addition, in the absence of a preliminary injunction and in the accomplishment of the Defendants' hard switch, consumers will pay almost $300 million more for a memantine drug than if the present sales patter is maintained. Although this is a projected financial loss to Alzheimer's patients, it can be avoided by maintaining the status quo. See Bon-Ton Stores v. May Dep't Stores Co., 881 F. Supp. 860, 866 (W.D.N.Y. 1994) ("With respect to irreparable harm, doubts as to whether an injunction sought is necessary . . . should be resolved in favor of granting the injunction.") (internal quotations and citations omitted).

B. The Balance of Hardships Tips in Favor of the State

In determining whether to grant a preliminary injunction, courts consider the balance of harms between the movant and the party subject to the injunction. See Amoco Prod. Co. v. Vill. of Gambell, 480 U.S. 531, 542 (1987); Random House, Inc. v. Rosetta Books LLC, 283 F.3d 490, 492 (2d Cir. 2002).

The facts found above demonstrate that the hard switch will injure competition and consumers. See generally FOF § VI. Conversely, the Defendants have not demonstrated any harm

resulting from their continuing the same IR distribution strategy they have been using since 2004. FOF ¶ 38. And Defendants have failed to quantify any material costs that would result from an injunction. FOF ¶¶ 116, 120. No evidence has been submitted that continuing to supply the market with Namenda IR, an activity they have been doing by choice for over a decade, constitutes a hardship. To the contrary, the evidence suggests that continuing to sell IR will be a net benefit to Defendants [redacted]. FOF ¶ 118.

Having to compete with other firms in the market is what the antitrust laws require, not a cognizable harm. Harm is not established by refraining conduct that "seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect." Abbott Labs., 432 F. Supp. 2d at 422. As found above, Defendants actually risk losing [redacted] in revenues gained through anticompetitive, i.e., illegally, conduct. This is not a cognizable harm.

C. The Public Interest Favors Granting the Injunction

Finally, "[c]ourts of equity may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved.") (internal quotations and citations omitted." United States v. First Nat'l City Bank, 379 U.S. 378, 383 (1965); accord Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 424 (2d Cir. 2004) quoting Standard & Poor's Corp. v. Commodity Exch., Inc., 683 F.2d 704, 711 (2d Cir. 1982).

Here, the State seeks to enforce laws on behalf of the public. FOF ¶ 1. Courts presume that government action taken in furtherance of a regulatory or statutory scheme is in the public interest. See, e.g., Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 424 (2d Cir. 2004). Enforcing the antitrust laws serves the public interest in a competitive marketplace, here the memantine market. See United States v. Siemens Corp., 621 F.2d 499, 506 (2d Cir. 1980).

Additionally, a preliminary injunction will protect the public interest by safeguarding the fundamental compromise envisioned by the Hatch-Waxman Act, which sought to reconcile the sometimes conflicting public policy goals of making affordable generic drugs available to consumers and protecting

pharmaceutical companies' incentives to innovate. FOF § II.E. Defendants have accepted a five-year extension to their patent rights, took advantage of pediatric exclusivity, and used Hatch-Waxman's mechanism for delaying generic entry by suing would-be generic competitors, thus delaying their approval. FOF ¶ 38. The hard switch violates the spirit of the Hatch-Waxman Act and the public policy underlying it.

Defendants have contended that allowing them to engage in the hard switch will allow increased innovation in the long term, as greater financial resources are made available to Defendants. Defs.' Mem. in Opp'n 23. However, optimizing the incentives for innovation requires that the legal system reward pharmaceutical companies for truly innovative conduct that benefits consumers, by means of better drugs that physicians and patients are willing to switch to voluntarily. Providing financial rewards for anticompetitive conduct is not in the public interest.

Conclusion

Based upon the finding of fact conclusions of law set forth above, a preliminary injunction will issue. The State will submit a proposed preliminary injunction by 5:00 PM on December 12, 2014, and a hearing will be held in Courtroom 23B on December 15, 2014 at noon.

It is so ordered.

New York, NY
December 11, 2014

ROBERT W. SWEET
U.S.D.J.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

14 Civ. 7473

-against-

ORDER

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

----------X

Upon the findings of fact and conclusions of law set forth in the Opinion of this Court dated December 11, 2014, it is hereby ORDERED that:

1. During the Injunction Term as defined below, the Defendants shall continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market).

2. On or before December 23, 2014, Defendants shall inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view the injunction) and the continued availability of Namenda IR in the same or

substantially similar manner in which they informed them of Defendants' plan to discontinue Namenda IR in February 2014.

3. The Defendants shall not impose a "medical necessity" requirement or form for the filing of prescriptions of Namenda IR during the Injunction Term.

4. In order to allow for an orderly transition, this injunction shall be effective from the date of issuance until thirty days after July 11, 2015 (the date when generic memantine will first be available) (the "Injunction Term").

New York, NY
December 15, 2014

ROBERT W. SWEET
U.S.D.J.

CONSTITUTION OF THE UNITED STATES

We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defence, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America.

Article. I.

Section. 1. All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.

Section. 2. The House of Representatives shall be composed of Members chosen every second Year by the People of the several States, and the Electors in each State shall have the Qualifications requisite for Electors of the most numerous Branch of the State Legislature.

No Person shall be a Representative who shall not have attained to the Age of twenty five Years, and been seven Years a Citizen of the United States, and who shall not, when elected, be an Inhabitant of that State in which he shall be chosen.

[Representatives and direct Taxes shall be apportioned among the several States which may be included within this Union, according to their respective Numbers, which shall be determined by adding to the whole Number of free Persons, including those bound to Service for a Term of Years, and excluding Indians not taxed, three fifths of all other Persons.]* The actual Enumeration

*Changed by section 2 of the Fourteenth Amendment.

the President of the United States; and before the Same shall take Effect, shall be approved by him, or being disapproved by him, shall be repassed by two thirds of the Senate and House of Representatives, according to the Rules and Limitations prescribed in the Case of a Bill.

Section. 8. The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

To borrow Money on the credit of the United States;

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

To establish an uniform Rule of Naturalization, and uniform Laws on the subject of Bankruptcies throughout the United States;

To coin Money, regulate the Value thereof, and of foreign Coin, and fix the Standard of Weights and Measures;

To provide for the Punishment of counterfeiting the Securities and current Coin of the United States;

To establish Post Offices and post Roads;

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

To constitute Tribunals inferior to the supreme Court;

To define and punish Piracies and Felonies committed on the high Seas, and Offenses against the Law of Nations;

To declare War, grant Letters of Marque and Reprisal, and make Rules concerning Captures on Land and Water;

HISTORICAL NOTE

This chapter includes among other statutory provisions the Sherman Act, comprising sections 1 to 7 of this title, the Clayton Act, comprising sections 12, 13, 14 to 19, 20, 21, and 22 to 27 of this title and sections 52 and 53 of Title 29, Labor, the Wilson Tariff Act, comprising sections 8 and 9 of this title, the Robinson-Patman Price Discrimination Act, comprising sections 13, 13a, 13b, and 21a of this title, the "Expediting Act", sections 28 and 29 of this title, and the "Hart-Scott-Rodino Antitrust Improvements Act of 1976", comprising sections 15c to 15h, 18a, and 66 of this title. For complete classification of the Hart-Scott-Rodino Act, see Short Title note under section 1 of this title.

CONGRESSIONAL INVESTIGATION OF MONOPOLY

Joint Res. June 16, 1938, ch. 456, 52 Stat. 705, created a Temporary National Economic Committee which was authorized to make a full investigation on monopoly and the concentration of economic power in and financial control over production and distribution of goods and services. The time for submitting the final report under Joint Res. June 16, 1938, ch. 456, 52 Stat. 705, as amended Apr. 26, 1939, ch. 104, §§1, 2, 53 Stat. 624, was extended to Apr. 3, 1941, by Joint Res. Dec. 16, 1940, ch. 932, 54 Stat. 1225. The committee's report was presented to Congress on Mar. 31, 1941, and was published in Senate Document No. 35.

EXECUTIVE ORDER NO. 12022

Ex. Ord. No. 12022, Dec. 1, 1977, 42 F.R. 61441, as amended by Ex. Ord. No. 12052, Apr. 7, 1978, 43 F.R. 15133, which related to the National Commission for the Review of Antitrust Laws and Procedures, was revoked by Ex. Ord. No. 12258, Dec. 31, 1980, 46 F.R. 1251, formerly set out as a note under section 14 of the Appendix to Title 5, Government Organization and Employees.

§ 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

(July 2, 1890, ch. 647, §1, 26 Stat. 209; Aug. 17, 1937, ch. 690, title VIII, 50 Stat. 693; July 7, 1955, ch. 281, 69 Stat. 282; Pub. L. 93–528, §3, Dec. 21, 1974, 88 Stat. 1708; Pub. L. 94–145, §2, Dec. 12, 1975, 89 Stat. 801; Pub. L. 101–588, §4(a), Nov. 16, 1990, 104 Stat. 2880; Pub. L. 108–237, title II, §215(a), June 22, 2004, 118 Stat. 668.)

AMENDMENTS

2004—Pub. L. 108–237 substituted "$100,000,000" for "$10,000,000", "$1,000,000" for "$350,000", and "10" for "three".

1990—Pub. L. 101–588 substituted "$10,000,000" for "one million dollars" and "$350,000" for "one hundred thousand dollars".

1975—Pub. L. 94–145 struck out from first sentence two provisos granting anti-trust exemption to State fair trade laws.

1974—Pub. L. 93–528 substituted "a felony, and, on conviction thereof, shall be punished by fine not exceeding one million dollars if a corporation, or, if any other person, one hundred thousand dollars, or by imprisonment not exceeding three years" for "a misdemeanor, and on conviction thereof, shall be punished by fine not exceeding fifty thousand dollars, or by imprisonment not exceeding one year".

1955—Act July 7, 1955, substituted "fifty thousand dollars" for "five thousand dollars".

1937—Act Aug. 17, 1937, inserted two provisos.

EFFECTIVE DATE OF 2001 AMENDMENT

Pub. L. 107–72, §4, Nov. 20, 2001, 115 Stat. 650, provided that: "This Act [enacting and amending provisions set out as notes under this section] and the amendments made by this Act shall take effect on September 30, 2001."

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94–145, §4, Dec. 12, 1974, 89 Stat. 801, provided that: "The amendments made by sections 2 and 3 of this Act [amending this section and section 45 of this title] shall take effect upon the expiration of the ninety-day period which begins on the date of enactment of this Act [Dec. 12, 1975]."

SHORT TITLE OF 2009 AMENDMENT

Pub. L. 111–30, §1, June 19, 2009, 123 Stat. 1775, provided that: "This Act [enacting and amending provisions set out as notes under this section] may be cited as the 'Antitrust Criminal Penalty Enhancement and Reform Act of 2004 Extension Act'."

SHORT TITLE OF 2008 AMENDMENT

Pub. L. 110–327, §1, Sept. 30, 2008, 122 Stat. 3566, provided that: "This Act [amending provisions set out as

a note under this section] may be cited as the 'Need-Based Educational Aid Act of 2008'."

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110–6, §1, Feb. 26, 2007, 121 Stat. 61, provided that: "This Act [amending provisions set out as a note under this section] may be cited as the 'Antitrust Modernization Commission Extension Act of 2007'."

SHORT TITLE OF 2004 AMENDMENT

Pub. L. 108–237, title II, §201, June 22, 2004, 118 Stat. 665, provided that: "This title [amending this section and sections 2, 3, and 16 of this title and enacting provisions set out as notes under this section and section 16 of this title] may be cited as the 'Antitrust Criminal Penalty Enhancement and Reform Act of 2004'."

SHORT TITLE OF 2002 AMENDMENT

Pub. L. 107–273, div. C, title IV, §14101, Nov. 2, 2002, 116 Stat. 1921, provided that: "This title [amending sections 3, 12, 27, and 44 of this title, section 225 of Title 7, Agriculture, section 1413 of Title 30, Mineral Lands and Mining, and section 2135 of Title 42, The Public Health and Welfare, repealing sections 30 and 31 of this title, enacting provisions set out as a note under section 3 of this title, amending provisions set out as notes under this section and section 8 of this title, and repealing provisions set out as notes under section 15 of this title and section 41309 of Title 49, Transportation] may be cited as the 'Antitrust Technical Corrections Act of 2002'."

SHORT TITLE OF 2001 AMENDMENT

Pub. L. 107–72, §1, Nov. 20, 2001, 115 Stat. 648, provided that: "This Act [enacting and amending provisions set out as notes under this section] may be cited as the 'Need-Based Educational Aid Act of 2001'."

SHORT TITLE OF 1998 AMENDMENT

Pub. L. 105–297, §1, Oct. 27, 1998, 112 Stat. 2824, provided that: "This Act [enacting section 26b of this title and provisions set out as a note under section 26b of this title] may be cited as the 'Curt Flood Act of 1998'."

SHORT TITLE OF 1997 AMENDMENTS

Pub. L. 105–43, §1, Sept. 17, 1997, 111 Stat. 1140, provided that: "This Act [enacting and amending provisions set out as notes below] may be cited as the 'Need-Based Educational Aid Antitrust Protection Act of 1997'."

Pub. L. 105–26, §1, July 3, 1997, 111 Stat. 241, provided that: "This Act [amending sections 37 and 37a of this title and enacting provisions set out as notes under section 37 of this title] may be cited as the 'Charitable Donation Antitrust Immunity Act of 1997'."

SHORT TITLE OF 1995 AMENDMENT

Pub. L. 104–63, §1, Dec. 8, 1995, 109 Stat. 687, provided that: "This Act [enacting sections 37 and 37a of this title and provisions set out as a note under section 37 of this title] may be cited as the 'Charitable Gift Annuity Antitrust Relief Act of 1995'."

SHORT TITLE OF 1990 AMENDMENT

Pub. L. 101–588, §1, Nov. 16, 1990, 104 Stat. 2879, provided: "That this Act [amending this section and sections 2, 3, 15a, and 19 of this title and repealing section 20 of this title] may be cited as the 'Antitrust Amendments Act of 1990'."

SHORT TITLE OF 1984 AMENDMENT

Pub. L. 98–544, §1, Oct. 24, 1984, 98 Stat. 2750, provided: "That this Act [enacting sections 34 to 36 of this title and provisions set out as a note under section 34 of this title] may be cited as the 'Local Government Antitrust Act of 1984'."

SHORT TITLE OF 1982 AMENDMENT

Pub. L. 97–290, title IV, §401, Oct. 8, 1982, 96 Stat. 1246, provided that: "This title [enacting section 6a of this title and amending section 45 of this title] may be cited as the 'Foreign Trade Antitrust Improvements Act of 1982'."

SHORT TITLE OF 1980 AMENDMENT

Pub. L. 96–493, §1, Dec. 2, 1980, 94 Stat. 2568, provided: "That this Act [enacting section 26a of this title] may be cited as the 'Gasohol Competition Act of 1980'."

SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94–435, §1, Sept. 30, 1976, 90 Stat. 1383, provided: "That this Act [enacting sections 15c to 15h, 18a, and 66 of this title, amending sections 12, 15b, 16, 26, and 1311 to 1314 of this title, section 1505 of Title 18, Crimes and Criminal Procedure, and section 1407 of Title 28, Judiciary and Judicial Procedure, and enacting provisions set out as notes under sections 8, 15c, 18a, and 1311 of this title] may be cited as the 'Hart-Scott-Rodino Antitrust Improvements Act of 1976'."

SHORT TITLE OF 1975 AMENDMENT

Pub. L. 94–145, §1, Dec. 12, 1975, 89 Stat. 801, provided: "That this Act [amending this section and section 45 of this title and enacting provisions set out as a note under this section] may be cited as the 'Consumer Goods Pricing Act of 1975'."

SHORT TITLE OF 1974 AMENDMENT

Pub. L. 93–528, §1, Dec. 21, 1974, 88 Stat. 1706, provided: "That this Act [amending this section and section 2, 3, 16, 28, and 29 of this title, section 401 of Title 47, Telecommunications, and sections 43, 44, and 45 of former Title 49, Transportation, and enacting provisions set out as notes under this section and section 29 of this title] may be cited as the 'Antitrust Procedures and Penalties Act'."

SHORT TITLE

Pub. L. 94–435, title III, §305(a), Sept. 30, 1976, 90 Stat. 1397, added immediately following the enacting clause of act July 2, 1890, the following: "That this Act [this section and sections 2 to 7 of this title] may be cited as the 'Sherman Act'."

ANTITRUST ENFORCEMENT ENHANCEMENTS AND COOPERATION INCENTIVES

Pub. L. 108–237, title II, §§211–214, June 22, 2004, 118 Stat. 666, 667, as amended by Pub. L. 111–30, §2, June 19, 2009, 123 Stat. 1775; Pub. L. 111–190, §§1–4, June 9, 2010, 124 Stat. 1275, 1276, provided that:

"SEC. 211. SUNSET.

"(a) IN GENERAL.—Except as provided in subsection (b), the provisions of sections 211 through 214 of this subtitle [this note] shall cease to have effect 16 years after the date of enactment of this Act [June 22, 2004].

"(b) EXCEPTIONS.—With respect to—

"(1) a person who receives a marker on or before the date on which the provisions of section 211 through 214 of this subtitle shall cease to have effect that later results in the execution of an antitrust leniency agreement; or

"(2) an applicant who has entered into an antitrust leniency agreement on or before the date on which the provisions of sections 211 through 214 of this subtitle shall cease to have effect,

the provisions of sections 211 through 214 of this subtitle shall continue in effect.

"SEC. 212. DEFINITIONS.

"In this subtitle [subtitle A (§§211–215) of title II of Pub. L. 108–237, amending this section and sections 2 and 3 of this title and enacting this note]:

"(1) ANTITRUST DIVISION.—The term 'Antitrust Division' means the United States Department of Justice Antitrust Division.

"(2) ANTITRUST LENIENCY AGREEMENT.—The term 'antitrust leniency agreement,' or 'agreement,' means a leniency letter agreement, whether condi-

tional or final, between a person and the Antitrust Division pursuant to the Corporate Leniency Policy of the Antitrust Division in effect on the date of execution of the agreement.

"(3) ANTITRUST LENIENCY APPLICANT.—The term 'antitrust leniency applicant,' or 'applicant,' means, with respect to an antitrust leniency agreement, the person that has entered into the agreement.

"(4) CLAIMANT.—The term 'claimant' means a person or class, that has brought, or on whose behalf has been brought, a civil action alleging a violation of section 1 or 3 of the Sherman Act [15 U.S.C. 1, 3] or any similar State law, except that the term does not include a State or a subdivision of a State with respect to a civil action brought to recover damages sustained by the State or subdivision.

"(5) COOPERATING INDIVIDUAL.—The term 'cooperating individual' means, with respect to an antitrust leniency agreement, a current or former director, officer, or employee of the antitrust leniency applicant who is covered by the agreement.

"(6) MARKER.—The term 'marker' means an assurance given by the Antitrust Division to a candidate for corporate leniency that no other company will be considered for leniency, for some finite period of time, while the candidate is given an opportunity to perfect its leniency application.

"(7) PERSON.—The term 'person' has the meaning given it in subsection (a) of the first section of the Clayton Act [15 U.S.C. 12(a)].

"SEC. 213. LIMITATION ON RECOVERY.

"(a) IN GENERAL.—Subject to subsection (d), in any civil action alleging a violation of section 1 or 3 of the Sherman Act [15 U.S.C. 1, 3], or alleging a violation of any similar State law, based on conduct covered by a currently effective antitrust leniency agreement, the amount of damages recovered by or on behalf of a claimant from an antitrust leniency applicant who satisfies the requirements of subsection (b), together with the amounts so recovered from cooperating individuals who satisfy such requirements, shall not exceed that portion of the actual damages sustained by such claimant which is attributable to the commerce done by the applicant in the goods or services affected by the violation.

"(b) REQUIREMENTS.—Subject to subsection (c), an antitrust leniency applicant or cooperating individual satisfies the requirements of this subsection with respect to a civil action described in subsection (a) if the court in which the civil action is brought determines, after considering any appropriate pleadings from the claimant, that the applicant or cooperating individual, as the case may be, has provided satisfactory cooperation to the claimant with respect to the civil action, which cooperation shall include—

"(1) providing a full account to the claimant of all facts known to the applicant or cooperating individual, as the case may be, that are potentially relevant to the civil action;

"(2) furnishing all documents or other items potentially relevant to the civil action that are in the possession, custody, or control of the applicant or cooperating individual, as the case may be, wherever they are located; and

"(3)(A) in the case of a cooperating individual—

"(i) making himself or herself available for such interviews, depositions, or testimony in connection with the civil action as the claimant may reasonably require; and

"(ii) responding completely and truthfully, without making any attempt either falsely to protect or falsely to implicate any person or entity, and without intentionally withholding any potentially relevant information, to all questions asked by the claimant in interviews, depositions, trials, or any other court proceedings in connection with the civil action; or

"(B) in the case of an antitrust leniency applicant, using its best efforts to secure and facilitate from cooperating individuals covered by the agreement the cooperation described in clauses (i) and (ii) and subparagraph (A).

"(c) TIMELINESS.—The court shall consider, in making the determination concerning satisfactory cooperation described in subsection (b), the timeliness of the applicant's or cooperating individual's cooperation with the claimant.

"(d) COOPERATION AFTER EXPIRATION OF STAY OR PROTECTIVE ORDER.—If the Antitrust Division does obtain a stay or protective order in a civil action based on conduct covered by an antitrust leniency agreement, once the stay or protective order, or a portion thereof, expires or is terminated, the antitrust leniency applicant and cooperating individuals shall provide without unreasonable delay any cooperation described in paragraphs (1) and (2) of subsection (b) that was prohibited by the expired or terminated stay or protective order, or the expired or terminated portion thereof, in order for the cooperation to be deemed satisfactory under such paragraphs.

"(e) CONTINUATION.—Nothing in this section shall be construed to modify, impair, or supersede the provisions of sections 4, 4A, and 4C of the Clayton Act [15 U.S.C. 15, 15a, 15c] relating to the recovery of costs of suit, including a reasonable attorney's fee, and interest on damages, to the extent that such recovery is authorized by such sections.

"SEC. 214. RIGHTS, AUTHORITIES, AND LIABILITIES NOT AFFECTED.

"Nothing in this subtitle [subtitle A (§§211–215) of title II of Pub. L. 108–237, amending this section and sections 2 and 3 of this title and enacting this note] shall be construed to—

"(1) affect the rights of the Antitrust Division to seek a stay or protective order in a civil action based on conduct covered by an antitrust leniency agreement to prevent the cooperation described in section 213(b) of this subtitle from impairing or impeding the investigation or prosecution by the Antitrust Division of conduct covered by the agreement;

"(2) create any right to challenge any decision by the Antitrust Division with respect to an antitrust leniency agreement; or

"(3) affect, in any way, the joint and several liability of any party to a civil action described in section 213(a) of this subtitle, other than that of the antitrust leniency applicant and cooperating individuals as provided in section 213(a) of this subtitle."

[Pub. L. 111–190, §6, June 9, 2010, 124 Stat. 1276, provided that: "The amendments made by section 1 [amending section 211 of Pub. L. 108–237, set out above] shall take effect immediately before June 22, 2010."]

[Pub. L. 111–30, §3, June 19, 2009, 123 Stat. 1775, provided that: "The amendment made by section 2 [amending section 211(a) of Pub. L. 108–237, set out above] shall take effect immediately before June 22, 2009."]

ANTITRUST MODERNIZATION COMMISSION

Pub. L. 107–273, div. C, title I, subtitle D, Nov. 2, 2002, 116 Stat. 1856, as amended by Pub. L. 110–6, §2, Feb. 26, 2007, 121 Stat. 61, provided that:

"SEC. 11051. SHORT TITLE.

"This subtitle may be cited as the 'Antitrust Modernization Commission Act of 2002'.

"SEC. 11052. ESTABLISHMENT.

"There is established the Antitrust Modernization Commission (in this subtitle referred to as the 'Commission').

"SEC. 11053. DUTIES OF THE COMMISSION.

"The duties of the Commission are—

"(1) to examine whether the need exists to modernize the antitrust laws and to identify and study related issues;

"(2) to solicit views of all parties concerned with the operation of the antitrust laws;

"(3) to evaluate the advisability of proposals and current arrangements with respect to any issues so identified; and

"(4) to prepare and to submit to Congress and the President a report in accordance with section 11058.

"SEC. 11054. MEMBERSHIP.

"(a) NUMBER AND APPOINTMENT.—The Commission shall be composed of 12 members appointed as follows:

"(1) Four members, no more than 2 of whom shall be of the same political party, shall be appointed by the President. The President shall appoint members of the opposing party only on the recommendation of the leaders of Congress from that party.

"(2) Two members shall be appointed by the majority leader of the Senate.

"(3) Two members shall be appointed by the minority leader of the Senate.

"(4) Two members shall be appointed by the Speaker of the House of Representatives.

"(5) Two members shall be appointed by the minority leader of the House of Representatives.

"(b) INELIGIBILITY FOR APPOINTMENT.—Members of Congress shall be ineligible for appointment to the Commission.

"(c) TERM OF APPOINTMENT.—

"(1) IN GENERAL.—Subject to paragraph (2), members of the Commission shall be appointed for the life of the Commission.

"(2) EARLY TERMINATION OF APPOINTMENT.—If a member of the Commission who is appointed to the Commission as—

"(A) an officer or employee of a government ceases to be an officer or employee of such government; or

"(B) an individual who is not an officer or employee of a government becomes an officer or employee of a government;

then such member shall cease to be a member of the Commission on the expiration of the 90-day period beginning on the date such member ceases to be such officer or employee of such government, or becomes an officer or employee of a government, as the case may be.

"(d) QUORUM.—Seven members of the Commission shall constitute a quorum, but a lesser number may conduct meetings.

"(e) APPOINTMENT DEADLINE.—Initial appointments under subsection (a) shall be made not later than 60 days after the date of enactment of this Act [Nov. 2, 2002].

"(f) MEETINGS.—The Commission shall meet at the call of the chairperson. The first meeting of the Commission shall be held not later than 30 days after the date on which all members of the Commission are first appointed under subsection (a) or funds are appropriated to carry out this subtitle, whichever occurs later.

"(g) VACANCY.—A vacancy on the Commission shall be filled in the same manner as the initial appointment is made.

"(h) CONSULTATION BEFORE APPOINTMENT.—Before appointing members of the Commission, the President, the majority and minority leaders of the Senate, the Speaker of the House of Representatives, and the minority leader of the House of Representatives shall consult with each other to ensure fair and equitable representation of various points of view in the Commission.

"(i) CHAIRPERSON; VICE CHAIRPERSON.—The President shall select the chairperson of the Commission from among its appointed members. The leaders of Congress from the opposing party of the President shall select the vice chairperson of the Commission from among its remaining members.

"SEC. 11055. COMPENSATION OF THE COMMISSION.

"(a) PAY.—

"(1) NONGOVERNMENT EMPLOYEES.—Each member of the Commission who is not otherwise employed by a government shall be entitled to receive the daily equivalent of the annual rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5 United States Code, as in effect from time to time, for each day (including travel time) during which such member is engaged in the actual performance of duties of the Commission.

"(2) GOVERNMENT EMPLOYEES.—A member of the Commission who is an officer or employee of a government shall serve without additional pay (or benefits in the nature of compensation) for service as a member of the Commission.

"(b) TRAVEL EXPENSES.—Members of the Commission shall receive travel expenses, including per diem in lieu of subsistence, in accordance with subchapter I of chapter 57 of title 5, United States Code.

"SEC. 11056. STAFF OF COMMISSION; EXPERTS AND CONSULTANTS.

"(a) STAFF.—

"(1) APPOINTMENT.—The chairperson of the Commission may, without regard to the provisions of chapter 51 of title 5 of the United States Code (relating to appointments in the competitive service), appoint and terminate an executive director and such other staff as are necessary to enable the Commission to perform its duties. The appointment of an executive director shall be subject to approval by the Commission.

"(2) COMPENSATION.—The chairperson of the Commission may fix the compensation of the executive director and other staff without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5 of the United States Code (relating to classification of positions and General Schedule pay rates), except that the rate of pay for the executive director and other staff may not exceed the rate of basic pay payable for level V of the Executive Schedule under section 5315 of title 5 United States Code, as in effect from time to time.

"(b) EXPERTS AND CONSULTANTS.—The Commission may procure temporary and intermittent services of experts and consultants in accordance with section 3109(b) of title 5, United States Code.

"SEC. 11057. POWERS OF THE COMMISSION.

"(a) HEARINGS AND MEETINGS.—The Commission, or a member of the Commission if authorized by the Commission, may hold such hearings, sit and act at such time and places, take such testimony, and receive such evidence, as the Commission considers to be appropriate. The Commission or a member of the Commission may administer oaths or affirmations to witnesses appearing before the Commission or such member.

"(b) OFFICIAL DATA.—The Commission may obtain directly from any executive agency (as defined in section 105 of title 5 of the United States Code) or court information necessary to enable it to carry out its duties under this subtitle. On the request of the chairperson of the Commission, and consistent with any other law, the head of an executive agency or of a Federal court shall provide such information to the Commission.

"(c) FACILITIES AND SUPPORT SERVICES.—The Administrator of General Services shall provide to the Commission on a reimbursable basis such facilities and support services as the Commission may request. On request of the Commission, the head of an executive agency may make any of the facilities or services of such agency available to the Commission, on a reimbursable or nonreimbursable basis, to assist the Commission in carrying out its duties under this subtitle.

"(d) EXPENDITURES AND CONTRACTS.—The Commission or, on authorization of the Commission, a member of the Commission may make expenditures and enter into contracts for the procurement of such supplies, services, and property as the Commission or such member considers to be appropriate for the purpose of carrying out the duties of the Commission. Such expenditures and contracts may be made only to such extent or in such amounts as are provided in advance in appropriation Acts.

"(e) MAILS.—The Commission may use the United States mails in the same manner and under the same

conditions as other departments and agencies of the United States.

"(f) GIFTS, BEQUESTS, AND DEVISES.—The Commission may accept, use, and dispose of gifts, bequests, or devises of services or property, both real and personal, for the purpose of aiding or facilitating the work of the Commission. Gifts, bequests, or devises of money and proceeds from sales of other property received as gifts, bequests, or devises shall be deposited in the Treasury and shall be available for disbursement upon order of the Commission.

"SEC. 11058. REPORT.

"Not later than 3 years after the first meeting of the Commission, the Commission shall submit to Congress and the President a report containing a detailed statement of the findings and conclusions of the Commission, together with recommendations for legislative or administrative action the Commission considers to be appropriate.

"SEC. 11059. TERMINATION OF COMMISSION.

"The Commission shall cease to exist 60 days after the date on which the report required by section 11058 is submitted.

"SEC. 11060. AUTHORIZATION OF APPROPRIATIONS.

"There is authorized to be appropriated $4,000,000 to carry out this subtitle."

YEAR 2000 INFORMATION AND READINESS DISCLOSURE

Pub. L. 105–271, Oct. 19, 1998, 112 Stat. 2386, as amended by Pub. L. 107–273, div. C, title IV, §14102(e), Nov. 2, 2002, 116 Stat. 1922, known as the Year 2000 Information and Readiness Disclosure Act, provided for the free disclosure and exchange of information about computer processing problems, solutions, test practices and test results, and related matters in connection with the transition to the year 2000.

APPLICATION OF ANTITRUST LAWS TO AWARD OF NEED-BASED EDUCATIONAL AID

Pub. L. 107–72, §3, Nov. 20, 2001, 115 Stat. 648, provided that:

"(a) STUDY.—

"(1) IN GENERAL.—The Comptroller General shall conduct a study of the effect of the antitrust exemption on institutional student aid under section 568 of the Improving America's Schools Act of 1994 (15 U.S.C. 1 note) [Pub. L. 103–382, see below].

"(2) CONSULTATION.—The Comptroller General shall have final authority to determine the content of the study under paragraph (1), but in determining the content of the study, the Comptroller General shall consult with—

"(A) the institutions of higher education participating under the antitrust exemption under section 568 of the Improving America's Schools Act of 1994 (15 U.S.C. 1 note) (referred to in this Act [see Short Title of 2001 Amendment note above] as the 'participating institutions');

"(B) the Antitrust Division of the Department of Justice; and

"(C) other persons that the Comptroller General determines are appropriate.

"(3) MATTERS STUDIED.—

"(A) IN GENERAL.—The study under paragraph (1) shall—

"(i) examine the needs analysis methodologies used by participating institutions;

"(ii) identify trends in undergraduate costs of attendance and institutional undergraduate grant aid among participating institutions, including—

"(I) the percentage of first-year students receiving institutional grant aid;

"(II) the mean and median grant eligibility and institutional grant aid to first-year students; and

"(III) the mean and median parental and student contributions to undergraduate costs of attendance for first year students receiving institutional grant aid;

"(iii) to the extent useful in determining the effect of the antitrust exemption under section 568 of the Improving America's Schools Act of 1994 (15 U.S.C. 1 note), examine—

"(I) comparison data, identified in clauses (i) and (ii), from institutions of higher education that do not participate under the antitrust exemption under section 568 of the Improving America's Schools Act of 1994 (15 U.S.C. 1 note); and

"(II) other baseline trend data from national benchmarks; and

"(iv) examine any other issues that the Comptroller General determines are appropriate, including other types of aid affected by section 568 of the Improving America's Schools Act of 1994 (15 U.S.C. 1 note).

"(B) ASSESSMENT.—

"(i) IN GENERAL.—The study under paragraph (1) shall assess what effect the antitrust exemption on institutional student aid has had on institutional undergraduate grant aid and parental contribution to undergraduate costs of attendance.

"(ii) CHANGES OVER TIME.—The assessment under clause (i) shall consider any changes in institutional undergraduate grant aid and parental contribution to undergraduate costs of attendance over time for institutions of higher education, including consideration of—

"(I) the time period prior to adoption of the consensus methodologies at participating institutions; and

"(II) the data examined pursuant to subparagraph (A)(iii).

"(b) REPORT.—

"(1) IN GENERAL.—Not later than September 30, 2006, the Comptroller General shall submit a report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives that contains the findings and conclusions of the Comptroller General regarding the matters studied under subsection (a).

"(2) IDENTIFYING INDIVIDUAL INSTITUTIONS.—The Comptroller General shall not identify an individual institution of higher education in information submitted in the report under paragraph (1) unless the information on the institution is available to the public.

"(c) RECORDKEEPING REQUIREMENT.—

"(1) IN GENERAL.—For the purpose of completing the study under subsection (a)(1), a participating institution shall—

"(A) collect and maintain for each academic year until the study under subsection (a)(1) is completed—

"(i) student-level data that is sufficient, in the judgment of the Comptroller General, to permit the analysis of expected family contributions, identified need, and undergraduate grant aid awards; and

"(ii) information on formulas used by the institution to determine need; and

"(B) submit the data and information under paragraph (1) to the Comptroller General at such time as the Comptroller General may reasonably require.

"(2) NON-PARTICIPATING INSTITUTIONS.—Nothing in this subsection shall be construed to require an institution of higher education that does not participate under the antitrust exemption under section 568 of the Improving America's Schools Act of 1994 (15 U.S.C. 1 note) to collect and maintain data under this subsection."

Pub. L. 103–382, title V, §568(a)–(d), Oct. 20, 1994, 108 Stat. 4060, 4061, as amended by Pub. L. 105–43, §2(a), Sept. 17, 1997, 111 Stat. 1140; Pub. L. 105–244, title I, §102(a)(3), Oct. 7, 1998, 112 Stat. 1618; Pub. L. 107–72, §2, Nov. 20, 2001, 115 Stat. 648; Pub. L. 110–327, §2, Sept. 30, 2008, 122 Stat. 3566, provided that:

"(a) EXEMPTION.—It shall not be unlawful under the antitrust laws for 2 or more institutions of higher education at which all students admitted are admitted on a need-blind basis, to agree or attempt to agree—

"(1) to award such students financial aid only on the basis of demonstrated financial need for such aid;

"(2) to use common principles of analysis for determining the need of such students for financial aid if the agreement to use such principles does not restrict financial aid officers at such institutions in their exercising independent professional judgment with respect to individual applicants for such financial aid;

"(3) to use a common aid application form for need-based financial aid for such students if the agreement to use such form does not restrict such institutions in their requesting from such students, or in their using, data in addition to the data requested on such form; or

"(4) to exchange through an independent third party, before awarding need-based financial aid to any of such students who is commonly admitted to the institutions of higher education involved, data submitted by the student so admitted, the student's family, or a financial institution on behalf of the student or the student's family relating to assets, liabilities, income, expenses, the number of family members, and the number of the student's siblings in college, if each of such institutions of higher education is permitted to retrieve such data only once with respect to the student.

"(b) LIMITATIONS.—Subsection (a) shall not apply with respect to—

"(1) any financial aid or assistance authorized by the Higher Education Act of 1965 (20 U.S.C. 1001 et seq.) [and 42 U.S.C. 2751 et seq.]; or

"(2) any contract, combination, or conspiracy with respect to the amount or terms of any prospective financial aid award to a specific individual.

"(c) DEFINITIONS.—For purposes of this section—

"(1) the term 'alien' has the meaning given such term in section 101(3) [101(a)(3)] of the Immigration and Nationality Act (8 U.S.C. 1101(3) [1101(a)(3)]);

"(2) the term 'antitrust laws' has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section applies to unfair methods of competition;

"(3) the term 'institution of higher education' has the meaning given such term in section 101 of the Higher Education Act of 1965 [20 U.S.C. 1001];

"(4) the term 'lawfully admitted for permanent residence' has the meaning given such term in section 101(20) [101(a)(20)] of the Immigration and Nationality Act (8 U.S.C. 1101(20) [1101(a)(20)]);

"(5) the term 'national of the United States' has the meaning given such term in section 101(22) [101(a)(22)] of the Immigration and Nationality Act (8 U.S.C. 1101(22) [1101(a)(22)]);

"(6) the term 'on a need-blind basis' means without regard to the financial circumstances of the student involved or the student's family; and

"(7) the term 'student' means, with respect to an institution of higher education, a national of the United States or an alien admitted for permanent residence who is admitted to attend an undergraduate program at such institution on a full-time basis.

"(d) EXPIRATION.—Subsection (a) shall expire on September 30, 2015."

[Pub. L. 105–43, §2(b), Sept. 17, 1997, 111 Stat. 1140, provided that: "The amendments made by subsection (a) [amending section 568(a)–(d) of Pub. L. 103–382, set out above] shall take effect immediately before September 30, 1997."]

§ 2. Monopolizing trade a felony; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

(July 2, 1890, ch. 647, §2, 26 Stat. 209; July 7, 1955, ch. 281, 69 Stat. 282; Pub. L. 93–528, §3, Dec. 21, 1974, 88 Stat. 1708; Pub. L. 101–588, §4(b), Nov. 16, 1990, 104 Stat. 2880; Pub. L. 108–237, title II, §215(b), June 22, 2004, 118 Stat. 668.)

AMENDMENTS

2004—Pub. L. 108–237 substituted "$100,000,000" for "$10,000,000", "$1,000,000" for "$350,000", and "10" for "three".

1990—Pub. L. 101–588 substituted "$10,000,000" for "one million dollars" and "$350,000" for "one hundred thousand dollars".

1974—Pub. L. 93–528 substituted "a felony, and, on conviction thereof, shall be punished by fine not exceeding one million dollars if a corporation, or, if any other person, one hundred thousand dollars, or by imprisonment not exceeding three years" for "a misdemeanor, and, on conviction thereof, shall be punished by fine not exceeding fifty thousand dollars, or by imprisonment not exceeding one year".

1955—Act July 7, 1955, substituted "fifty thousand dollars" for "five thousand dollars".

§ 3. Trusts in Territories or District of Columbia illegal; combination a felony

(a) Every contract, combination in form of trust or otherwise, or conspiracy, in restraint of trade or commerce in any Territory of the United States or of the District of Columbia, or in restraint of trade or commerce between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia and any State or States or foreign nations, is declared illegal. Every person who shall make any such contract or engage in any such combination or conspiracy, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or both said punishments, in the discretion of the court.

(b) Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce in any Territory of the United States or of the District of Columbia, or between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia, and any State or States or foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

(July 2, 1890, ch. 647, §3, 26 Stat. 209; July 7, 1955, ch. 281, 69 Stat. 282; Pub. L. 93–528, §3, Dec. 21, 1974, 88 Stat. 1708; Pub. L. 101–588, §4(c), Nov. 16,

"(a) EXEMPTION.—It shall not be unlawful under the antitrust laws for 2 or more institutions of higher education at which all students admitted are admitted on a need-blind basis, to agree or attempt to agree—

"(1) to award such students financial aid only on the basis of demonstrated financial need for such aid;

"(2) to use common principles of analysis for determining the need of such students for financial aid if the agreement to use such principles does not restrict financial aid officers at such institutions in their exercising independent professional judgment with respect to individual applicants for such financial aid;

"(3) to use a common aid application form for need-based financial aid for such students if the agreement to use such form does not restrict such institutions in their requesting from such students, or in their using, data in addition to the data requested on such form; or

"(4) to exchange through an independent third party, before awarding need-based financial aid to any of such students who is commonly admitted to the institutions of higher education involved, data submitted by the student so admitted, the student's family, or a financial institution on behalf of the student or the student's family relating to assets, liabilities, income, expenses, the number of family members, and the number of the student's siblings in college, if each of such institutions of higher education is permitted to retrieve such data only once with respect to the student.

"(b) LIMITATIONS.—Subsection (a) shall not apply with respect to—

"(1) any financial aid or assistance authorized by the Higher Education Act of 1965 (20 U.S.C. 1001 et seq.) [and 42 U.S.C. 2751 et seq.]; or

"(2) any contract, combination, or conspiracy with respect to the amount or terms of any prospective financial aid award to a specific individual.

"(c) DEFINITIONS.—For purposes of this section—

"(1) the term 'alien' has the meaning given such term in section 101(3) [101(a)(3)] of the Immigration and Nationality Act (8 U.S.C. 1101(3) [1101(a)(3)]);

"(2) the term 'antitrust laws' has the meaning given such term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section applies to unfair methods of competition;

"(3) the term 'institution of higher education' has the meaning given such term in section 101 of the Higher Education Act of 1965 [20 U.S.C. 1001];

"(4) the term 'lawfully admitted for permanent residence' has the meaning given such term in section 101(20) [101(a)(20)] of the Immigration and Nationality Act (8 U.S.C. 1101(20) [1101(a)(20)]);

"(5) the term 'national of the United States' has the meaning given such term in section 101(22) [101(a)(22)] of the Immigration and Nationality Act (8 U.S.C. 1101(22) [1101(a)(22)]);

"(6) the term 'on a need-blind basis' means without regard to the financial circumstances of the student involved or the student's family; and

"(7) the term 'student' means, with respect to an institution of higher education, a national of the United States or an alien admitted for permanent residence who is admitted to attend an undergraduate program at such institution on a full-time basis.

"(d) EXPIRATION.—Subsection (a) shall expire on September 30, 2015."

[Pub. L. 105–43, §2(b), Sept. 17, 1997, 111 Stat. 1140, provided that: "The amendments made by subsection (a) [amending section 568(a)–(d) of Pub. L. 103–382, set out above] shall take effect immediately before September 30, 1997."]

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(July 2, 1890, ch. 647, §2, 26 Stat. 209; July 7, 1955, ch. 281, 69 Stat. 282; Pub. L. 93–528, §3, Dec. 21, 1974, 88 Stat. 1708; Pub. L. 101–588, §4(b), Nov. 16, 1990, 104 Stat. 2880; Pub. L. 108–237, title II, §215(b), June 22, 2004, 118 Stat. 668.)

AMENDMENTS

2004—Pub. L. 108–237 substituted "$100,000,000" for "$10,000,000", "$1,000,000" for "$350,000", and "10" for "three".

1990—Pub. L. 101–588 substituted "$10,000,000" for "one million dollars" and "$350,000" for "one hundred thousand dollars".

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1955—Act July 7, 1955, substituted "fifty thousand dollars" for "five thousand dollars".

§ 3. Trusts in Territories or District of Columbia illegal; combination a felony

(a) Every contract, combination in form of trust or otherwise, or conspiracy, in restraint of trade or commerce in any Territory of the United States or of the District of Columbia, or in restraint of trade or commerce between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia and any State or States or foreign nations, is declared illegal. Every person who shall make any such contract or engage in any such combination or conspiracy, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or both said punishments, in the discretion of the court.

(b) Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce in any Territory of the United States or of the District of Columbia, or between any such Territory and another, or between any such Territory or Territories and any State or States or the District of Columbia, or with foreign nations, or between the District of Columbia, and any State or States or foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

(July 2, 1890, ch. 647, §3, 26 Stat. 209; July 7, 1955, ch. 281, 69 Stat. 282; Pub. L. 93–528, §3, Dec. 21, 1974, 88 Stat. 1708; Pub. L. 101–588, §4(c), Nov. 16,

§ 13c. Exemption of non-profit institutions from price discrimination provisions

Nothing in the Act approved June 19, 1936, known as the Robinson-Patman Antidiscrimination Act, shall apply to purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit.

(May 26, 1938, ch. 283, 52 Stat. 446.)

REFERENCES IN TEXT

The Act approved June 19, 1936, known as the Robinson-Patman Antidiscrimination Act, referred to in text, is act June 19, 1936, ch. 592, 49 Stat. 1526, also known as the Robinson-Patman Price Discrimination Act, which enacted sections 13a, 13b, and 21a of this title and amended section 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 13 of this title and Tables.

§ 14. Sale, etc., on agreement not to use goods of competitor

It shall be unlawful for any person engaged in commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods, wares, merchandise, machinery, supplies, or other commodities, whether patented or unpatented, for use, consumption, or resale within the United States or any Territory thereof or the District of Columbia or any insular possession or other place under the jurisdiction of the United States, or fix a price charged therefor, or discount from, or rebate upon, such price, on the condition, agreement, or understanding that the lessee or purchaser thereof shall not use or deal in the goods, wares, merchandise, machinery, supplies, or other commodities of a competitor or competitors of the lessor or seller, where the effect of such lease, sale, or contract for sale or such condition, agreement, or understanding may be to substantially lessen competition or tend to create a monopoly in any line of commerce.

(Oct. 15, 1914, ch. 323, § 3, 38 Stat. 731.)

§ 15. Suits by persons injured

(a) Amount of recovery; prejudgment interest

Except as provided in subsection (b) of this section, any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee. The court may award under this section, pursuant to a motion by such person promptly made, simple interest on actual damages for the period beginning on the date of service of such person's pleading setting forth a claim under the antitrust laws and ending on the date of judgment, or for any shorter period therein, if the court finds that the award of such interest for such period is just in the circumstances. In determining whether an award of interest under this section for any period is just in the circumstances, the court shall consider only—

(1) whether such person or the opposing party, or either party's representative, made motions or asserted claims or defenses so lacking in merit as to show that such party or representative acted intentionally for delay, or otherwise acted in bad faith;

(2) whether, in the course of the action involved, such person or the opposing party, or either party's representative, violated any applicable rule, statute, or court order providing for sanctions for dilatory behavior or otherwise providing for expeditious proceedings; and

(3) whether such person or the opposing party, or either party's representative, engaged in conduct primarily for the purpose of delaying the litigation or increasing the cost thereof.

(b) Amount of damages payable to foreign states and instrumentalities of foreign states

(1) Except as provided in paragraph (2), any person who is a foreign state may not recover under subsection (a) of this section an amount in excess of the actual damages sustained by it and the cost of suit, including a reasonable attorney's fee.

(2) Paragraph (1) shall not apply to a foreign state if—

(A) such foreign state would be denied, under section 1605(a)(2) of title 28, immunity in a case in which the action is based upon a commercial activity, or an act, that is the subject matter of its claim under this section;

(B) such foreign state waives all defenses based upon or arising out of its status as a foreign state, to any claims brought against it in the same action;

(C) such foreign state engages primarily in commercial activities; and

(D) such foreign state does not function, with respect to the commercial activity, or the act, that is the subject matter of its claim under this section as a procurement entity for itself or for another foreign state.

(c) Definitions

For purposes of this section—

(1) the term "commercial activity" shall have the meaning given it in section 1603(d) of title 28, and

(2) the term "foreign state" shall have the meaning given it in section 1603(a) of title 28.

(Oct. 15, 1914, ch. 323, § 4, 38 Stat. 731; Pub. L. 96–349, § 4(a)(1), Sept. 12, 1980, 94 Stat. 1156; Pub. L. 97–393, Dec. 29, 1982, 96 Stat. 1964.)

REFERENCES IN TEXT

The antitrust laws, referred to in subsec. (a), are defined in section 12 of this title.

PRIOR PROVISIONS

Section supersedes two former similar sections enacted by act July 2, 1890, ch. 647, § 7, 26 Stat. 210, and act Aug. 27, 1894, ch. 349, § 77, 28 Stat. 570, each of which were restricted in operation to the particular act cited. Section 7 of act July 2, 1890, was repealed by act July 7, 1955, ch. 283, § 3, 69 Stat. 283, effective six months after July 7, 1955. Section 77 of act Aug. 27, 1894, was repealed by Pub. L. 107–273, div. C, title IV, §§ 14102(c)(1)(A), 14103, Nov. 2, 2002, 116 Stat. 1921, 1922, effective Nov. 2, 2002, and applicable only with respect to cases commenced on or after Nov. 2, 2002.

AMENDMENTS

1982—Pub. L. 97-393 designated existing provisions as subsec. (a), inserted "Except as provided in subsection (b) of this section,", and added subsecs. (b) and (c).

1980—Pub. L. 96-349 inserted provisions respecting award of prejudgment interest including considerations for the court in determining whether an award is just under the circumstances.

EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96-349, §4(b), Sept. 12, 1980, 94 Stat. 1157, provided that: "The amendments made by this section [amending this section and sections 15a and 15c of this title] shall apply only with respect to actions commenced after the date of the enactment of this Act [Sept 12, 1980]."

§ 15a. Suits by United States; amount of recovery; prejudgment interest

Whenever the United States is hereafter injured in its business or property by reason of anything forbidden in the antitrust laws it may sue therefor in the United States district court for the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by it sustained and the cost of suit. The court may award under this section, pursuant to a motion by the United States promptly made, simple interest on actual damages for the period beginning on the date of service of the pleading of the United States setting forth a claim under the antitrust laws and ending on the date of judgment, or for any shorter period therein, if the court finds that the award of such interest for such period is just in the circumstances. In determining whether an award of interest under this section for any period is just in the circumstances, the court shall consider only—

(1) whether the United States or the opposing party, or either party's representative, made motions or asserted claims or defenses so lacking in merit as to show that such party or representative acted intentionally for delay or otherwise acted in bad faith;

(2) whether, in the course of the action involved, the United States or the opposing party, or either party's representative, violated any applicable rule, statute, or court order providing for sanctions for dilatory behavior or otherwise providing for expeditious proceedings;

(3) whether the United States or the opposing party, or either party's representative, engaged in conduct primarily for the purpose of delaying the litigation or increasing the cost thereof; and

(4) whether the award of such interest is necessary to compensate the United States adequately for the injury sustained by the United States.

(Oct. 15, 1914, ch. 323, §4A, as added July 7, 1955, ch. 283, §1, 69 Stat. 282; amended Pub. L. 96-349, §4(a)(2), Sept. 12, 1980, 94 Stat. 1156; Pub. L. 101-588, §5, Nov. 16, 1990, 104 Stat. 2880.)

REFERENCES IN TEXT

The antitrust laws, referred to in text, are defined in section 12 of this title.

AMENDMENTS

1990—Pub. L. 101-588 substituted "threefold the" for "actual".

1980—Pub. L. 96-349 inserted provisions respecting award of prejudgment interest including considerations for the court in determining whether an award is just under the circumstances.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96-349 applicable only with respect to actions commenced after Sept. 12, 1980, see section 4(b) of Pub. L. 96-349, set out as a note under section 15 of this title.

EFFECTIVE DATE

Section effective six months after July 7, 1955, see note set out under section 15b of this title.

§ 15b. Limitation of actions

Any action to enforce any cause of action under section 15, 15a, or 15c of this title shall be forever barred unless commenced within four years after the cause of action accrued. No cause of action barred under existing law on the effective date of this Act shall be revived by this Act.

(Oct. 15, 1914, ch. 323, §4B, as added July 7, 1955, ch. 283, §1, 69 Stat. 283; amended Pub. L. 94-435, title III, §302(1), Sept. 30, 1976, 90 Stat. 1396.)

REFERENCES IN TEXT

The effective date of this Act, referred to in text, probably refers to the effective date of act July 7, 1955, ch. 283, 69 Stat. 282, which was six months after July 7, 1955.

This Act, referred to in text, probably refers to act July 7, 1955.

AMENDMENTS

1976—Pub. L. 94-435 substituted "section 15, 15a, or 15c" for "sections 15 or 15a".

EFFECTIVE DATE

Act July 7, 1955, ch. 283, §4, 69 Stat. 283, provided: "This Act [enacting this section and section 15a of this title, amending section 16 of this title, and repealing provisions set out as a note under section 15 of this title] shall take effect six months after its enactment [July 7, 1955]."

§ 15c. Actions by State attorneys general

(a) Parens patriae; monetary relief; damages; prejudgment interest

(1) Any attorney general of a State may bring a civil action in the name of such State, as parens patriae on behalf of natural persons residing in such State, in any district court of the United States having jurisdiction of the defendant, to secure monetary relief as provided in this section for injury sustained by such natural persons to their property by reason of any violation of sections 1 to 7 of this title. The court shall exclude from the amount of monetary relief awarded in such action any amount of monetary relief (A) which duplicates amounts which have been awarded for the same injury, or (B) which is properly allocable to (i) natural persons who have excluded their claims pursuant to subsection (b)(2) of this section, and (ii) any business entity.

(2) The court shall award the State as monetary relief threefold the total damage sustained as described in paragraph (1) of this subsection, and the cost of suit, including a reasonable attorney's fee. The court may award under this paragraph, pursuant to a motion by such State

$5,000 or by imprisonment for not exceeding one year, or by both, in the discretion of the court.

(Oct. 15, 1914, ch. 323, § 14, 38 Stat. 736.)

REFERENCES IN TEXT

The antitrust laws, referred to in text, are defined in section 12 of this title.

§ 25. Restraining violations; procedure

The several district courts of the United States are invested with jurisdiction to prevent and restrain violations of this Act, and it shall be the duty of the several United States attorneys, in their respective districts, under the direction of the Attorney General, to institute proceedings in equity to prevent and restrain such violations. Such proceedings may be by way of petition setting forth the case and praying that such violation shall be enjoined or otherwise prohibited. When the parties complained of shall have been duly notified of such petition, the court shall proceed, as soon as may be, to the hearing and determination of the case; and pending such petition, and before final decree, the court may at any time make such temporary restraining order or prohibition as shall be deemed just in the premises. Whenever it shall appear to the court before which any such proceeding may be pending that the ends of justice require that other parties should be brought before the court, the court may cause them to be summoned whether they reside in the district in which the court is held or not, and subpoenas to that end may be served in any district by the marshal thereof.

(Oct. 15, 1914, ch. 323, § 15, 38 Stat. 736; June 25, 1948, ch. 646, § 1, 62 Stat. 909.)

REFERENCES IN TEXT

This Act, referred to in text, is act Oct. 15, 1914, ch. 323, 38 Stat. 730, as amended, which is classified generally to sections 12, 13, 14 to 19, 20, 21, and 22 to 27 of this title, and sections 52 and 53 of Title 29, Labor. For further details and complete classification of this Act to the Code, see References in Text note set out under section 12 of this title and Tables.

CHANGE OF NAME

Act June 25, 1948, eff. Sept. 1, 1948, substituted "United States attorneys" for "district attorneys of the United States". See section 541 et seq. of Title 28, Judiciary and Judicial Procedure.

§ 26. Injunctive relief for private parties; exception; costs

Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws, including sections 13, 14, 18, and 19 of this title, when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity, under the rules governing such proceedings, and upon the execution of proper bond against damages for an injunction improvidently granted and a showing that the danger of irreparable loss or damage is immediate, a preliminary injunction may issue: *Provided*, That nothing herein contained shall be construed to entitle any person, firm, corporation, or association, except the United States, to bring suit for injunctive relief against any common carrier subject to the jurisdiction of the Surface Transportation Board under subtitle IV of title 49. In any action under this section in which the plaintiff substantially prevails, the court shall award the cost of suit, including a reasonable attorney's fee, to such plaintiff.

(Oct. 15, 1914, ch. 323, § 16, 38 Stat. 737; Pub. L. 94–435, title III, § 302(3), Sept. 30, 1976, 90 Stat. 1396; Pub. L. 104–88, title III, § 318(3), Dec. 29, 1995, 109 Stat. 949.)

REFERENCES IN TEXT

The antitrust laws, referred to in text, are defined in section 12 of this title.

AMENDMENTS

1995—Pub. L. 104–88 substituted "for injunctive relief against any common carrier subject to the jurisdiction of the Surface Transportation Board under subtitle IV of title 49" for "in equity for injunctive relief against any common carrier subject to the provisions of the Act to regulate commerce, approved February fourth, eighteen hundred and eighty-seven, in respect of any matter subject to the regulation, supervision, or other jurisdiction of the Interstate Commerce Commission."

1976—Pub. L. 94–435 inserted provision authorizing court to award costs, including attorneys' fees, to a successful plaintiff.

EFFECTIVE DATE OF 1995 AMENDMENT

Amendment by Pub. L. 104–88 effective Jan. 1, 1996, see section 2 of Pub. L. 104–88, set out as an Effective Date note under section 701 of Title 49, Transportation.

§ 26a. Restrictions on the purchase of gasohol and synthetic motor fuel

(a) Limitations on the use of credit instruments; sales, resales, and transfers

Except as provided in subsection (b) of this section, it shall be unlawful for any person engaged in commerce, in the course of such commerce, directly or indirectly to impose any condition, restriction, agreement, or understanding that—

(1) limits the use of credit instruments in any transaction concerning the sale, resale, or transfer of gasohol or other synthetic motor fuel of equivalent usability in any case in which there is no similar limitation on transactions concerning such person's conventional motor fuel; or

(2) otherwise unreasonably discriminates against or unreasonably limits the sale, resale, or transfer of gasohol or other synthetic motor fuel of equivalent usability in any case in which such synthetic or conventional motor fuel is sold for use, consumption, or resale within the United States.

(b) Credit fees; equivalent conventional motor fuel sales; labeling of pumps; product liability disclaimers; advertising support; furnishing facilities

(1) Nothing in this section or in any other provision of law in effect on December 2, 1980, which is specifically applicable to the sale of petroleum products shall preclude any person referred to in subsection (a) of this section from imposing a reasonable fee for credit on the sale, re-

may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 355 of this title or section 262 of title 42, a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

(f) Rule of construction

Nothing in this section may be construed as having any effect on requirements under section 352(n) of this title or on the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).

(June 25, 1938, ch. 675, §503B, as added Pub. L. 110–85, title IX, §901(d)(2), Sept. 27, 2007, 121 Stat. 939.)

EFFECTIVE DATE

Section effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as an Effective Date of 2007 Amendment note under section 331 of this title.

§ 354. Veterinary feed directive drugs

(a) Lawful veterinary feed directive requirement

(1) A drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 360b(b) of this title, a conditionally-approved application filed pursuant to section 360ccc of this title, or an index listing pursuant to section 360ccc–1 of this title to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 352(f) of this title.

(2) A veterinary feed directive is lawful if it—

(A) contains such information as the Secretary may by general regulation or by order require; and

(B) is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to section 360b(i) of this title, or the index listing pursuant to section 360ccc–1(e) of this title.

(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution. Such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier.

(B) Every person required under subparagraph (A) to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging in such distribution notify the Secretary of that person's name and place of business. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

(b) Labeling and advertising

A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if their labeling fails to bear such cautionary statement and such other information as the Secretary may by general regulation or by order prescribe, or their advertising fails to conform to the conditions and indications for use published pursuant to section 360b(i) of this title, or the index listing pursuant to section 360ccc–1(e) of this title or fails to contain the general cautionary statement prescribed by the Secretary.

(c) Nonprescription status

Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.

(June 25, 1938, ch. 675, §504, as added Pub. L. 104–250, §5(b), Oct. 9, 1996, 110 Stat. 3155; amended Pub. L. 108–282, title I, §102(b)(5)(G), (H), Aug. 2, 2004, 118 Stat. 903.)

PRIOR PROVISIONS

A prior section 354, act June 25, 1938, ch. 675, §504, 52 Stat. 1052, which directed Secretary to promulgate regulations for listing of coal-tar colors, was repealed effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86–618, by Pub. L. 86–618, title I, §103(a)(2), title II, §202, July 12, 1960, 74 Stat. 398, 404.

AMENDMENTS

2004—Subsec. (a)(1). Pub. L. 108–282, §102(b)(5)(G), substituted "360b(b) of this title, a conditionally-approved application filed pursuant to section 360ccc of this title, or an index listing pursuant to section 360ccc–1 of this title" for "360b(b) of this title".

Subsecs. (a)(2)(B), (b). Pub. L. 108–282, §102(b)(5)(H), substituted "360b(i) of this title, or the index listing pursuant to section 360ccc–1(e) of this title" for "360b(i) of this title".

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show wheth-

er or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) of this section prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of

regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim or, with respect to an applicant for approval of a biological product under section 262(k) of title 42, any necessary clinical study or studies. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 282(j)(5)(B) of title 42. Such certification shall not be considered an element of such application.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A) of this section:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.

Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section; and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 282 of title 42.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the ap-

plicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term ''listed drug'' for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route

of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no

cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term ''180-day exclusivity period'' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term ''first applicant'' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term ''substantially complete application'' means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term ''tentative approval'' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc),

the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the hold-

er of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the ap-

proval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 262 of title 42, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after September 27, 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 355–1(b) of this title) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends,

made, purchased or used as specified, or for the manufacture, use or sale of which substantial preparation was made after the date the application became abandoned or patent lapsed for failure to pay the fee but prior to the grant or restoration of the patent, and it may also provide for the continued practice of any process covered by the patent, practiced, or for the practice of which substantial preparation was made, after the date the application became abandoned or patent lapsed for failure to pay the issue fee but prior to the grant or restoration of the patent, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant or restoration of the patent."

§ 152. Issue of patent to assignee

Patents may be granted to the assignee of the inventor of record in the Patent and Trademark Office, upon the application made and the specification sworn to by the inventor, except as otherwise provided in this title.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 93–596, §1, Jan. 2, 1975, 88 Stat. 1949.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §44 (R.S. 4895).

Language is changed and the reference to reissue is omitted in view of the general provision in section 251.

AMENDMENTS

1975—Pub. L. 93–596 substituted "Patent and Trademark Office" for "Patent Office".

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–596 effective Jan. 2, 1975, see section 4 of Pub. L. 93–596, set out as a note under section 1111 of Title 15, Commerce and Trade.

§ 153. How issued

Patents shall be issued in the name of the United States of America, under the seal of the Patent and Trademark Office, and shall be signed by the Director or have his signature placed thereon and shall be recorded in the Patent and Trademark Office.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 93–596, §1, Jan. 2, 1975, 88 Stat. 1949; Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, §§13203(c), 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1902, 1906.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §39 (R.S. 4883, amended (1) Feb. 18, 1888, ch. 15, 25 Stat. 40, (2) April 11, 1903, ch. 417, 32 Stat. 95, (3) Feb. 18, 1922, ch. 58, §5, 42 Stat. 391).

The phrases referring to the attesting officers and to the recording of the patents are broadened.

AMENDMENTS

2002—Pub. L. 107–273, §13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113. See 1999 Amendment note below.

Pub. L. 107–273, §13203(c), struck out "and attested by an officer of the Patent and Trademark Office designated by the Director," after "signature placed thereon".

1999—Pub. L. 106–113, as amended by Pub. L. 107–273, §13206(b)(1)(B), substituted "Director" for "Commissioner" in two places.

1975—Pub. L. 93–596 substituted "Patent and Trademark Office" for "Patent Office" wherever appearing.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, §4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–596 effective Jan. 2, 1975, see section 4 of Pub. L. 93–596, set out as a note under section 1111 of Title 15, Commerce and Trade.

§ 154. Contents and term of patent; provisional rights

(a) IN GENERAL.—

(1) CONTENTS.—Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) TERM.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c), from the date on which the earliest such application was filed.

(3) PRIORITY.—Priority under section 119, 365(a), or 365(b) shall not be taken into account in determining the term of a patent.

(4) SPECIFICATION AND DRAWING.—A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(b) ADJUSTMENT OF PATENT TERM.—

(1) PATENT TERM GUARANTEES.—

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—

(I) the date on which an application was filed under section 111(a); or

(II) the date of commencement of the national stage under section 371 in an international application;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Patent Trial and Appeal Board under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid

under section 151 and all outstanding requirements were satisfied,

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OF ADJUSTMENTS FOR DELAYS DUE TO DERIVATION PROCEEDINGS, SECRECY ORDERS, AND APPEALS.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135(a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Patent Trial and Appeal Board or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability,

the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(2) LIMITATIONS.—

(A) IN GENERAL.—To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) DISCLAIMED TERM.—No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

(3) PROCEDURES FOR PATENT TERM ADJUSTMENT DETERMINATION.—

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall—

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination no later than the date of issuance of the patent; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

(D) The Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.

(4) APPEAL OF PATENT TERM ADJUSTMENT DETERMINATION.—

(A) An applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the

period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

(B) The determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent.

(c) CONTINUATION.—

(1) DETERMINATION.—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) REMEDIES.—The remedies of sections 283, 284, and 285 shall not apply to acts which—

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) REMUNERATION.—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)).

(d) PROVISIONAL RIGHTS.—

(1) IN GENERAL.—In addition to other rights provided by this section, a patent shall include the right to obtain a reasonable royalty from any person who, during the period beginning on the date of publication of the application for such patent under section 122(b), or in the case of an international application filed under the treaty defined in section 351(a) designating the United States under Article 21(2)(a) of such treaty, the date of publication of the application, and ending on the date the patent is issued—

(A)(i) makes, uses, offers for sale, or sells in the United States the invention as claimed in the published patent application or imports such an invention into the United States; or

(ii) if the invention as claimed in the published patent application is a process, uses, offers for sale, or sells in the United States or imports into the United States products made by that process as claimed in the published patent application; and

(B) had actual notice of the published patent application and, in a case in which the right arising under this paragraph is based upon an international application designating the United States that is published in a language other than English, had a translation of the international application into the English language.

(2) RIGHT BASED ON SUBSTANTIALLY IDENTICAL INVENTIONS.—The right under paragraph (1) to obtain a reasonable royalty shall not be available under this subsection unless the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application.

(3) TIME LIMITATION ON OBTAINING A REASONABLE ROYALTY.—The right under paragraph (1) to obtain a reasonable royalty shall be available only in an action brought not later than 6 years after the patent is issued. The right under paragraph (1) to obtain a reasonable royalty shall not be affected by the duration of the period described in paragraph (1).

(4) REQUIREMENTS FOR INTERNATIONAL APPLICATIONS.—

(A) EFFECTIVE DATE.—The right under paragraph (1) to obtain a reasonable royalty based upon the publication under the treaty defined in section 351(a) of an international application designating the United States shall commence on the date of publication under the treaty of the international application, or, if the publication under the treaty of the international application is in a language other than English, on the date on which the Patent and Trademark Office receives a translation of the publication in the English language.

(B) COPIES.—The Director may require the applicant to provide a copy of the international application and a translation thereof.

(July 19, 1952, ch. 950, 66 Stat. 804; Pub. L. 89–83, § 5, July 24, 1965, 79 Stat. 261; Pub. L. 96–517, § 4, Dec. 12, 1980, 94 Stat. 3018; Pub. L. 100–418, title IX, § 9002, Aug. 23, 1988, 102 Stat. 1563; Pub. L. 103–465, title V, § 532(a)(1), Dec. 8, 1994, 108 Stat. 4983; Pub. L. 104–295, § 20(e)(1), Oct. 11, 1996, 110 Stat. 3529; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, §§ 4402(a), 4504], Nov. 29, 1999, 113 Stat. 1536, 1501A–557, 1501A–564; Pub. L. 107–273, div. C, title III, §§ 13204, 13206(a)(8), Nov. 2, 2002, 116 Stat. 1902, 1904; Pub. L. 112–29, §§ 3(j)(1), (2)(B), 9(a), 20(j), Sept. 16, 2011, 125 Stat. 290, 316, 335; Pub. L. 112–211, title I, § 102(6), Dec. 18, 2012, 126 Stat. 1531; Pub. L. 112–274, § 1(h), Jan. 14, 2013, 126 Stat. 2457.)

AMENDMENT OF SECTION

Pub. L. 112–211, title I, §§ 102(6), 103, Dec. 18, 2012, 126 Stat. 1531, 1532, provided that, effective on the later of the date that is 1 year after Dec. 18, 2012, or the date that the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs enters into force with respect to the United States, and applicable only to certain applications filed on and after that effective date and patents issuing thereon, this section is amended as follows:

(1) in subsection (a)(2), by substituting "section 120, 121, 365(c), or 386(c)" for "section 120, 121, or 365(c)";

(2) in subsection (a)(3), by substituting "section 119, 365(a), 365(b), 386(a), or 386(b)" for "section 119, 365(a), or 365(b)"; and

(3) in subsection (d)(1), by inserting "or an international design application filed under the treaty defined in section 381(a)(1) designating the United States under Article 5 of such treaty" after "Article 21(2)(a) of such treaty".

See 2012 Amendment notes below.

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §40 (R.S. 4884, amended May 23, 1930, ch. 312, §1, 46 Stat. 376).

The reference to plants is omitted for inclusion in another section and the reference to the title is shortened since the title is of no legal significance.

The wording of the granting clause is changed to "the right to exclude others from making, using, or selling", following language used by the Supreme Court, to render the meaning clearer.

"United States" is defined in section 100.

REFERENCES IN TEXT

The date of the enactment of the Uruguay Round Agreements Act, referred to in subsec. (c)(1), (2)(A), is the date of enactment of Pub. L. 103–465, which was approved Dec. 8, 1994.

AMENDMENTS

2013—Subsec. (b)(1)(A)(i)(II). Pub. L. 112–274, §1(h)(1)(A), which directed substitution of "of commencement of the national stage under section 371 in an international application" for "on which an international application fulfilled the requirements of section 371 of this title", was executed by making the substitution for "on which an international application fulfilled the requirements of section 371", to reflect the probable intent of Congress and the intervening amendment by Pub. L. 112–29, §20(j). See 2011 Amendment note below.

Subsec. (b)(1)(B). Pub. L. 112–274, §1(h)(1)(B), substituted "the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application" for "the application in the United States" in introductory provisions.

Subsec. (b)(3)(B)(i). Pub. L. 112–274, §1(h)(2), substituted "no later than the date of issuance of the patent" for "with the written notice of allowance of the application under section 151".

Subsec. (b)(4)(A). Pub. L. 112–274, §1(h)(3), substituted "the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy" for "a determination made by the Director under paragraph (3) shall have remedy" and "the date of the Director's decision on the applicant's request for reconsideration" for "the grant of the patent".

2012—Subsec. (a)(2). Pub. L. 112–211, §102(6)(A)(i), substituted "section 120, 121, 365(c), or 386(c)" for "section 120, 121, or 365(c)".

Subsec. (a)(3). Pub. L. 112–211, §102(6)(A)(ii), substituted "section 119, 365(a), 365(b), 386(a), or 386(b)" for "section 119, 365(a), or 365(b)".

Subsec. (d)(1). Pub. L. 112–211, §102(6)(B), inserted "or an international design application filed under the treaty defined in section 381(a)(1) designating the United States under Article 5 of such treaty" after "Article 21(2)(a) of such treaty" in introductory provisions.

2011—Subsec. (a)(2). Pub. L. 112–29, §20(j), struck out "of this title" after "365(c)".

Subsec. (a)(3). Pub. L. 112–29, §20(j), struck out "of this title" after "365(b)".

Subsec. (b)(1)(A)(i). Pub. L. 112–29, §20(j), in introductory provisions, struck out "of this title" after "132" and after "151".

Subsec. (b)(1)(A)(i)(I). Pub. L. 112–29, §20(j), struck out "of this title" after "111(a)".

Subsec. (b)(1)(A)(i)(II). Pub. L. 112–29, §20(j), struck out "of this title" after "371".

Subsec. (b)(1)(A)(iii), (B)(ii). Pub. L. 112–29, §3(j)(1), substituted "Patent Trial and Appeal Board" for "Board of Patent Appeals and Interferences".

Subsec. (b)(1)(C). Pub. L. 112–29, §3(j)(2)(B), amended heading generally. Prior to amendment, heading read as follows: "Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals".

Subsec. (b)(1)(C)(iii). Pub. L. 112–29, §3(j)(1), substituted "Patent Trial and Appeal Board" for "Board of Patent Appeals and Interferences".

Subsec. (b)(4)(A). Pub. L. 112–29, §9(a), substituted "United States District Court for the Eastern District of Virginia" for "United States District Court for the District of Columbia".

Subsec. (c)(2). Pub. L. 112–29, §20(j), in introductory provisions, struck out "of this title" after "285".

Subsec. (c)(3). Pub. L. 112–29, §20(j), struck out "of this title" after "excluded by paragraph (2))".

2002—Subsec. (b)(4)(A). Pub. L. 107–273, §13206(a)(8), struck out ", United States Code," after "title 5".

Subsec. (d)(4)(A). Pub. L. 107–273, §13204, amended subsec. (d)(4)(A) as in effect on Nov. 29, 2000, by substituting "the date of" for "the date on which the Patent and Trademark Office receives a copy of the" and "publication in the English language" for "international application in the English language".

1999—Pub. L. 106–113, §1000(a)(9) [title IV, §4504(1)], inserted "; provisional rights" after "patent" in section catchline.

Subsec. (b). Pub. L. 106–113, §1000(a)(9) [title IV, §4402(a)], amended heading and text of subsec. (b) generally. Prior to amendment, text provided for interference delay or secrecy orders, extensions for appellate review, a limitations period, and a maximum period of 5 years duration for all extensions.

Subsec. (d). Pub. L. 106–113, §1000(a)(9) [title IV, §4504(2)], added subsec. (d).

1996—Subsec. (c)(2). Pub. L. 104–295 substituted "acts" for "Acts" in introductory provisions.

1994—Pub. L. 103–465 amended section catchline and text generally. Prior to amendment, text read as follows: "Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,, referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof."

1988—Pub. L. 100–418 inserted "and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process," after "United States".

1980—Pub. L. 96–517 substituted "payment of fees" for "payment of issue fees".

1965—Pub. L. 89–83 added "subject to the payment of issue fees as provided for in this title".

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 112–274 effective Jan. 14, 2013, and applicable to proceedings commenced on or after such date, see section 1(n) of Pub. L. 112–274, set out as a note under section 5 of this title.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–211 effective on the later of the date that is 1 year after Dec. 18, 2012, or the date that the Geneva Act of the Hague Agreement Concerning the International Registration of Industrial Designs enters into force with respect to the United States, and applicable only to certain applications filed on and after that effective date and patents issuing thereon, see section 103 of Pub. L. 112–211, set out as a note under section 100 of this title.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 3(j)(1), (2)(B) of Pub. L. 112–29 effective upon the expiration of the 18-month period beginning on Sept. 16, 2011, and applicable to certain applications for patent and any patents issuing thereon, see section 3(n) of Pub. L. 112–29, set out as an Effective Date of 2011 Amendment; Savings Provisions note under section 100 of this title.

Amendment by section 9(a) of Pub. L. 112–29 effective Sept. 16, 2011, and applicable to any civil action commenced on or after that date, see section 9(b) of Pub. L. 112–29, set out as a note under section 1071 of Title 15, Commerce and Trade.

Amendment by section 20(j) of Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4405(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A–560, provided that: "The amendments made by sections 4402 and 4404 [amending this section, sections 156 and 282 of this title, and section 1295 of Title 28, Judiciary and Judicial Procedure] shall take effect on the date that is 6 months after the date of the enactment of this Act [Nov. 29, 1999] and, except for a design patent application filed under chapter 16 of title 35, United States Code, shall apply to any application filed on or after the date that is 6 months after the date of the enactment of this Act."

Amendment by section 1000(a)(9) [title IV, §4504] of Pub. L. 106–113 effective Nov. 29, 2000, applicable only to applications (including international applications designating the United States) filed on or after that date, and additionally applicable to any pending application filed before Nov. 29, 2000, if such pending application is published pursuant to a request of the applicant under such procedures as may be established by the Director, see section 1000(a)(9) [title IV, §4508] of Pub. L. 106–113, as amended, set out as a note under section 10 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103–465, title V, §534, Dec. 8, 1994, 108 Stat. 4990, provided that:

"(a) IN GENERAL.—Subject to subsection (b), the amendments made by this subtitle [subtitle C (§§531–534) of title V of Pub. L. 103–465, amending this section and sections 41, 104, 111, 119, 156, 172, 173, 252, 262, 271, 272, 287, 292, 295, 307, 365, and 373 of this title] take effect on the date that is one year after the date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995].

"(b) PATENT APPLICATIONS.—

"(1) IN GENERAL.—Subject to paragraph (2), the amendments made by section 532 [amending this section and sections 41, 111, 119, 156, 172, 173, 365, and 373 of this title] take effect on the date that is 6 months after the date of the enactment of this Act [Dec. 8, 1994] and shall apply to all patent applications filed in the United States on or after the effective date.

"(2) SECTION 154(a)(1).—Section 154(a)(1) of title 35, United States Code, as amended by section 532(a)(1) of this Act, shall take effect on the effective date described in subsection (a).

"(3) EARLIEST FILING.—The term of a patent granted on an application that is filed on or after the effective date described in subsection (a) and that contains a specific reference to an earlier application filed under the provisions of section 120, 121, or 365(c) of title 35, United States Code, shall be measured from the filing date of the earliest filed application."

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 effective 6 months after Aug. 23, 1988, and, subject to enumerated exceptions, applicable only with respect to products made or imported after such effective date, see section 9006 of Pub. L. 100–418, set out as a note under section 271 of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96–517 effective Dec. 12, 1980, see section 8(a) of Pub. L. 96–517, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–83 effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as a note under section 41 of this title.

REGULATIONS

Pub. L. 103–465, title V, §532(a)(2), Dec. 8, 1994, 108 Stat. 4985, authorized the Commissioner of Patents and Trademarks to prescribe regulations for further limited reexamination of applications pending 2 years or longer and for examination of more than 1 independent and distinct invention in applications pending 3 years or longer, as of the effective date of section 154(a)(2) of this title, and to establish appropriate related fees.

[§§ 155, 155A. Repealed. Pub. L. 112–29, § 20(k), Sept. 16, 2011, 125 Stat. 335]

Section 155, added Pub. L. 97–414, §11(a), Jan. 4, 1983, 96 Stat. 2065; amended Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(a)(6), (10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, §13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906, related to patent term extension.

Section 155A, added Pub. L. 98–127, §4(a), Oct. 13, 1983, 97 Stat. 832; amended Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(a)(7), (10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, §13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906, related to patent term restoration.

EFFECTIVE DATE OF REPEAL

Repeal effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as an Effective Date of 2011 Amendment note under section 2 of this title.

§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial market-

(1) Any patent which encompasses within its scope a composition of matter which is a new drug product, if during the regulatory review of the product by the Federal Food and Drug Administration—

(A) the Federal Food and Drug Administration notified the patentee, by letter dated February 20, 1976, that such product's new drug application was not approvable under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act;

(B) in 1977 the patentee submitted to the Federal Food and Drug Administration the results of a health effects test to evaluate the carcinogenic potential of such product;

(C) the Federal Food and Drug Administration approved, by letter dated December 18, 1979, the new drug application for such product; and

(D) the Federal Food and Drug Administration approved, by letter dated May 26, 1981, a supplementary application covering the facility for the production of such product.

(2) Any patent which encompasses within its scope a process for using the composition of matter described in paragraph (1).

(b) The term of any patent described in subsection (a) shall be extended for a period equal to the period beginning February 20, 1976, and ending May 26, 1981, and such patent shall have the effect as if originally issued with such extended term.

(c) The patentee of any patent described in subsection (a) of this section shall, within ninety days after the date of enactment of this section, notify the Director of the number of any patent so extended. On receipt of such notice, the Director shall confirm such extension by placing a notice thereof in the official file of such patent and publishing an appropriate notice of such extension in the Official Gazette of the Patent and Trademark Office.

(Added Pub. L. 98–127, §4(a), Oct. 13, 1983, 97 Stat. 832; amended Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(a)(7), (10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, §13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906.)

REPEAL OF SECTION

Pub. L. 112–29, §20(k), (l), Sept. 16, 2011, 125 Stat. 335, provided that, effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, this section is repealed.

REFERENCES IN TEXT

Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act, referred to in subsec. (a)(1)(A), is classified to section 355(b)(1) of Title 21, Food and Drugs.

The date of enactment of this section, referred to in subsec. (c), is the date of enactment of Pub. L. 98–127, which was approved Oct. 13, 1983.

AMENDMENTS

2002—Subsec. (c). Pub. L. 107–273 made technical correction to directory language of Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Subsec. (c). Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(10)(A)], as amended by Pub. L. 107–273, substituted "Director shall confirm" for "Commissioner shall confirm".

Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(7)], substituted "notify the Director" for "notify the Commissioner of Patents and Trademarks".

EFFECTIVE DATE OF REPEAL

Repeal effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as an Effective Date of 2011 Amendment note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, §4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

§ 156. Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1) the term of the patent has not expired before an application is submitted under subsection (d)(1) for its extension;

(2) the term of the patent has never been extended under subsection (e)(1) of this section;

(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of paragraphs (1) through (4) of subsection (d);

(4) the product has been subject to a regulatory review period before its commercial marketing or use;

(5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred;

(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent; or

(C) for purposes of subparagraph (A), in the case of a patent which—

(i) claims a new animal drug or a veterinary biological product which (I) is not covered by the claims in any other patent which has been extended, and (II) has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and

(ii) was not extended on the basis of the regulatory review period for use in non-food-producing animals,

the permission for the commercial marketing or use of the drug or product after the regulatory review period for use in food-producing

animals is the first permitted commercial marketing or use of the drug or product for administration to a food-producing animal.

The product referred to in paragraphs (4) and (5) is hereinafter in this section referred to as the "approved product".

(b) Except as provided in subsection (d)(5)(F), the rights derived from any patent the term of which is extended under this section shall during the period during which the term of the patent is extended—

(1) in the case of a patent which claims a product, be limited to any use approved for the product—

(A) before the expiration of the term of the patent—

(i) under the provision of law under which the applicable regulatory review occurred, or

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based;

(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the product—

(A) before the expiration of the term of the patent—

(i) under any provision of law under which an applicable regulatory review occurred, and

(ii) under the provision of law under which any regulatory review described in paragraph (1), (4), or (5) of subsection (g) occurred, and

(B) on or after the expiration of the regulatory review period upon which the extension of the patent was based; and

(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make—

(A) the approved product, or

(B) the product if it has been subject to a regulatory review period described in paragraph (1), (4), or (5) of subsection (g).

As used in this subsection, the term "product" includes an approved product.

(c) The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued, except that—

(1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period;

(2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and

(4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

(d)(1) To obtain an extension of the term of a patent under this section, the owner of record of the patent or its agent shall submit an application to the Director. Except as provided in paragraph (5), such an application may only be submitted within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. The application shall contain—

(A) the identity of the approved product and the Federal statute under which regulatory review occurred;

(B) the identity of the patent for which an extension is being sought and the identity of each claim of such patent which claims the approved product or a method of using or manufacturing the approved product;

(C) information to enable the Director to determine under subsections (a) and (b) the eligibility of a patent for extension and the rights that will be derived from the extension and information to enable the Director and the Secretary of Health and Human Services or the Secretary of Agriculture to determine the period of the extension under subsection (g);

(D) a brief description of the activities undertaken by the applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; and

(E) such patent or other information as the Director may require.

For purposes of determining the date on which a product receives permission under the second sentence of this paragraph, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to receive such permission on the next business day. For purposes of the preceding sentence, the term "business day" means any Monday, Tuesday, Wednesday, Thursday, or Friday, excluding any legal holiday under section 6103 of title 5.

(2)(A) Within 60 days of the submittal of an application for extension of the term of a patent under paragraph (1), the Director shall notify—

(i) the Secretary of Agriculture if the patent claims a drug product or a method of using or manufacturing a drug product and the drug product is subject to the Virus-Serum-Toxin Act, and

(ii) the Secretary of Health and Human Services if the patent claims any other drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive

and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act,

of the extension application and shall submit to the Secretary who is so notified a copy of the application. Not later than 30 days after the receipt of an application from the Director, the Secretary receiving the application shall review the dates contained in the application pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Director of the determination, and shall publish in the Federal Register a notice of such determination.

(B)(i) If a petition is submitted to the Secretary making the determination under subparagraph (A), not later than 180 days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary making the determination shall, in accordance with regulations promulgated by such Secretary, determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary making the determination shall make such determination not later than 90 days after the receipt of such a petition. For a drug product, device, or additive subject to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, the Secretary may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Director[1] of Food and Drugs. For a product subject to the Virus-Serum-Toxin Act, the Secretary of Agriculture may not delegate the authority to make the determination prescribed by this clause to an office below the Office of the Assistant Secretary for Marketing and Inspection Services.

(ii) The Secretary making a determination under clause (i) shall notify the Director of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary making the determination to hold an informal hearing on the determination. If such a request is made within such period, such Secretary shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary who is holding the hearing shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary shall affirm or revise the determination which was the subject of the hearing and shall notify the Director of any revision of the determination and shall publish any such revision in the Federal Register.

(3) For the purposes of paragraph (2)(B), the term "due diligence" means that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(4) An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.

(5)(A) If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days, before such term is due to expire. The application shall contain—

(i) the identity of the product subject to regulatory review and the Federal statute under which such review is occurring;

(ii) the identity of the patent for which interim extension is being sought and the identity of each claim of such patent which claims the product under regulatory review or a method of using or manufacturing the product;

(iii) information to enable the Director to determine under subsection (a)(1), (2), and (3) the eligibility of a patent for extension;

(iv) a brief description of the activities undertaken by the applicant during the applicable regulatory review period to date with respect to the product under review and the significant dates applicable to such activities; and

(v) such patent or other information as the Director may require.

(B) If the Director determines that, except for permission to market or use the product commercially, the patent would be eligible for an extension of the patent term under this section, the Director shall publish in the Federal Register a notice of such determination, including the identity of the product under regulatory review, and shall issue to the applicant a certificate of interim extension for a period of not more than 1 year.

(C) The owner of record of a patent, or its agent, for which an interim extension has been granted under subparagraph (B), may apply for not more than 4 subsequent interim extensions under this paragraph, except that, in the case of a patent subject to subsection (g)(6)(C), the owner of record of the patent, or its agent, may apply for only 1 subsequent interim extension under this paragraph. Each such subsequent application shall be made during the period beginning 60 days before, and ending 30 days before, the expiration of the preceding interim extension.

(D) Each certificate of interim extension under this paragraph shall be recorded in the official file of the patent and shall be considered part of the original patent.

(E) Any interim extension granted under this paragraph shall terminate at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use, except that, if within

[1] So in original. Probably should be "Commissioner".

that 60-day period the applicant notifies the Director of such permission and submits any additional information under paragraph (1) of this subsection not previously contained in the application for interim extension, the patent shall be further extended, in accordance with the provisions of this section—

(i) for not to exceed 5 years from the date of expiration of the original patent term; or

(ii) if the patent is subject to subsection (g)(6)(C), from the date on which the product involved receives approval for commercial marketing or use.

(F) The rights derived from any patent the term of which is extended under this paragraph shall, during the period of interim extension—

(i) in the case of a patent which claims a product, be limited to any use then under regulatory review;

(ii) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent then under regulatory review; and

(iii) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product then under regulatory review.

(e)(1) A determination that a patent is eligible for extension may be made by the Director solely on the basis of the representations contained in the application for the extension. If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent.

(2) If the term of a patent for which an application has been submitted under subsection (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension.

(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

(B) Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act), or

(B) a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Virus-Serum-Toxin Act) which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques, including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(3) The term "major health or environmental effects test" means a test which is reasonably related to the evaluation of the health or environmental effects of a product, which requires at least six months to conduct, and the data from which is submitted to receive permission for commercial marketing or use. Periods of analysis or evaluation of test results are not to be included in determining if the conduct of a test required at least six months.

(4)(A) Any reference to section 351 is a reference to section 351 of the Public Health Service Act.

(B) Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act.

(C) Any reference to the Virus-Serum-Toxin Act is a reference to the Act of March 4, 1913 (21 U.S.C. 151–158).

(5) The term "informal hearing" has the meaning prescribed for such term by section 201(y)[2] of the Federal Food, Drug, and Cosmetic Act.

(6) The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) The term "date of enactment" as used in this section means September 24, 1984, for a human drug product, a medical device, food additive, or color additive.

(8) The term "date of enactment" as used in this section means the date of enactment of the Generic Animal Drug and Patent Term Restoration Act for an animal drug or a veterinary biological product.

(g) For purposes of this section, the term "regulatory review period" has the following meanings:

(1)(A) In the case of a product which is a new drug, antibiotic drug, or human biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new drug, antibiotic drug, or human biological product is the sum of—

(i) the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507[2] became effective for the approved product and ending on the date an application was initially submitted for such drug product under section 351, 505, or 507,[2] and

(ii) the period beginning on the date the application was initially submitted for the approved product under section 351, subsection (b) of section 505, or section 507[2] and ending on the date such application was approved under such section.

(2)(A) In the case of a product which is a food additive or color additive, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

[2] See References in Text note below.

(B) The regulatory review period for a food or color additive is the sum of—

(i) the period beginning on the date a major health or environmental effects test on the additive was initiated and ending on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and

(ii) the period beginning on the date a petition was initially submitted with respect to the product under the Federal Food, Drug, and Cosmetic Act requesting the issuance of a regulation for use of the product, and ending on the date such regulation became effective or, if objections were filed to such regulation, ending on the date such objections were resolved and commercial marketing was permitted or, if commercial marketing was permitted and later revoked pending further proceedings as a result of such objections, ending on the date such proceedings were finally resolved and commercial marketing was permitted.

(3)(A) In the case of a product which is a medical device, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a medical device is the sum of—

(i) the period beginning on the date a clinical investigation on humans involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and

(ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and ending on the date such application was approved under such Act or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(4)(A) In the case of a product which is a new animal drug, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory review period for a new animal drug product is the sum of—

(i) the period beginning on the earlier of the date a major health or environmental effects test on the drug was initiated or the date an exemption under subsection (j) of section 512 became effective for the approved new animal drug product and ending on the date an application was initially submitted for such animal drug product under section 512, and

(ii) the period beginning on the date the application was initially submitted for the approved animal drug product under subsection (b) of section 512 and ending on the date such application was approved under such section.

(5)(A) In the case of a product which is a veterinary biological product, the term means the period described in subparagraph (B) to which the limitation described in paragraph (6) applies.

(B) The regulatory period for a veterinary biological product is the sum of—

(i) the period beginning on the date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective and ending on the date an application for a license was submitted under the Virus-Serum-Toxin Act, and

(ii) the period beginning on the date an application for a license was initially submitted for approval under the Virus-Serum-Toxin Act and ending on the date such license was issued.

(6) A period determined under any of the preceding paragraphs is subject to the following limitations:

(A) If the patent involved was issued after the date of the enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(B) If the patent involved was issued before the date of the enactment of this section and—

(i) no request for an exemption described in paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted,

(ii) no major health or environmental effects test described in paragraph (2)(B) or (4)(B) was initiated and no petition for a regulation or application for registration described in such paragraph was submitted, or

(iii) no clinical investigation described in paragraph (3) was begun or product development protocol described in such paragraph was submitted,

before such date for the approved product the period of extension determined on the basis of the regulatory review period determined under any such paragraph may not exceed five years.

(C) If the patent involved was issued before the date of the enactment of this section and if an action described in subparagraph (B) was taken before the date of the enactment of this section with respect to the approved product and the commercial marketing or use of the product has not been approved before such date, the period of extension determined on the basis of the regulatory review period determined under such paragraph may not exceed two years or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years.

(h) The Director may establish such fees as the Director determines appropriate to cover the costs to the Office of receiving and acting upon applications under this section.

(Added Pub. L. 98–417, title II, §201(a), Sept. 24, 1984, 98 Stat. 1598; amended Pub. L. 100–670, title II, §201(a)–(h), Nov. 16, 1988, 102 Stat. 3984–3987;

Pub. L. 103–179, §§5, 6, Dec. 3, 1993, 107 Stat. 2040, 2042; Pub. L. 103–465, title V, §532(c)(1), Dec. 8, 1994, 108 Stat. 4987; Pub. L. 105–115, title I, §125(b)(2)(P), Nov. 21, 1997, 111 Stat. 2326; Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §§4404, 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–560, 1501A–582; Pub. L. 107–273, div. C, title III, §13206(a)(9), (b)(1)(B), Nov. 2, 2002, 116 Stat. 1904, 1906; Pub. L. 112–29, §37(a), Sept. 16, 2011, 125 Stat. 341.)

REFERENCES IN TEXT

The Virus-Serum-Toxin Act, referred to in subsecs. (d)(2)(A)(i), (B)(i), (f)(2)(B), (4)(C), and (g)(5)(B), (6)(C), is the eighth paragraph under the heading "Bureau of Animal Industry" of act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended, which is classified generally to chapter 5 (§151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (d)(2)(A)(ii), (B)(ii), (f), and (g)(2)(B), (3)(B)(ii), (6)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Public Health Service Act, referred to in subsecs. (d)(2)(B)(i) and (f)(2)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Sections 503, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (f)(4)(B) and (g)(1)(B), (3)(B), are classified, respectively, to sections 353, 355, 360b, and 360e of Title 21, Food and Drugs. Section 507 of the Act, referred to in subsec. (g)(1)(B), was classified to section 357 of Title 21, prior to repeal by Pub. L. 105–115, title I, §125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

Section 201 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (f)(5), which is classified to section 321 of Title 21, was subsequently amended, and section 201(y) no longer defines the term "informal hearing". However, such term is defined elsewhere in that section.

Section 351 of the Public Health Service Act, referred to in subsecs. (f)(4)(A) and (g)(1)(B)(i), (ii), is classified to section 262 of Title 42, The Public Health and Welfare.

The date of enactment of the Generic Animal Drug and Patent Term Restoration Act, referred to in subsec. (f)(8), is the date of enactment of Pub. L. 100–670, which was approved Nov. 16, 1988.

The date of the enactment of this section, referred to in subsec. (g)(6), is the date of the enactment of Pub. L. 98–417, which was approved Sept. 24, 1984.

AMENDMENTS

2011—Subsec. (d)(1). Pub. L. 112–29 inserted concluding provisions.

2002—Subsec. (b)(3)(B). Pub. L. 107–273, §13206(a)(9)(A), substituted "paragraph" for "paragraphs".

Subsec. (d). Pub. L. 107–273, §13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(10)(A)]. See 1999 Amendment note below.

Subsec. (d)(2)(B)(i). Pub. L. 107–273, §13206(a)(9)(B), substituted "below the Office" for "below the office".

Subsec. (e). Pub. L. 107–273, §13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(10)(A)]. See 1999 Amendment note below.

Subsec. (g)(6)(B)(iii). Pub. L. 107–273, §13206(a)(9)(C), substituted "submitted" for "submittted".

Subsec. (h). Pub. L. 107–273, §13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Subsec. (a). Pub. L. 106–113, §1000(a)(9) [title IV, §4404], in introductory provisions, inserted ", which shall include any patent term adjustment granted under section 154(b)," after "the original expiration date of the patent".

Subsecs. (d), (e), (h). Pub. L. 106–113, §1000(a)(9) [title IV, §4732(a)(10)(A)], as amended by Pub. L. 107–273, §13206(b)(1)(B), substituted "Director" for "Commissioner" wherever appearing.

1997—Subsec. (f)(4)(B). Pub. L. 105–115, §125(b)(2)(P), struck out "507," after "505," in two places.

1994—Subsec. (a)(2). Pub. L. 103–465 inserted "under subsection (e)(1) of this section" after "extended".

1993—Subsec. (a)(1). Pub. L. 103–179, §6(1)(A), substituted "subsection (d)(1)" for "subsection (d)".

Subsec. (a)(3). Pub. L. 103–179, §6(1)(B), substituted "paragraphs (1) through (4) of subsection (d)" for "subsection (d)".

Subsec. (b). Pub. L. 103–179, §6(2), substituted "Except as provided in subsection (d)(5)(F), the rights" for "The rights" in introductory provisions.

Subsec. (c)(4). Pub. L. 103–179, §5(1), substituted "extended under subsection (e)(1)" for "extended".

Subsec. (d)(1). Pub. L. 103–179, §5(2), substituted "Except as provided in paragraph (5), such" for "Such" in second sentence.

Subsec. (d)(5). Pub. L. 103–179, §5(3), added par. (5).

Subsec. (e)(1). Pub. L. 103–179, §6(3)(A), substituted "paragraphs (1) through (4) of subsection (d)" for "subsection (d)".

Subsec. (e)(2). Pub. L. 103–179, §6(3)(B), substituted "subsection (d)(1)" for "subsection (d)".

1988—Subsec. (a)(5)(A). Pub. L. 100–670, §201(a)(1), inserted "or (C)" after "in subparagraph (B)".

Subsec. (a)(5)(C). Pub. L. 100–670, §201(a)(2), (3), added subpar. (C).

Subsec. (b). Pub. L. 100–670, §201(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

"(1) in the case of a patent which claims a product, be limited to any use approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred;

"(2) in the case of a patent which claims a method of using a product, be limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred; and

"(3) in the case of a patent which claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the approved product."

Subsec. (c)(2). Pub. L. 100–670, §201(c), substituted "(3)(B)(i), (4)(B)(i), and (5)(B)(i)" for "and (3)(B)(i)".

Subsec. (d)(1)(C). Pub. L. 100–670, §201(d), inserted "or the Secretary of Agriculture" after "and Human Services".

Subsec. (d)(2)(A). Pub. L. 100–670, §201(e), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "Within sixty days of the submittal of an application for extension of the term of a patent under paragraph (1), the Commissioner shall notify the Secretary of Health and Human Services if the patent claims any human drug product, a medical device, or a food additive or color additive or a method of using or manufacturing such a product, device, or additive and if the product, device, and additive are subject to the Federal Food, Drug, and Cosmetic Act, of the extension application and shall submit to the Secretary a copy of the application. Not later than thirty days after the receipt of an application from the Commissioner, the Secretary shall review the dates contained in the appli-

cation pursuant to paragraph (1)(C) and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination."

Subsec. (d)(2)(B). Pub. L. 100–670, §201(f), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows:

"(i) If a petition is submitted to the Secretary under subparagraph (A), not later than one hundred and eighty days after the publication of the determination under subparagraph (A), upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period, the Secretary shall, in accordance with regulations promulgated by the Secretary determine if the applicant acted with due diligence during the applicable regulatory review period. The Secretary shall make such determination not later than ninety days after the receipt of such a petition. The Secretary may not delegate the authority to make the determination prescribed by this subparagraph to an office below the Office of the Commissioner of Food and Drugs.

"(ii) The Secretary shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination together with the factual and legal basis for such determination. Any interested person may request, within the sixty-day period beginning on the publication of a determination, the Secretary to hold an informal hearing on the determination. If such a request is made within such period, the Secretary shall hold such hearing not later than thirty days after the date of the request, or at the request of the person making the request, not later than sixty days after such date. The Secretary shall provide notice of the hearing to the owner of the patent involved and to any interested person and provide the owner and any interested person an opportunity to participate in the hearing. Within thirty days after the completion of the hearing, the Secretary shall affirm or revise the determination which was the subject of the hearing and notify the Commissioner of any revision of the determination and shall publish any such revision in the Federal Register."

Subsec. (f)(1)(A). Pub. L. 100–670, §201(g)(1), struck out "human" before "drug product".

Subsec. (f)(2). Pub. L. 100–670, §201(g)(1), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "The term 'human drug product' means the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient."

Subsec. (f)(4)(B), (C). Pub. L. 100–670, §201(g)(2), which directed general amendment of subpars. (B) and (C) of par. (4), was executed by amending subpar. (B) generally, and adding subpar. (C) as probable intent of Congress in light of absence of subpar. (C) in par. (4). Prior to amendment, subpar. (B) read as follows: "Any reference to section 503, 505, 507, or 515 is a reference to section 503, 505, 507, or 515 of the Federal Food, Drug, and Cosmetic Act."

Subsec. (f)(7), (8). Pub. L. 100–670, §201(g)(3), added pars. (7) and (8).

Subsec. (g)(1)(A). Pub. L. 100–670, §201(h)(1)(A), (2), substituted "new drug, antibiotic drug, or human biological product" for "human drug product" and "paragraph (6)" for "paragraph (4)".

Subsec. (g)(1)(B). Pub. L. 100–670, §201(h)(1)(B), substituted "new drug, antibiotic drug, or human biological product" for "human drug product" in introductory provisions and "product" for "human drug product" in cls. (i) and (ii).

Subsec. (g)(2)(A), (3)(A). Pub. L. 100–670, §201(h)(3), substituted "paragraph (6)" for "paragraph (4)".

Subsec. (g)(4), (5). Pub. L. 100–670, §201(h)(4), added pars. (4) and (5). Former par. (4) redesignated (6).

Subsec. (g)(6). Pub. L. 100–670, §201(h)(4), redesignated former par. (4) as (6).

Subsec. (g)(6)(B)(i). Pub. L. 100–670, §201(h)(5)(A), substituted "paragraph (1)(B) or (4)(B) was submitted and no request for the authority described in paragraph (5)(B) was submitted" for "paragraph (1)(B) was submitted".

Subsec. (g)(6)(B)(ii). Pub. L. 100–670, §201(h)(5)(B), substituted "paragraph (2)(B) or (4)(B)" for "paragraph (2)".

Subsec. (g)(6)(C). Pub. L. 100–670, §201(h)(5)(C), inserted "or in the case of an approved product which is a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act), three years" after "exceed two years".

EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 112–29, §37(b), Sept. 16, 2011, 125 Stat. 341, provided that: "The amendment made by subsection (a) [amending this section] shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of the enactment of this Act [Sept. 16, 2011]."

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(9) [title IV, §4404] of Pub. L. 106–113 effective on date that is 6 months after Nov. 29, 1999, and, except for design patent application filed under chapter 16 of this title, applicable to any application filed on or after such date, see section 1000(a)(9) [title IV, §4405(a)] of Pub. L. 106–113, set out as a note under section 154 of this title.

Amendment by section 1000(a)(9) [title IV, §4732(a)(10)(A)] of Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, §4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective 6 months after Dec. 8, 1994, and applicable to all patent applications filed in the United States on or after that effective date, with provisions relating to earliest filed patent application, see section 534(b)(1), (3) of Pub. L. 103–465, set out as a note under section 154 of this title.

§ 157. Statutory invention registration

(a) Notwithstanding any other provision of this title, the Director is authorized to publish a statutory invention registration containing the specification and drawings of a regularly filed application for a patent without examination if the applicant—

(1) meets the requirements of section 112 of this title;

(2) has complied with the requirements for printing, as set forth in regulations of the Director;

(3) waives the right to receive a patent on the invention within such period as may be prescribed by the Director; and

(4) pays application, publication, and other processing fees established by the Director.

If an interference is declared with respect to such an application, a statutory invention registration may not be published unless the issue of priority of invention is finally determined in favor of the applicant.

(b) The waiver under subsection (a)(3) of this section by an applicant shall take effect upon publication of the statutory invention registration.

(c) A statutory invention registration published pursuant to this section shall have all of

stituted "An interest that constitutes an assignment" for "An assignment" in fourth par.

1982—Pub. L. 97–247 inserted ", or apostille of an official designated by a foreign country which, by treaty or convention, accords like effect to apostilles of designated officials in the United States".

1975—Pub. L. 93–596 substituted "Patent and Trademark Office" for "Patent Office".

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–211 effective on the date that is 1 year after Dec. 18, 2012, applicable to patents issued before, on, or after that effective date and patent applications pending on or filed after that effective date, and not effective with respect to patents in litigation commenced before that effective date, see section 203 of Pub. L. 112–211, set out as an Effective Date note under section 27 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97–247 effective Aug. 27, 1982, see section 17(a) of Pub. L. 97–247, set out as a note under section 41 of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 93–596 effective Jan. 2, 1975, see section 4 of Pub. L. 93–596, set out as a note under section 1111 of Title 15, Commerce and Trade.

§ 262. Joint owners

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.

(July 19, 1952, ch. 950, 66 Stat. 810; Pub. L. 103–465, title V, § 533(b)(3), Dec. 8, 1994, 108 Stat. 4989.)

HISTORICAL AND REVISION NOTES

This section states a condition in existing law not expressed in the existing statutes.

AMENDMENTS

1994—Pub. L. 103–465 substituted "use, offer to sell, or sell" for "use or sell" and inserted "within the United States, or import the patented invention into the United States," after "invention".

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

CHAPTER 27—GOVERNMENT INTERESTS IN PATENTS

AMENDMENTS

1965—Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261, struck out item 266 "Issue of patents without fees to Government employees".

[§ 266. Repealed. Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261]

Section, act July 19, 1952, ch. 950, § 1, 66 Stat. 811, provided for issuance of patents to government employees without fees.

EFFECTIVE DATE OF REPEAL

Repeal effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as an Effective Date of 1965 Amendment note under section 41 of this title.

§ 267. Time for taking action in Government applications

Notwithstanding the provisions of sections 133 and 151, the Director may extend the time for taking any action to three years, when an application has become the property of the United States and the head of the appropriate department or agency of the Government has certified to the Director that the invention disclosed therein is important to the armament or defense of the United States.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), Nov. 2, 2002, 116 Stat. 1906; Pub. L. 112–29, § 20(j), Sept. 16, 2011, 125 Stat. 335.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 37 (R.S. 4894, amended (1) Mar. 3, 1897, ch. 391, § 4, 29 Stat. 692, 693, (2) July 6, 1916, ch. 225, § 1, 39 Stat. 345, 347–8, (3) Mar. 2, 1927, ch. 273, § 1, 44 Stat. 1335, (4) Aug. 7, 1939, ch. 568, 53 Stat. 1264).

This provision, which appears as the last two sentences of the corresponding section of the present statute (see note to section 133) is made a separate section and rewritten in simpler form.

AMENDMENTS

2011—Pub. L. 112–29 struck out "of this title" after "151".

2002—Pub. L. 107–273 made technical correction to directory language of Pub. L. 106–113. See 1999 Amendment note below.

1999—Pub. L. 106–113, as amended by Pub. L. 107–273, substituted "Director" for "Commissioner" in two places.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 20(j) of Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

CHAPTER 28—INFRINGEMENT OF PATENTS

AMENDMENTS

2011—Pub. L. 112–29, § 5(b), Sept. 16, 2011, 125 Stat. 299, amended item 273 generally, substituting "Defense to infringement based on prior commercial use" for "Defense to infringement based on earlier inventor".

1999—Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4302(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–557, added item 273.

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers

to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151–158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(*l*)(4) of the Public Health Service Act or the lists of patents described in section 351(*l*)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(*l*)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(*l*)(3)(A) of the Public Health Service Act, including as provided under section 351(*l*)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

(July 19, 1952, ch. 950, 66 Stat. 811; Pub. L. 98–417, title II, § 202, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 98–622, title I, § 101(a), Nov. 8, 1984, 98 Stat. 3383; Pub. L. 100–418, title IX, § 9003, Aug. 23, 1988, 102 Stat. 1563; Pub. L. 100–670, title II, § 201(i), Nov. 16, 1988, 102 Stat. 3988; Pub. L. 100–703, title II, § 201, Nov. 19, 1988, 102 Stat. 4676; Pub. L. 102–560, § 2(a)(1), Oct. 28, 1992, 106 Stat. 4230; Pub. L. 103–465, title V, § 533(a), Dec. 8, 1994, 108 Stat. 4988; Pub. L. 108–173, title XI, § 1101(d), Dec. 8, 2003, 117 Stat. 2457; Pub. L. 111–148, title VII, § 7002(c)(1), Mar. 23, 2010, 124 Stat. 815.)

HISTORICAL AND REVISION NOTES

The first paragraph of this section is declaratory only, defining infringement.

Paragraphs (b) and (c) define and limit contributory infringement of a patent and paragraph (d) is ancillary to these paragraphs, see preliminary general description of bill. One who actively induces infringement as by aiding and abetting the same is liable as an infringer, and so is one who sells a component part of a patented invention or material or apparatus for use therein knowing the same to be especially made or especially adapted for use in the infringement of the patent except in the case of a staple article or commodity of commerce having other uses. A patentee is not deemed to have misused his patent solely by reason of doing anything authorized by the section.

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(1), (2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9

(§ 301 et seq.) of Title 21, Food and Drugs. Sections 505 and 512 of the Act are classified to sections 355 and 360b, respectively, of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Act of March 4, 1913, referred to in subsec. (e)(1), (2), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are contained in the eighth paragraph under the heading "Bureau of Animal Industry" of act Mar. 4, 1913, at 37 Stat. 832, and are classified generally to chapter 5 (§ 151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

Section 351 of the Public Health Service Act, referred to in subsec. (e)(2)(C), (4)(D), (6)(A), (C), is classified to section 262 of Title 42, The Public Health and Welfare.

AMENDMENTS

2010—Subsec. (e)(2). Pub. L. 111–148, § 7002(c)(1)(A)(iv), substituted ", veterinary biological product, or biological product" for "or veterinary biological product" in concluding provisions.

Subsec. (e)(2)(C). Pub. L. 111–148, § 7002(c)(1)(A)(i)–(iii), added subpar. (C).

Subsec. (e)(4). Pub. L. 111–148, § 7002(c)(1)(B)(iv), substituted "(C), and (D)" for "and (C)" in concluding provisions.

Subsec. (e)(4)(B). Pub. L. 111–148, § 7002(c)(1)(B)(i), substituted ", veterinary biological product, or biological product" for "or veterinary biological product" and struck out "and" at end.

Subsec. (e)(4)(C). Pub. L. 111–148, § 7002(c)(1)(B)(ii), substituted ", veterinary biological product, or biological product" for "or veterinary biological product" and ", and" for period at end.

Subsec. (e)(4)(D). Pub. L. 111–148, § 7002(c)(1)(B)(iii), added subpar. (D).

Subsec. (e)(6). Pub. L. 111–148, § 7002(c)(1)(C), added par. (6).

2003—Subsec. (e)(5). Pub. L. 108–173 added par. (5).

1994—Subsec. (a). Pub. L. 103–465, § 533(a)(1), inserted ", offers to sell," after "uses" and "or imports into the United States any patented invention" after "the United States".

Subsec. (c). Pub. L. 103–465, § 533(a)(2), substituted "offers to sell or sells within the United States or imports into the United States" for "sells".

Subsec. (e)(1). Pub. L. 103–465, § 533(a)(3)(A), substituted "offer to sell, or sell within the United States or import into the United States" for "or sell".

Subsec. (e)(3). Pub. L. 103–465, § 533(a)(3)(B), substituted "offering to sell, or selling within the United States or importing into the United States" for "or selling".

Subsec. (e)(4)(B), (C). Pub. L. 103–465, § 533(a)(3)(C), (D), substituted "offer to sell, or sale within the United States or importation into the United States" for "or sale".

Subsec. (g). Pub. L. 103–465, § 533(a)(4), substituted "offers to sell, sells," for "sells", "importation, offer to sell, sale," for "importation, sale,", and "other use, offer to sell, or" for "other use or".

Subsec. (i). Pub. L. 103–465, § 533(a)(5), added subsec. (i).

1992—Subsec. (h). Pub. L. 102–560 added subsec. (h).

1988—Subsec. (d). Pub. L. 100–703 added cls. (4) and (5).

Subsec. (e)(1). Pub. L. 100–670, § 201(i)(1), inserted "which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques" after "March 4, 1913)" and "or veterinary biological products" after "sale of drugs".

Subsec. (e)(2). Pub. L. 100–670, § 201(i)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

Subsec. (e)(4). Pub. L. 100–670, § 201(i)(3), inserted "or veterinary biological product" after "drug" in subpars. (A) to (C).

Subsec. (g). Pub. L. 100–418 added subsec. (g).

1984—Subsec. (e). Pub. L. 98–417 added subsec. (e).

Subsec. (f). Pub. L. 98–622 added subsec. (f).

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–560 effective with respect to violations that occur on or after Oct. 28, 1992, see section 4 of Pub. L. 102–560, set out as a note under section 2541 of Title 7, Agriculture.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–703, title II, § 202, Nov. 19, 1988, 102 Stat. 4676, provided that: "The amendment made by this title [amending this section] shall apply only to cases filed on or after the date of the enactment of this Act [Nov. 19, 1988]."

Pub. L. 100–418, title IX, § 9006, Aug. 23, 1988, 102 Stat. 1566, provided that:

"(a) IN GENERAL.—The amendments made by this subtitle [subtitle A (§§ 9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending this section and sections 154 and 287 of this title] take effect 6 months after the date of enactment of this Act [Aug. 23, 1988] and, subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.

"(b) EXCEPTIONS.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This subsection shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

"(c) RETENTION OF OTHER REMEDIES.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930 [19 U.S.C. 1337], or under any other provision of law."

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–622 applicable only to the supplying, or causing to be supplied, of any component or components of a patented invention after Nov. 8, 1984, see section 106(c) of Pub. L. 98–622, set out as a note under section 103 of this title.

REPORTS TO CONGRESS; EFFECT ON DOMESTIC INDUSTRIES OF PROCESS PATENT AMENDMENTS ACT OF 1988

Pub. L. 100–418, title IX, § 9007, Aug. 23, 1988, 102 Stat. 1567, provided that the Secretary of Commerce was to

make annual reports to Congress covering each of the successive five 1-year periods beginning 6 months after Aug. 23, 1988, on the effect of the amendments made by subtitle A (§§ 9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending sections 154, 271, and 287 of this title, on those domestic industries that submit complaints to the Department of Commerce alleging that their legitimate sources of supply have been adversely affected by the amendments.

§ 272. Temporary presence in the United States

The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold in or used for the manufacture of anything to be sold in or exported from the United States.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 103–465, title V, § 533(b)(4), Dec. 8, 1994, 108 Stat. 4989.)

HISTORICAL AND REVISION NOTES

This section follows the requirement of the International Convention for the Protection of Industrial Property, to which the United States is a party, and also codifies the holding of the Supreme Court that use of a patented invention on board a foreign ship does not infringe a patent.

AMENDMENTS

1994—Pub. L. 103–465 substituted "not offered for sale or sold" for "not sold".

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

§ 273. Defense to infringement based on prior commercial use

(a) IN GENERAL.—A person shall be entitled to a defense under section 282(b) with respect to subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process, that would otherwise infringe a claimed invention being asserted against the person if—

(1) such person, acting in good faith, commercially used the subject matter in the United States, either in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use; and

(2) such commercial use occurred at least 1 year before the earlier of either—

(A) the effective filing date of the claimed invention; or

(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

(b) BURDEN OF PROOF.—A person asserting a defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

(c) ADDITIONAL COMMERCIAL USES.—

(1) PREMARKETING REGULATORY REVIEW.—Subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed to be commercially used for purposes of subsection (a)(1) during such regulatory review period.

(2) NONPROFIT LABORATORY USE.—A use of subject matter by a nonprofit research laboratory or other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, shall be deemed to be a commercial use for purposes of subsection (a)(1), except that a defense under this section may be asserted pursuant to this paragraph only for continued and noncommercial use by and in the laboratory or other nonprofit entity.

(d) EXHAUSTION OF RIGHTS.—Notwithstanding subsection (e)(1), the sale or other disposition of a useful end result by a person entitled to assert a defense under this section in connection with a patent with respect to that useful end result shall exhaust the patent owner's rights under the patent to the extent that such rights would have been exhausted had such sale or other disposition been made by the patent owner.

(e) LIMITATIONS AND EXCEPTIONS.—

(1) PERSONAL DEFENSE.—

(A) IN GENERAL.—A defense under this section may be asserted only by the person who performed or directed the performance of the commercial use described in subsection (a), or by an entity that controls, is controlled by, or is under common control with such person.

(B) TRANSFER OF RIGHT.—Except for any transfer to the patent owner, the right to assert a defense under this section shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

(C) RESTRICTION ON SITES.—A defense under this section, when acquired by a person as part of an assignment or transfer described in subparagraph (B), may only be asserted for uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

(2) DERIVATION.—A person may not assert a defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.

(3) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter for which it has been established

§ 282. Presumption of validity; defenses

(a) IN GENERAL.—A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

(b) DEFENSES.—The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability.

(2) Invalidity of the patent or any claim in suit on any ground specified in part II as a condition for patentability.

(3) Invalidity of the patent or any claim in suit for failure to comply with—

(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

(B) any requirement of section 251.

(4) Any other fact or act made a defense by this title.

(c) NOTICE OF ACTIONS; ACTIONS DURING EXTENSION OF PATENT TERM.—In an action involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 because of the material failure—

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 89–83, § 10, July 24, 1965, 79 Stat. 261; Pub. L. 94–131, § 10, Nov. 14, 1975, 89 Stat. 692; Pub. L. 97–164, title I, § 161(7), Apr. 2, 1982, 96 Stat. 49; Pub. L. 98–417, title II, § 203, Sept. 24, 1984, 98 Stat. 1603; Pub. L. 104–41, § 2, Nov. 1, 1995, 109 Stat. 352; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, §§ 4402(b)(1), 4732(a)(10)(A)], Nov. 29, 1999, 113 Stat. 1536, 1501A–560, 1501A–582; Pub. L. 107–273, div. C, title III, § 13206(b)(1)(B), (4), Nov. 2, 2002, 116 Stat. 1906; Pub. L. 112–29, §§ 15(a), 20(g), (j), Sept. 16, 2011, 125 Stat. 328, 334, 335.)

HISTORICAL AND REVISION NOTES

Derived from Title 35, U.S.C., 1946 ed., § 69 (R.S. 4920, amended (1) Mar. 3, 1897, ch. 391, § 2, 29 Stat. 692, (2) Aug. 5, 1939, ch. 450, § 1, 53 Stat. 1212).

The first paragraph declares the existing presumption of validity of patents.

The five defenses named in R.S. 4920 are omitted and replaced by a broader paragraph specifying defenses in general terms.

The third paragraph, relating to notice of prior patents, publications and uses, is based on part of the last paragraph of R.S. 4920 which was superseded by the Federal Rules of Civil Procedure but which is reinstated with modifications.

AMENDMENTS

2011—Pub. L. 112–29, § 20(g)(1), (2)(A), (C), (3), (j), designated first to third pars. as subsecs. (a) to (c), respectively, inserted headings, in subsec. (a), struck out third sentence which read "Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1).", in par. (2) of subsec. (b), struck out "of this title" after "II" and substituted "patentability." for "patentability,", and in introductory provisions of subsec. (c), struck out "of this title" after "156" and substituted "In an action involving the validity or infringement of a patent" for "In actions involving the validity or infringement of a patent" and "Court of Federal Claims" for "Claims Court".

Pub. L. 112–29, § 20(g)(2)(B), which directed substitution of "unenforceability." for "uneforceability," in par. (1) of former second par. which was designated subsec. (b), was executed by making the substitution for "unenforceability,", to reflect the probable intent of Congress.

Pub. L. 112–29, § 15(a), amended second par. by substituting "(3) Invalidity of the patent or any claim in suit for failure to comply with—

"(A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

"(B) any requirement of section 251."

for "(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,".

2002—Third par. Pub. L. 107–273, § 13206(b)(4), made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4402(b)(1)]. See 1999 Amendment note below.

Pub. L. 107–273, § 13206(b)(1)(B), made technical correction to directory language of Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)]. See 1999 Amendment note below.

1999—Third par. Pub. L. 106–113, § 1000(a)(9) [title IV, § 4732(a)(10)(A)], as amended by Pub. L. 107–273, § 13206(b)(1)(B), substituted "(2) by the Director," for "(2) by the Commissioner,".

Pub. L. 106–113, § 1000(a)(9) [title IV, § 4402(b)(1)], as amended by Pub. L. 107–273, § 13206(b)(4), substituted "154(b) or 156 of this title" for "156 of this title".

1995—First par. Pub. L. 104–41 inserted after second sentence "Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1)."

1984—Pub. L. 98–417 inserted provision at end that the invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure by the applicant for the extension, or by the Commissioner, to comply with the require-

ments of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded, and that a due diligence determination under section 156(d)(2) is not subject to review in such an action.

1982—Third par. Pub. L. 97–164 substituted "Claims Court" for "Court of Claims".

1975—First par. Pub. L. 94–131 made presumption of validity applicable to claim of a patent in multiple dependent form and multiple dependent claims and substituted "asserting such invalidity" for "asserting it".

1965—Pub. L. 89–83 required each claim of a patent (whether in independent or dependent form) to be presumed valid independently of the validity of other claims and required dependent claims to be presumed valid even though dependent upon an invalid claim.

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by section 15(a) of Pub. L. 112–29 effective on Sept. 16, 2011, and applicable to proceedings commenced on or after that date, see section 15(c) of Pub. L. 112–29, set out as a note under section 119 of this title.

Amendment by section 20(g), (j) of Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(9) [title IV, § 4402(b)(1)] of Pub. L. 106–113 effective on date that is 6 months after Nov. 29, 1999, and, except for design patent application filed under chapter 16 of this title, applicable to any application filed on or after such date, see section 1000(a)(9) [title IV, § 4405(a)] of Pub. L. 106–113, set out as a note under section 154 of this title.

Amendment by section 1000(a)(9) [title IV, § 4732(a)(10)(A)] of Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106–113, set out as a note under section 1 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97–164 effective Oct. 1, 1982, see section 402 of Pub. L. 97–164, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 94–131 effective Jan. 24, 1978, and applicable on and after that date to patent applications filed in the United States and to international applications, where applicable, see section 11 of Pub. L. 94–131, set out as an Effective Date note under section 351 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–83 effective 3 months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as a note under section 41 of this title.

§ 283. Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

(July 19, 1952, ch. 950, 66 Stat. 812.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 70, part (R.S. 4921, amended (1) Mar. 3, 1897, ch. 391, § 6, 29 Stat. 694, (2) Feb. 18, 1922, ch. 58, § 8, 42 Stat. 392, (3) Aug. 1, 1946, ch. 726, § 1, 60 Stat. 778).

This section is the same as the provision which opens R.S. 4921 with minor changes in language.

§ 284. Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d).

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

(July 19, 1952, ch. 950, 66 Stat. 813; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4507(9)], Nov. 29, 1999, 113 Stat. 1536, 1501A–566; Pub. L. 112–29, § 20(j), Sept. 16, 2011, 125 Stat. 335.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §§ 67 and 70, part (R.S. 4919; R.S. 4921, amended (1) Mar. 3, 1897, ch. 391, § 6, 29 Stat. 694, (2) Feb. 18, 1922, ch. 58, § 8, 42 Stat. 392, (3) Aug. 1, 1946, ch. 726, § 1, 60 Stat. 778).

This section consolidates the provisions relating to damages in R.S. 4919 and 4921, with some changes in language.

AMENDMENTS

2011—Second par. Pub. L. 112–29 struck out "of this title" after "154(d)".

1999—Second par. Pub. L. 106–113 inserted at end "Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title."

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112–29 effective upon the expiration of the 1-year period beginning on Sept. 16, 2011, and applicable to proceedings commenced on or after that effective date, see section 20(*l*) of Pub. L. 112–29, set out as a note under section 2 of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective Nov. 29, 2000, and applicable only to applications (including international applications designating the United States) filed on or after that date, see section 1000(a)(9) [title IV, § 4508] of Pub. L. 106–113, as amended, set out as a note under section 10 of this title.

§ 285. Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

(July 19, 1952, ch. 950, 66 Stat. 813.)

HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., § 70, part (R.S. 4921, amended (1) Mar. 3, 1897, ch. 391, § 6, 29 Stat. 694, (2) Feb. 18, 1922, ch. 58, § 8, 42 Stat. 392, (3) Aug. 1, 1946, ch. 726, § 1, 60 Stat. 778).

This section is substantially the same as the corresponding provision in R.S. 4921; "in exceptional cases" has been added as expressing the intention of the present statute as shown by its legislative history and as interpreted by the courts.

§ 286. Time limitation on damages

Except as otherwise provided by law, no recovery shall be had for any infringement committed

(b) NOTICE TO THE COURT OF APPEALS. The movant must promptly notify the circuit clerk under Federal Rule of Appellate Procedure 12.1 if the district court states that it would grant the motion or that the motion raises a substantial issue.

(c) REMAND. The district court may decide the motion if the court of appeals remands for that purpose.

(As added Mar. 26, 2009, eff. Dec. 1, 2009.)

Rule 63. Judge's Inability to Proceed

If a judge conducting a hearing or trial is unable to proceed, any other judge may proceed upon certifying familiarity with the record and determining that the case may be completed without prejudice to the parties. In a hearing or a nonjury trial, the successor judge must, at a party's request, recall any witness whose testimony is material and disputed and who is available to testify again without undue burden. The successor judge may also recall any other witness.

(As amended Mar. 2, 1987, eff. Aug. 1, 1987; Apr. 30, 1991, eff. Dec. 1, 1991; Apr. 30, 2007, eff. Dec. 1, 2007.)

TITLE VIII. PROVISIONAL AND FINAL REMEDIES

Rule 64. Seizing a Person or Property

(a) REMEDIES UNDER STATE LAW—IN GENERAL. At the commencement of and throughout an action, every remedy is available that, under the law of the state where the court is located, provides for seizing a person or property to secure satisfaction of the potential judgment. But a federal statute governs to the extent it applies.

(b) SPECIFIC KINDS OF REMEDIES. The remedies available under this rule include the following—however designated and regardless of whether state procedure requires an independent action:

- arrest;
- attachment;
- garnishment;
- replevin;
- sequestration; and
- other corresponding or equivalent remedies.

(As amended Apr. 30, 2007, eff. Dec. 1, 2007.)

Rule 65. Injunctions and Restraining Orders

(a) PRELIMINARY INJUNCTION.

(1) *Notice.* The court may issue a preliminary injunction only on notice to the adverse party.

(2) *Consolidating the Hearing with the Trial on the Merits.* Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing. Even when consolidation is not ordered, evidence that is received on the motion and that would be admissible at trial becomes part of the trial record and need not be repeated at trial. But the court must preserve any party's right to a jury trial.

(b) TEMPORARY RESTRAINING ORDER.

(1) *Issuing Without Notice.* The court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if:

(A) specific facts in an affidavit or a verified complaint clearly show that immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition; and

(B) the movant's attorney certifies in writing any efforts made to give notice and the reasons why it should not be required.

(2) *Contents; Expiration.* Every temporary restraining order issued without notice must state the date and hour it was issued; describe the injury and state why it is irreparable; state why the order was issued without notice; and be promptly filed in the clerk's office and entered in the record. The order expires at the time after entry—not to exceed 14 days—that the court sets, unless before that time the court, for good cause, extends it for a like period or the adverse party consents to a longer extension. The reasons for an extension must be entered in the record.

(3) *Expediting the Preliminary-Injunction Hearing.* If the order is issued without notice, the motion for a preliminary injunction must be set for hearing at the earliest possible time, taking precedence over all other matters except hearings on older matters of the same character. At the hearing, the party who obtained the order must proceed with the motion; if the party does not, the court must dissolve the order.

(4) *Motion to Dissolve.* On 2 days' notice to the party who obtained the order without notice—or on shorter notice set by the court—the adverse party may appear and move to dissolve or modify the order. The court must then hear and decide the motion as promptly as justice requires.

(c) SECURITY. The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained. The United States, its officers, and its agencies are not required to give security.

(d) CONTENTS AND SCOPE OF EVERY INJUNCTION AND RESTRAINING ORDER.

(1) *Contents.* Every order granting an injunction and every restraining order must:

(A) state the reasons why it issued;

(B) state its terms specifically; and

(C) describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required.

(2) *Persons Bound.* The order binds only the following who receive actual notice of it by personal service or otherwise:

(A) the parties;

(B) the parties' officers, agents, servants, employees, and attorneys; and

(C) other persons who are in active concert or participation with anyone described in Rule 65(d)(2)(A) or (B).

(e) OTHER LAWS NOT MODIFIED. These rules do not modify the following:

(1) any federal statute relating to temporary restraining orders or preliminary injunctions in actions affecting employer and employee;

(2) 28 U.S.C. §2361, which relates to preliminary injunctions in actions of interpleader or in the nature of interpleader; or

(3) 28 U.S.C. §2284, which relates to actions that must be heard and decided by a three-judge district court.

(f) COPYRIGHT IMPOUNDMENT. This rule applies to copyright-impoundment proceedings.

(As amended Dec. 27, 1946, eff. Mar. 19, 1948; Dec. 29, 1948, eff. Oct. 20, 1949; Feb. 28, 1966, eff. July 1, 1966; Mar. 2, 1987, eff. Aug. 1, 1987; Apr. 23, 2001, eff. Dec. 1, 2001; Apr. 30, 2007, eff. Dec. 1, 2007; Mar. 26, 2009, eff. Dec. 1, 2009.)

Rule 65.1. Proceedings Against a Surety

Whenever these rules (including the Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeiture Actions) require or allow a party to give security, and security is given through a bond or other undertaking with one or more sureties, each surety submits to the court's jurisdiction and irrevocably appoints the court clerk as its agent for receiving service of any papers that affect its liability on the bond or undertaking. The surety's liability may be enforced on motion without an independent action. The motion and any notice that the court orders may be served on the court clerk, who must promptly mail a copy of each to every surety whose address is known.

(As added Feb. 28, 1966, eff. July 1, 1966; amended Mar. 2, 1987, eff. Aug. 1, 1987; Apr. 12, 2006, eff. Dec. 1, 2006; Apr. 30, 2007, eff. Dec. 1, 2007.)

Rule 66. Receivers

These rules govern an action in which the appointment of a receiver is sought or a receiver sues or is sued. But the practice in administering an estate by a receiver or a similar court-appointed officer must accord with the historical practice in federal courts or with a local rule. An action in which a receiver has been appointed may be dismissed only by court order.

(As amended Dec. 27, 1946, eff. Mar. 19, 1948; Dec. 29, 1948, eff. Oct. 20, 1949; Apr. 30, 2007, eff. Dec. 1, 2007.)

Rule 67. Deposit into Court

(a) DEPOSITING PROPERTY. If any part of the relief sought is a money judgment or the disposition of a sum of money or some other deliverable thing, a party—on notice to every other party and by leave of court—may deposit with the court all or part of the money or thing, whether or not that party claims any of it. The depositing party must deliver to the clerk a copy of the order permitting deposit.

(b) INVESTING AND WITHDRAWING FUNDS. Money paid into court under this rule must be deposited and withdrawn in accordance with 28 U.S.C. §§2041 and 2042 and any like statute. The money must be deposited in an interest-bearing account or invested in a court-approved, interest-bearing instrument.

(As amended Dec. 29, 1948, eff. Oct. 20, 1949; Apr. 28, 1983, eff. Aug. 1, 1983; Apr. 30, 2007, eff. Dec. 1, 2007.)

*** This section is current through 2014 released chapters 1-431 ***

EDUCATION LAW
TITLE VIII. THE PROFESSIONS
ARTICLE 137. PHARMACY

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NY CLS Educ § 6816-a (2014)

§ 6816-a. When substitution is required

1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:

(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber does not prohibit substitution, or in the case of oral prescriptions, the prescriber must expressly state whether substitution is to be permitted or prohibited. Any oral prescription that does not include such an express statement shall not be filled; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser, the laws of that state shall prevail.

McKinney's Consolidated Laws of New York Annotated
Executive Law (Refs & Annos)
Chapter Eighteen. Of the Consolidated Laws
Article 5. Department of Law (Refs & Annos)

McKinney's Executive Law § 63

§ 63. General duties

Effective: March 31, 2014
Currentness

The attorney-general shall:

1. Prosecute and defend all actions and proceedings in which the state is interested, and have charge and control of all the legal business of the departments and bureaus of the state, or of any office thereof which requires the services of attorney or counsel, in order to protect the interest of the state, but this section shall not apply to any of the military department bureaus or military offices of the state. No action or proceeding affecting the property or interests of the state shall be instituted, defended or conducted by any department, bureau, board, council, officer, agency or instrumentality of the state, without a notice to the attorney-general apprising him of the said action or proceeding, the nature and purpose thereof, so that he may participate or join therein if in his opinion the interests of the state so warrant.

2. Whenever required by the governor, attend in person, or by one of his deputies, any term of the supreme court or appear before the grand jury thereof for the purpose of managing and conducting in such court or before such jury criminal actions or proceedings as shall be specified in such requirement; in which case the attorney-general or his deputy so attending shall exercise all the powers and perform all the duties in respect of such actions or proceedings, which the district attorney would otherwise be authorized or required to exercise or perform; and in any of such actions or proceedings the district attorney shall only exercise such powers and perform such duties as are required of him by the attorney-general or the deputy attorney-general so attending. In all such cases all expenses incurred by the attorney-general, including the salary or other compensation of all deputies employed, shall be a county charge.

3. Upon request of the governor, comptroller, secretary of state, commissioner of transportation, superintendent of financial services, commissioner of taxation and finance, commissioner of motor vehicles, or the state inspector general, or the head of any other department, authority, division or agency of the state, investigate the alleged commission of any indictable offense or offenses in violation of the law which the officer making the request is especially required to execute or in relation to any matters connected with such department, and to prosecute the person or persons believed to have committed the same and any crime or offense arising out of such investigation or prosecution or both, including but not limited to appearing before and presenting all such matters to a grand jury.

4. Cause all persons indicted for corrupting or attempting to corrupt any member or member-elect of the legislature, or the commissioner of general services, to be brought to trial.

5. When required by the comptroller or the superintendent of public works, [1] prepare proper drafts for contracts, obligations and other instruments for the use of the state.

6. Upon receipt thereof, pay into the treasury all moneys received by him for debts due or penalties forfeited to the people of the state.

7. He may, on behalf of the state, agree upon a case containing a statement of the facts and submit a controversy for decision to a court of record which would have jurisdiction of an action brought on the same case. He may agree that a referee, to be appointed in an action to which the state is a party, shall receive such compensation at such rate per day as the court in the order of reference may specify. He may with the approval of the governor retain counsel to recover moneys or property belonging to the state, or to the possession of which the state is entitled, upon an agreement that such counsel shall receive reasonable compensation, to be fixed by the attorney-general, out of the property recovered, and not otherwise.

8. Whenever in his judgment the public interest requires it, the attorney-general may, with the approval of the governor, and when directed by the governor, shall, inquire into matters concerning the public peace, public safety and public justice. For such purpose he may, in his discretion, and without civil service examination, appoint and employ, and at pleasure remove, such deputies, officers and other persons as he deems necessary, determine their duties and, with the approval of the governor, fix their compensation. All appointments made pursuant to this subdivision shall be immediately reported to the governor, and shall not be reported to any other state officer or department. Payments of salaries and compensation of officers and employees and of the expenses of the inquiry shall be made out of funds provided by the legislature for such purposes, which shall be deposited in a bank or trust company in the names of the governor and the attorney-general, payable only on the draft or check of the attorney-general, countersigned by the governor, and such disbursements shall be subject to no audit except by the governor and the attorney-general. The attorney-general, his deputy, or other officer, designated by him, is empowered to subpoena witnesses, compel their attendance, examine them under oath before himself or a magistrate and require that any books, records, documents or papers relevant or material to the inquiry be turned over to him for inspection, examination or audit, pursuant to the civil practice law and rules. If a person subpoenaed to attend upon such inquiry fails to obey the command of a subpoena without reasonable cause, or if a person in attendance upon such inquiry shall, without reasonable cause, refuse to be sworn or to be examined or to answer a question or to produce a book or paper, when ordered so to do by the officer conducting such inquiry, he shall be guilty of a misdemeanor. It shall be the duty of all public officers, their deputies, assistants and subordinates, clerks and employees, and all other persons, to render and furnish to the attorney-general, his deputy or other designated officer, when requested, all information and assistance in their possession and within their power. Each deputy or other officer appointed or designated to conduct such inquiry shall make a weekly report in detail to the attorney-general, in form to be approved by the governor and the attorney-general, which report shall be in duplicate, one copy of which shall be forthwith, upon its receipt by the attorney-general, transmitted by him to the governor. Any officer participating in such inquiry and any person examined as a witness upon such inquiry who shall disclose to any person other than the governor or the attorney-general the name of any witness examined or any information obtained upon such inquiry, except as directed by the governor or the attorney-general, shall be guilty of a misdemeanor.

9. Bring and prosecute or defend upon request of the industrial commissioner[2] or the state division of human rights, any civil action or proceeding, the institution or defense of which in his judgment is necessary for effective enforcement of the laws of this state against discrimination by reason of age, race, creed, color or national origin, or for enforcement of any order or determination of such commissioner or division made pursuant to such laws.

10. Prosecute every person charged with the commission of a criminal offense in violation of any of the laws of this state against discrimination because of race, creed, color, or national origin, in any case where in his judgment, because of the extent of the offense, such prosecution cannot be effectively carried on by the district attorney of the county wherein the offense or a portion thereof is alleged to have been committed, or where in his judgment the district attorney has erroneously failed or refused to

prosecute. In all such proceedings, the attorney-general may appear in person or by his deputy or assistant before any court or any grand jury and exercise all the powers and perform all the duties in respect of such actions or proceedings which the district attorney would otherwise be authorized or required to exercise or perform.

11. Prosecute and defend all actions and proceedings in connection with safeguarding and enforcing the state's remainder interest in any trust which meets the requirements of subparagraph two of paragraph (b) of subdivision two of section three hundred sixty-six of the social services law.

12. Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply, in the name of the people of the state of New York, to the supreme court of the state of New York, on notice of five days, for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, directing restitution and damages and, in an appropriate case, cancelling any certificate filed under and by virtue of the provisions of section four hundred forty of the former penal law[3] or section one hundred thirty of the general business law, and the court may award the relief applied for or so much thereof as it may deem proper. The word "fraud" or "fraudulent" as used herein shall include any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions. The term "persistent fraud" or "illegality" as used herein shall include continuance or carrying on of any fraudulent or illegal act or conduct. The term "repeated" as used herein shall include repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person. Notwithstanding any law to the contrary, all monies recovered or obtained under this subdivision by a state agency or state official or employee acting in their official capacity shall be subject to subdivision eleven of section four of the state finance law.

In connection with any such application, the attorney general is authorized to take proof and make a determination of the relevant facts and to issue subpoenas in accordance with the civil practice law and rules. Such authorization shall not abate or terminate by reason of any action or proceeding brought by the attorney general under this section.

13. Prosecute any person for perjury committed during the course of any investigation conducted by the attorney-general pursuant to statute. In all such proceedings, the attorney-general may appear in person or by his deputy or assistant before any court or any grand jury and exercise all the powers and perform all the duties necessary or required to be exercised or performed in prosecuting any such person for such offense.

15.[4] In any case where the attorney general has authority to institute a civil action or proceeding in connection with the enforcement of a law of this state, in lieu thereof he may accept an assurance of discontinuance of any act or practice in violation of such law from any person engaged or who has engaged in such act or practice. Such assurance may include a stipulation for the voluntary payment by the alleged violator of the reasonable costs and disbursements incurred by the attorney general during the course of his investigation. Evidence of a violation of such assurance shall constitute prima facie proof of violation of the applicable law in any civil action or proceeding thereafter commenced by the attorney general.

16. (a) Notwithstanding any other law to the contrary, in resolving, by agreed judgment, stipulation, decree, agreement to settle, assurance of discontinuance or otherwise, any claim or cause of action, whether filed or unfiled, actual or potential, and whether arising under common law, equity, or any provision of law, a state agency or a state official or employee acting in their official capacity shall not have the authority to include or agree to include in such resolution any term or condition that would provide the state agency, official, or employee, their agent or designee, the settling party, or any third party with control or discretion over how any moneys to be paid by the settling party would be used, spent, or allocated.

(b) Paragraph (a) of this subdivision shall not apply to any provision in the resolution of a claim or cause of action providing (1) moneys to be distributed to the federal government, to a local government, or to any holder of a bond or other debt instrument issued by the state, any public authority, or any public benefit corporation; (2) moneys to be distributed solely or exclusively as a payment of damages or restitution to individuals or entities that were specifically injured or harmed by the defendant's or settling party's conduct and that are identified in, or can be identified by the terms of, the relevant judgment, stipulation, decree, agreement to settle, assurance of discontinuance, or relevant instrument resolving the claim or cause of action; (3) moneys recovered or obtained by the attorney general where application of paragraph (a) of this subdivision is prohibited by federal law, rule, or regulation, or would result in the reduction or loss of federal funds or eligibility for federal benefits pursuant to federal law, rule, or regulation; (4) moneys recovered or obtained by or on behalf of a public authority, a public benefit corporation, the department of taxation and finance, the workers' compensation board, the New York state higher education services corporation, the tobacco settlement financing corporation, a state or local retirement system, an employee health benefit program administered by the New York state department of civil service, the Title IV-D child support fund, the lottery prize fund, the abandoned property fund, or an endowment of the state university of New York or any unit thereof or any state agency, provided that all of the moneys received or recovered are immediately transferred to the relevant public authority, public benefit corporation, department, fund, program, or endowment; (5) moneys to be refunded to an individual or entity as (i) an overpayment of a tax, fine, penalty, fee, insurance premium, loan payment, charge or surcharge; (ii) a return of seized assets; or (iii) a payment made in error; and (6) moneys to be used to prevent, abate, restore, mitigate or control any identifiable instance of prior or ongoing water, land or air pollution.

(c) Where an agreed judgment, stipulation, decree, agreement to settle, assurance of discontinuance or other legal instrument resolves (1) any claim or any cause of action asserted by a state agency or a state official or employee acting in their official capacity and (2) any claim or cause of action asserted by one or more foreign jurisdictions or third parties, paragraph (a) of this subdivision shall only apply to the resolution of the claim or cause of action asserted by the state agency, official, or employee.

Credits

(L.1951, c. 800. Amended L.1954, c. 698, § 2; L.1955, c. 586; L.1956, cc. 118, 592; L.1958, cc. 35, 84, 175; L.1959, c. 242; L.1962, c. 60, § 12; L.1962, c. 165, § 3; L.1962, c. 310, §§ 129, 130; L.1962, cc. 562, 743; L.1963, c. 589; L.1965, cc. 666, 790; L.1967, c. 680, § 33; L.1968, c. 420, § 103; L.1969, c. 359, § 1; L.1969, c. 814; L.1970, c. 44; L.1975, c. 115, § 1; L.1977, c. 451, § 5; L.1977, c. 539, § 1; L.1981, c. 476, § 1; L.1982, c. 656, § 1; L.1985, c. 86, § 1; L.1988, c. 108, § 1; L.1994, c. 170, § 455; L.2005, c. 766, § 29, eff. Jan. 13, 2006; L.2011, c. 62, pt. A, § 104, eff. Oct. 3, 2011; L.2012, c. 155, § 49, eff. July 18, 2012; L.2014, c. 55, pt. HH, §§ 3, 4, eff. March 31, 2014.)

Notes of Decisions (364)

Footnotes

1 Now commissioner of transportation. See Transportation Law § 267.

2 Now commissioner of labor. See Labor Law § 10.

3 Now General Business Law § 130.

4 So in original. There is no subd. 14.

McKinney's Executive Law § 63, NY EXEC § 63

Current through L.2014, chapters 1 to 504, 506 to 508, 510 to 523, 525 to 533, 535, 538, 540, 543.

End of Document

McKinney's Consolidated Laws of New York Annotated
Public Health Law (Refs & Annos)
Chapter 45. Of the Consolidated Laws (Refs & Annos)
Article 2. The Department of Health
Title I. Officers and Employees

McKinney's Public Health Law § 206

§ 206. Commissioner; general powers and duties

Effective: July 22, 2014
Currentness

1. The commissioner shall:

(a) take cognizance of the interests of health and life of the people of the state, and of all matters pertaining thereto and exercise the functions, powers and duties of the department prescribed by law;

(b) exercise general supervision over the work of all local boards of health and health officers, unless otherwise provided by law;

(c) exercise general supervision and control of the medical treatment of patients in the state institutions, public health centers and clinics in the department;

(d) investigate the causes of disease, epidemics, the sources of mortality, and the effect of localities, employments and other conditions, upon the public health;

(e) obtain, collect and preserve such information relating to marriage, birth, mortality, disease and health as may be useful in the discharge of his duties or may contribute to the promotion of health or the security of life in the state; establish rules and regulations for the determination of asymptomatic conditions including, but not limited to RH sensitivity, anemia, sickle cell anemia, cooley's anemia and venereal disease;

(f) enforce the public health law, the sanitary code and the provisions of the medical assistance program, or its successor, pursuant to titles eleven, eleven-A and eleven-B of the social services law, as amended by this chapter;

(g) cause to be made from time to time examinations and inspections of the sanitary conditions of each state institution and transmit copies of the reports and recommendations thereon to the head of the state department having jurisdiction over the institution examined;

(h) cause to be made from time to time, examinations and inspections of all labor camps and enforce the provisions of the sanitary code relating thereto;

(i) cause to be made, from time to time, examinations and inspections of all Indian reservations, and enforce all provisions of the sanitary code relating thereto.

(j) cause to be made such scientific studies and research which have for their purpose the reduction of morbidity and mortality and the improvement of the quality of medical care through the conduction of medical audits within the state. In conducting such studies and research, the commissioner is authorized to receive reports on forms prepared by him and the furnishing of such information to the commissioner, or his authorized representatives, shall not subject any person, hospital, sanitarium, rest home, nursing home, or other person or agency furnishing such information to any action for damages or other relief. Such information when received by the commissioner, or his authorized representatives, shall be kept confidential and shall be used solely for the purposes of medical or scientific research or the improvement of the quality of medical care through the conduction of medical audits. Such information shall not be admissible as evidence in any action of any kind in any court or before any other tribunal, board, agency, or person.

(k) notwithstanding any other provision of law, with the advice and assistance of the commissioner of agriculture and markets, establish rules and regulations to require such treatment of food or food products, including the addition or removal of specific substances, as may be necessary for the protection of the public health against the hazards of ionizing radiation.

(l) establish and operate such adult and child immunization programs as are necessary to prevent or minimize the spread of disease and to protect the public health. Such programs may include the purchase and distribution of vaccines to providers and municipalities, the operation of public immunization programs, quality assurance for immunization related activities and other immunization related activities. The commissioner may promulgate such regulations as are necessary for the implementation of this paragraph. Nothing in this paragraph shall authorize mandatory immunization of adults or children, except as provided in sections twenty-one hundred sixty-four and twenty-one hundred sixty-five of this chapter.

(m) make such rules and regulations which may be necessary to require pre-employment physical examination and thereafter require such annual examinations of all hospital employees for discovery of tuberculosis and other communicable diseases as he deems necessary for the safety and well being of the people of the state.

(n) by rule and regulation establish criteria for identification of areas and conditions involving high risk of lead poisoning, specify methods of detection of lead in dwellings, provide for the administration of prescribed tests for lead poisoning and the recording and reporting of the results thereof, and provide for professional and public education, as may be necessary for the protection of the public health against the hazards of lead poisoning.

(*o*) establish and publish a list of drug products, each of which shall meet the following conditions:

(1) The drug product has been certified or approved by the commissioner of the Federal Food and Drug Administration as being safe and effective for its labeled indications for use, and a new-drug application or an abbreviated new-drug application approved pursuant to the Federal Food, Drug, and Cosmetic Act [1] is held for such drug product; and

(2) The commissioner of the Federal Food and Drug Administration has evaluated such drug product as pharmaceutically and therapeutically equivalent and has listed such drug product on the list of approved drugs products with the therapeutic equivalence evaluations, provided, however, that the list prepared by the commissioner shall not include any drug product which

the commissioner of the Federal Food and Drug Administration has identified as having an actual or potential bioequivalence problem.

(p) promulgate rules and regulations establishing procedures to be used in implementing the provisions of article thirteen-E of this chapter as limited by section thirteen hundred ninety-nine-x of article thirteen-E of this chapter. Such rules and regulations shall include, but not be limited to, such matters as may be required to ensure that the established procedures thereunder shall at least be in compliance with the relevant provisions of the code of fair procedure set forth in section seventy-three of the civil rights law.

(q) have the authority to carry out the provisions of section one hundred seventy-seven-a of the navigation law.

(r) [Paragraph (r) as added by L.1997, c. 187. See, also, par. (r), below.] shall prepare for publication, and cause to be distributed by general hospitals to patients upon inpatient admission, a booklet containing the information and materials required to be distributed to patients pursuant to this chapter and federal law. Where reasonable and appropriate, the booklet may summarize or describe information and materials required to be distributed to the patient, and how they may be obtained. The commissioner shall prepare and distribute to general hospitals physical, electronic or other materials from which the booklet can be produced. The commissioner shall revise and update such prepared booklet on a timely basis to reflect any changes in patient information and materials required to be distributed pursuant to law.

(r) [Paragraph (r) as added by L.1997, c. 443. See, also, par. (r), above.] by rule and regulation, establish standards necessary and appropriate for the implementation of item (ii) of clause (a) of section three hundred twenty-two-c of the general business law. Such rules and regulations shall be approved by the New York state fire prevention and building code council.

(s) issue a readiness report to the legislature, detailing the status of the statewide health benefit exchange, state enrollment center, and state Medicaid enrollment center established under executive order number forty-two of two thousand twelve, by August thirtieth, two thousand thirteen. The readiness report may be provided in electronic format and shall be distributed to the temporary president of the senate, the speaker of the assembly, the chair of the senate standing committee on health, and the chair of the assembly health committee. The readiness report shall outline the progress and preparedness of the health benefit exchange, state enrollment center, and state Medicaid enrollment center and detail how the exchange, state enrollment center, and state Medicaid enrollment center will carry out their respective functions including but not limited to:

(i) the process by which the health benefit exchange, state enrollment center, and state Medicaid enrollment center will begin accepting applications on October first, two thousand thirteen;

(ii) the process by which the health benefit exchange, state enrollment center, and state Medicaid enrollment center will certify qualified health plans;

(iii) the anticipated cost of individual and small group plans being offered in the health benefit exchange;

(iv) the number of navigators approved;

(v) the plan for full operation by January first, two thousand fourteen; and

(vi) the plan to become fiscally self-sustaining by January first, two thousand fifteen.

(t) The department shall submit as part of its annual report prepared pursuant to section one hundred sixty-four of the executive law, which may be submitted in electronic format, comprehensive information including, but not limited to, a detailed description of the department's mission, priorities and goals for the upcoming year, achievements of the past year, and any relevant data and statistics.

(u) The commissioner shall provide a written or electronic copy of any state plan amendment submitted to the centers for Medicare and Medicaid services to the chair of the senate standing committee on health and the chair of the assembly health committee, no later than five business days from the date of mailing or submission.

2. The commissioner and any person authorized by him so to do, may, without fee or hindrance, enter, examine and survey all grounds, erections, vehicles, structures, apartments, buildings and places.

3. The commissioner may, on behalf and in the interest of the health of the people of the state enter into such contracts or agreements with individuals, colleges, universities, associations, corporations, municipalities and other units of government as may be deemed necessary and advisable to carry out the general intent and purposes of the public health law and the sanitary code. Such contracts may provide for payment by the state, within the limit of funds available, for materials, equipment or services.

4. The commissioner may:

(a) issue subpoenas, compel the attendance of witnesses and compel them to testify in any matter or proceeding before him, and may also require a witness to attend and give testimony in a county where he resides or has a place of business without the payment of any fees;

(b) annul or modify an order, regulation, by-law or ordinance of a local board of health concerning a matter which in his judgment affects the public health beyond the territory over which such local board of health has jurisdiction;

(c) assess any penalty prescribed for a violation of or a failure to comply with any term or provision of this chapter or of any lawful notice, order or regulation pursuant thereto, not exceeding two thousand dollars for every such violation or failure, which penalty may be assessed after a hearing or an opportunity to be heard;

(d) assess civil penalties against a public water system which provides water to the public for human consumption through pipes or other constructed conveyances, as further defined in the state sanitary code or, in the case of mass gatherings, the person who holds or promotes the mass gathering as defined in subdivision five of section two hundred twenty-five of this article not to exceed twenty-five thousand dollars per day, for each violation of or failure to comply with any term or provision of the state sanitary code as it relates to public water systems that serve a population of five thousand or more persons or any mass gatherings, which penalty may be assessed after a hearing or an opportunity to be heard.

5. Subject to the provisions of the state finance law, the commissioner is authorized to take, and administer for the state any grant, gift or bequest to be applied, principal or income or both, for the purposes specified in such grant, to the maintenance and use of any hospital, institution or service in the department.

6. The commissioner may enter into contracts:

(a) with corporations duly licensed in the state of New York to transact the business of accident and health insurance to provide to sick and disabled persons insured by them such home care, including nursing and other paramedical services (excluding physicians' services) as may be needed by them;

(b) with hospital service corporations organized and operating in accordance with article forty-three of the insurance law to provide to their subscribers nursing service and such other paramedical services as would have been available in a hospital (excluding physicians' services) at rates which shall prior to payment be approved as to reasonableness by the superintendent of financial services;

(c) with any municipal corporation or local, state or federal agency to provide such home care, including nursing and other paramedical services (excluding physicians' services) as may be needed by sick and disabled persons;

(d) with medical expense indemnity corporations organized and operating in accordance with article forty-three of the insurance law to provide their subscribers with such home care, including nursing and other paramedical services, as may be needed by them at rates which shall prior to payment be approved as to reasonableness by the superintendent of financial services; and

(e) with any non-profit corporation, agency or association established for the purpose of improvement of health services or for the purpose of providing home care for sick and disabled persons, including nursing and other paramedical services (excluding physicians' services) as may be needed by such persons.

Such services may be provided by the state health commissioner by subcontract with a city or county rendering nursing and other paramedical services or any non-profit corporation, agency or association established for the purpose of the improvement of health services or for the purpose of providing home care for sick and disabled persons including nursing and other paramedical services (excluding physicians' services).

The state health commissioner shall establish the fees to be charged for such services to be rendered pursuant to such contracts and, upon receipt of such fees, shall remit the same to the comptroller.

7. The commissioner may establish fees for nursing and other paramedical services (excluding physicians' services) rendered to people sick at home.

Such services may be provided by the state health commissioner or by subcontract with a city or county rendering nursing and other paramedical services or any non-profit corporation, agency, or association established for the purpose of the improvement of health services or for the purpose of providing home care for sick and disabled persons including nursing and other paramedical services (excluding physicians' services).

8. Whenever, in this chapter, the commissioner is empowered to or charged with the responsibility to do or perform any act, he may deputize in writing any officer or employee in the department to do or perform the act in his place and stead.

9. The commissioner may deputize in writing any local health officer to do or perform in his place and stead those duties and responsibilities charged upon the commissioner by paragraphs (d), (g), (h) and (i) of subdivision one of this section, those duties of inspection and enforcement charged upon the commissioner by paragraph f of subdivision three of section six thousand five hundred fifty-eight of the education law and those duties of inspection and supervision charged upon the department by paragraphs (m), (n), (r) and (s) of subdivision one of section two hundred one of this chapter; provided, however, in the city of New York such deputization shall be subject to the prior approval of the mayor of such city.

10. The commissioner, with the approval of the state director of the budget, shall establish and promulgate a schedule of proportional shares for cost sharing under subdivision one of section three hundred sixty-nine-d of the social services law. In developing such a schedule, the commissioner shall take into consideration various options available for obtaining health care services, the availability of such services, and the impact of cost sharing on prudent utilization and efficient provision of services without undue barriers to care for persons eligible for assistance under the catastrophic health care expense program established by section three hundred sixty-nine-c of the social services law.

11. The commissioner shall cooperate with the commissioner of the state department of environmental conservation, district attorneys and the department of law in providing assistance in the investigation and prosecutions of violations of article twenty-seven of the environmental conservation law.

12. [See L.1983, c. 83 legislation note.] (a) The commissioner shall establish and assess a regulatory assessment fee which will be charged to providers of health-care services regulated by the department under the provisions of articles twenty-eight, thirty-six and forty-four of this chapter, including health maintenance organizations established pursuant to article forty-three of the insurance law. The level of such regulatory fees shall be sufficient to recover the costs related to regulating such providers and costs related to the establishment and auditing of rates of reimbursement for the state fiscal year ending during the annual period in which such fee shall be assessed. Such costs will be certified by the director of the budget to the commissioner and shall include direct and indirect costs. The commissioner, subject to the approval of the director of the budget, shall develop a means of distributing the assessment of such a fee among the affected health-care providers based upon each provider's proportionate share of the sum of total costs and revenues reported for all such providers. For the purposes of this section, the sum of total costs and revenues shall be calculated by including, for the most recent annual period for which certified data is available, total reported costs of a facility except that amounts included for general hospital outpatient and emergency services and treatment or diagnostic center services shall be based upon reported, or in its absence, estimated revenues, and costs included for article forty-four providers, and article forty-three providers of the insurance law shall exclude costs associated with the purchase of inpatient services.

(b) The fees assessed pursuant to this subdivision shall be deemed allowable operating costs in the determination of reimbursement rates and charges established pursuant to articles twenty-eight, thirty-six and forty-four of this chapter and article forty-three of the insurance law. The costs incurred for this purpose during a given rate year shall be included in the respective reimbursement rates for each such year. Charges established pursuant to subdivisions six and thirteen of section twenty-eight hundred seven-a of this chapter shall also be permitted to increase to include the annual costs associated with the assessment of such fee. The cost of such fee shall not be subject to reimbursement ceilings or other penalties used by the commissioner for the purpose of establishing rates of reimbursement pursuant to articles twenty-eight, thirty-six and forty-four of this chapter and article forty-three of the insurance law. Whenever an adjustment in such fees is made, reimbursement rates shall also be adjusted to include the increase or decrease in costs associated with such assessment fee.

(c) There is hereby created and established in the joint custody of the comptroller and the commissioner of taxation and finance an account to be known as the health care regulatory account. Notwithstanding section one hundred twenty-one of the state finance law or any other law to the contrary, the commissioner shall pay to the state treasurer for deposit into such account any revenues received from the regulatory fee or amounts withheld pursuant to paragraph (d) of this subdivision. The commissioner shall establish by regulation a schedule of payments which to the extent practicable shall reflect the timeliness of reimbursement received by providers for the cost of such fee and define timely payments of the regulatory assessment fee for the purposes of implementing paragraph (d) of this subdivision. Payments established pursuant to this paragraph shall not be due until reimbursement rates established pursuant to articles twenty-eight, thirty-six and forty-four of this chapter and article forty-three of the insurance law are adjusted to include the annual cost of such fee. The fee may be adjusted by the commissioner at any time, but in no event shall the fees exceed the amount appropriated for transfer to the general fund from the health care regulatory account.

(d) Upon receipt of notification from the commissioner or the director of the budget, the comptroller or a fiscal intermediary designated by the director of the budget shall withhold from the amount of any payment to be made by the state to a provider enumerated in paragraph (a) of this subdivision the amount of such arrearage resulting from such provider's failure to make a timely payment of the regulatory assessment fee in accordance with the schedule promulgated by the commissioner. Upon withholding such amount, the comptroller or a designated fiscal intermediary shall pay the commissioner such amount withheld.

13. [See L.1983, c. 83 legislation note.] (a) The commissioner shall establish and assess a fee which will be charged to providers of health-care services regulated by the department under the provisions of articles twenty-eight, thirty-six and forty-four of this chapter, including health maintenance organizations established pursuant to article forty-three of the insurance law. The level of such fee shall be sufficient to recover the costs of making grants to health systems agencies and to match other contributions pursuant to subdivision (g) of section two thousand nine hundred four-b of this chapter (the health systems agency fee). The commissioner, subject to the approval of the director of the budget, shall develop a means of distributing the assessment of the fee among the affected health-care providers based upon each provider's proportionate share of the sum of total costs and revenues reported for all such providers. For the purposes of this section, the sum of total costs and revenues shall be calculated by including, for the most recent annual period for which certified data is available, total reported costs of a facility except that amounts included for general hospital outpatient and emergency services and treatment or diagnostic center services shall be based upon reported, or in its absence estimated revenues, and costs included for article forty-four providers and article forty-three providers of the insurance law, shall exclude costs associated with the purchase of inpatient services. The fee shall not exceed one-tenth of one percent of the total costs or revenues reported by such provider. There is hereby created and established in the joint custody of the comptroller and the commissioner of taxation and finance an account to be known as the health systems agency account. Notwithstanding section one hundred twenty-one of the state finance law, or any other law to the contrary, the commissioner shall pay to the state treasurer for deposit into such account any revenues received from the health systems agency fees or amounts withheld pursuant to paragraph (c) of this subdivision for health systems agency fee obligations into the health systems agency account. The monies deposited to the health systems agency account shall be used to make grants to health systems agencies pursuant to subdivision (f) of section twenty-nine hundred four-b of this chapter and to match contributions pursuant to subdivision (g) of section two thousand nine hundred four-b of this chapter. The commissioner shall establish by regulation a schedule of payments which to the extent practicable shall reflect the timeliness of reimbursement received by providers for the cost of such fee and a definition of timely payments for the purposes of implementing paragraph (c) of this subdivision. No payment shall be due until reimbursement rates established pursuant to articles twenty-eight, thirty-six and forty-four of this chapter and article forty-three of the insurance law are adjusted to include the costs of the fee. The fee may be adjusted by the commissioner at any time, but in no event shall the fees exceed the limitation set forth in this paragraph.

(b) The fees assessed pursuant to this subdivision shall be deemed allowable operating costs in the determination of reimbursement rates and charges established pursuant to articles twenty-eight, thirty-six and forty-four of this chapter and article forty-three of the insurance law. The costs incurred for this purpose during a given rate year shall be included in the respective reimbursement rates for each such year. Charges established pursuant to subdivisions six and thirteen of section twenty-eight hundred seven-a of this chapter shall also be permitted to increase to include the annual costs associated with the assessment of such fee. The cost of such fee shall not be subject to reimbursement ceilings or other penalties used by the commissioner for the purpose of establishing rates of reimbursement pursuant to articles twenty-eight, thirty-six and forty-four of this chapter and article forty-three of the insurance law. Whenever an adjustment in such fees is made, reimbursement rates shall also be adjusted to include the increase or decrease in costs associated with such fee.

(c) Upon receipt of notification from the commissioner or the director of the budget, the comptroller or a fiscal intermediary designated by the director of the budget shall withhold from the amount of any payment to be made by the state to a provider enumerated in paragraph (a) of this subdivision the amount of such arrearage resulting from such provider's failure to make a timely payment of the fee in accordance with the schedule promulgated by the commissioner. Upon withholding such amount, the comptroller or a designated fiscal intermediary shall pay the commissioner such amount withheld.

14. (a) Notwithstanding section one hundred twelve of the state finance law or any other provision of law to the contrary, the commissioner is authorized to establish a plan for the collection and disbursement of clinical practice income resulting from the clinical practice of licensed health professionals employed by Roswell Park Cancer Institute.

(b) For the purposes of this subdivision the following words shall have the following meanings:

(i) "clinical practice" means providing all forms of medical and health care, including patient consultations, and performing clinical investigation involving patients, at or through Roswell Park Cancer Institute, for which acts a fee for professional service is customarily charged.

(ii) "clinical practice income" means the income from fees for services of licensed health professionals rendered in connection with clinical practice.

(iii) "clinical practice plan" means a facility-based plan established to provide for the management, including collection and disbursement, of clinical practice income, subject to direction by a facility-based governing board.

(c) The commissioner is authorized to promulgate such rules and regulations as may be necessary to implement the provisions of this subdivision. Such rules shall include, but not be limited to, criteria for participation in the clinical practice plan, including who contributes and who may receive income from the plan, the purposes for which such income may be disbursed, the maximum allowable compensation, the fringe benefits provided by the plan, provision for an accounting system for recording all receipts and disbursements of fees received, and provision for fiscal reports to the commissioner and an annual audit of such accounts by the state and/or an independent auditor.

Notwithstanding any law, rule or regulation to the contrary, the commissioner may determine the fringe benefits to be provided to the clinical practice plan members from clinical practice income and may authorize the expenditure of clinical practice income for this purpose or to supplement fringe benefits provided from state appropriations.

(d) Any clinical practice plan established pursuant to this subdivision shall not restrict the authority of the comptroller in paragraph (c) of subdivision two of section four hundred nine of this chapter to maintain at all times on deposit in the department of health income fund established pursuant to section four hundred nine of this chapter the aggregate amount of money needed by the department during six calendar months to comply in full with all obligations of the department under the terms of every lease, sublease, or agreement of the department with the dormitory authority which is then in effect.

(e) Employees with a faculty appointment participating in a clinical practice plan at Roswell Park Cancer Institute established pursuant to subdivision fourteen of section two hundred six of this chapter who are eligible to participate in the New York state employees' retirement system may elect, within ninety days of becoming eligible to participate in such system, in lieu of participating in such system, to participate in the optional retirement program available to employees of the state university of New York pursuant to article eight-B of the education law, subject to the terms and conditions of that article and to the provisions of the retirement and social security law.

15. [As added by L.1993, c. 267. See, also, subds. 15 below.] Notwithstanding any other provision of law to the contrary, the commissioner is authorized to establish a statewide in-line skate, skate board, and bicycle helmet public education and awareness program and a statewide in-line skate, skate board, and bicycle helmet distribution program. The purpose of the statewide in-line skate, skate board, and bicycle helmet public education and awareness program is to provide a plan for the coordination of county, city, town and village efforts to reduce in-line skate, skate board, and bicycle related injuries and fatalities. The purpose of the statewide in-line skate, skate board, and bicycle helmet distribution program is to provide a plan for the coordination of county, city, town and village efforts to distribute helmets to persons who can demonstrate an economic hardship that precludes them from purchasing such helmet. The commissioner shall make all necessary efforts to ensure that an in-line skate, skate board, and bicycle helmet distribution program is instituted in each county of the state. The commissioner is authorized to promulgate such rules and regulations as may be necessary to implement the provisions of this subdivision.

15. [As added by L.1993, c. 432. See, also, subds. 15 above and below.] (a) The commissioner shall promulgate rules and regulations which establish:

(i) procedures to review and approve rape crisis programs that provide training to rape crisis counselors as defined in section four thousand five hundred ten of the civil practice law and rules;

(ii) minimum training standards for rape crisis counselors;

(iii) procedures to enable approved rape crisis programs to certify current and future rape crisis counselors, including volunteer counselors, provided such rape crisis counselors have met the minimum training standards as set forth in this subdivision; and

(iv) procedures to periodically review approved training programs to assure they continue to satisfy established standards.

(b) Rape crisis programs approved by the commissioner shall provide training programs consisting of at least thirty hours of pre-service training and within the first year of service at least ten hours of in-service training for rape crisis counselors. This training shall include but not be limited to, instruction on the following:

(i) the dynamics of sexual offenses, sexual abuses or incest;

(ii) crisis intervention techniques;

(iii) client-counselor confidentiality requirements;

(iv) communication skills and intervention techniques;

(v) an overview of the state criminal justice system;

(vi) an update and review of state laws on sexual offenses, sexual abuse or incest;

(vii) the availability of state and community resources for clients;

(viii) working with a diverse population;

(ix) an overview of child abuse and maltreatment identification and reporting responsibilities; and

(x) information on the availability of medical and legal assistance for such clients.

(c) The department shall provide technical assistance to approved rape crisis programs to implement training programs in accordance with the minimum standards set forth in this subdivision.

15. [As added by L.1993, c. 731. Expired June 30, 1996, pursuant to L.1993, c. 731, § 76(1). See, also, subds. 15, above.] The commissioner is authorized to make grants and enter into contracts, as recommended by the state task force on clinical practice guidelines and medical technology assessment established pursuant to section twenty-eight hundred four-a of this chapter, for research and/or projects to promote the identification, evaluation, development and/or application of clinical practice guidelines and appropriate use of medical technology, but in no way to direct or mandate the use of such guidelines or technology, to the extent of funds available therefor from the commissioner's priority distributions pursuant to subparagraph (ii) or paragraph (f) of subdivision nineteen of section twenty-eight hundred seven-c of this chapter. No grants or contracts executed pursuant to this section shall be for the purpose of developing clinical practice guideline based reimbursement methodologies or any other regulations. For the purposes of this subdivision, "clinical practice guidelines" shall mean systematically developed statements to assist physician and patient decisions about the appropriate health care for specific clinical circumstances, and "medical technology" shall mean an instrument or unit of equipment or technique for use as a health related treatment, testing or diagnostic tool.

16. The commissioner, in consultation with the commissioner of the department of motor vehicles, shall promulgate rules and regulations specifying the medical conditions based on health and safety which justify granting an exception to the requirements of subparagraphs one and two of paragraph (b) of subdivision twelve-a of section three hundred seventy-five of the vehicle and traffic law.

17. [As added by L. 1998, c. 2. See, also, subd. 17 below.] (a) The commissioner shall enter into an agreement with the commissioner of taxation and finance which shall set forth the procedures for the crediting of overpayments of tax owed to an individual taxpayer, estate or trust to the repayment of overpayments of medical assistance payments owed to the department or a social services district by such person pursuant to the provisions of section one hundred seventy-one-f of the tax law and is authorized to furnish to the commissioner of taxation and finance such information and to take such other actions as may be necessary to carry out the agreement provided for in such section, for the crediting of overpayments of tax to repayment of overpayments of medical assistance payments received by an individual who is or has been enrolled as a provider in the New York state medical assistance program as established under title eleven of article five of the social services law.

(b) The department shall by regulation establish procedures by which any individual, estate or trust which is the subject of a certification to the department of taxation and finance in accordance with such agreement may contest such certification. Such regulations and the notice required by subdivision three of section one hundred seventy-one-f of the tax law shall set forth defenses which may be available to the individual, estate or trust to contest such certification and the manner in which a review of the certification based on such defenses may be obtained.

(c) In accordance with such agreement and the provisions of section one hundred seventy-one-f of the tax law, the department shall be entitled to receive payments to satisfy the payment obligation of a person who is receiving or has received payment as a provider in the New York state medical assistance program established under title eleven of article five of the social services law, in accordance with a written final determination of the department, provided that a proceeding for administrative or judicial review shall not be pending and the time for initiation of such proceedings shall be expired.

17. [As added by L.1998, c. 533. See, also, subd. 17 above.] The department, upon completion of a review of the existing scientific research regarding allergic reactions to natural rubber latex products, shall issue guidelines, in consultation with health care providers, for a latex management program, in health care settings.

18. [As added by L.1999, c. 395. See, also, subd. 18, below.] The commissioner is authorized and directed to promulgate rules and regulations to establish standards for water wells, including but not limited to drilling, construction, abandonment, repair, maintenance, water flow, including testing thereof, and pump standards for such wells.

18. [As added by L.1999, c. 595. See, also, subd. 18, above.] The commissioner, subject to the approval of the director of the budget, is authorized to approve and implement medicaid demonstration programs designed to provide additional knowledge and experience and to collect information concerning alternative methodologies for reimbursement, delivery of medical services, or eligibility for medical assistance in hospice operated nursing homes and is further authorized to waive such provisions of article twenty-eight of this chapter and title eleven of article five of the social services law as are necessary to implement such demonstration programs when such waiver will promote the efficient delivery of appropriate, quality, cost-effective services and when the health, safety and general welfare of patients will not be impaired as a result of such waiver.

18-a. (a) Health information technology demonstration program. (i) The commissioner is authorized to issue grant funding to one or more organizations broadly representative of physicians licensed in this state, from funds made available for the purpose of funding research and demonstration projects under subparagraph (ii) of this paragraph designed to promote the development of electronic health information exchange technologies in order to facilitate the adoption of interoperable health records.

(ii) Project funding shall be disbursed to projects pursuant to a request for proposals based on criteria relating to promoting the efficient and effective delivery of quality physician services. Demonstration projects eligible for funding under this paragraph shall include, but not be limited to:

(A) efforts to incentivize electronic health record adoption;

(B) interconnection of physicians through regional collaborations;

(C) efforts to promote personalized health care and consumer choice;

(D) efforts to enhance health care outcomes and health status generally through interoperable public health surveillance systems and streamlined quality monitoring.

(iii) The department shall issue a report to the governor, the temporary president of the senate and the speaker of the assembly within one year following the issuance of the grants. Such report shall contain, at a minimum, the following information: the demonstration projects implemented pursuant to this paragraph, their date of implementation, their costs and the appropriateness of a broader application of the health information technology program to increase the quality and efficiency of health care across the state.

(b) [Eff. until March 31, 2015, pursuant to L.2011, c. 59, pt. H, § 111, subd. o. See, also, par. (b), below.] The commissioner shall:

(i) convene a workgroup to:

(A) evaluate the state's health information technology infrastructure and systems, as well as other related plans and projects designed to make improvements or modifications to such infrastructure and systems including, but not limited to, the all payor database (APD), the state planning and research cooperative system (SPARCS), regional health information organizations (RHIOs), the statewide health information network of New York (SHIN-NY) and medical assistance eligibility systems; and

(B) develop recommendations for the state to move toward a comprehensive health claims and clinical database aimed at improving quality of care, efficiency, cost of care and patient satisfaction available in a self-sustainable, non-duplicative, interactive and interoperable manner that ensures safeguards for privacy, confidentiality and security;

(ii) submit a report to the governor and the temporary president of the senate and the speaker of the assembly, which shall fully consider the evaluation and recommendations of the workgroup, on or before December first, two thousand fourteen.

(b) [Eff. March 31, 2015, pursuant to L.2011, c. 59, pt. H, § 111, subd. o. See, also, par. (b), above.] The commissioner shall make such rules and regulations as may be necessary to implement federal policies and disburse funds as required by the American Recovery and Reinvestment Act of 2009[2] and to promote the development of a statewide health information network of New York (SHIN-NY) to enable widespread interoperability among disparate health information systems, including electronic health records, personal health records and public health information systems, while protecting privacy and security.

Such rules and regulations shall include, but not be limited to, requirements for organizations covered by 42 U.S.C. 17938 or any other organizations that exchange health information through the SHIN-NY.

(c) The members of the workgroup shall include, at a minimum, three members who represent RHIOs, two members employed by the department who are involved in the development of the SHIN-NY and the APD, two members who represent physicians, two members who represent hospitals, two members who represent home care agencies, one member who represents federally qualified health centers, the chair of the senate health committee or his or her designee, the chair of the assembly health committee or his or her designee, and other individuals with expertise in matters relevant to the charge of the workgroup.

(d) The commissioner may make such rules and regulations as may be necessary to implement federal policies and disburse funds as required by the American Recovery and Reinvestment Act of 2009 and to promote the development of a self-sufficient SHIN-NY to enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records, personal health records, health care claims, payment and other administrative data, and public health information systems, while protecting privacy and security. Such rules and regulations shall include, but not be limited to, requirements for organizations covered by 42 U.S.C. 17938 or any other organizations that exchange health information through the SHIN-NY or any other statewide health information system recommended by the workgroup. The commissioner shall consider the recommendations of the workgroup. If the commissioner acts in a manner inconsistent with the recommendations of the workgroup, he or she shall provide the reasons therefor.

19. [As added by L.2001, c. 562. See, also subd. 19 below.] The commissioner is authorized and directed to promulgate rules and regulations as may be necessary, with respect to the form and content of applications for licenses, the fees to be charged for obtaining licenses, permits, duplicates and renewals, the reception thereof, the investigation and examination of applicants and of prospective applicants taking examinations and their qualifications, the inquiry into the operation of body piercing or tattooing studios and the conducting of periodic inspection of facilities to determine compliance by the tattoo or body piercing studio with applicable statutes, rules and regulations, appropriate penalties for failure to abide by rules and regulations promulgated pursuant to this article, and additional visits that may be made to tattoo or body piercing studios to determine whether violations or deficiencies have been corrected, to investigate any complaint, and for any other purposes deemed necessary and appropriate by the commissioner. Such regulations shall include, but not be limited to, the hygienic requirements for sterilization of sharps, needles, and other supplies and equipment, the general cleanliness of the body piercing studio or tattoo studio, the disposal of each sharp and other single use supplies after use on one customer, the proper disposal of contaminated supplies and equipment, and other matters incidental or appropriate to the powers and duties of the commissioner as prescribed by this subdivision and for the proper administration and enforcement of the provisions of this subdivision to ensure the health, safety and welfare of the public.

19. [As added by L.2003, c. 62. See, also, subd. 19 above.] (a) The commissioner shall ensure that any contracts entered into, renewed, extended, modified or in any way made or continued with entities pursuant to article twenty-eight of this chapter to receive, distribute and otherwise administer funds for the pools specified in this subdivision, require such pool administrators to submit directly to the temporary president of the senate and the speaker of the assembly quarterly reports on the collection, pooling and distribution of funds pursuant to the following sections of this chapter:

(i) paragraph (a) of subdivision eighteen of section twenty-eight hundred seven-c of this chapter, providing for a one percent assessment on hospital revenues;

(ii) section twenty-eight hundred seven-j, establishing allowances on net patient service revenues;

(iii) section twenty-eight hundred seven-k, establishing the general hospital indigent care pool;

(iv) section twenty-eight hundred seven-l, establishing the health care initiatives pool;

(v) section twenty-eight hundred seven-m, establishing regional professional education pools;

(vi) section twenty-eight hundred seven-s, establishing professional education pool funding;

(vii) section twenty-eight hundred seven-t, establishing assessments on covered lives; and

(viii) section twenty-eight hundred seven-v, establishing tobacco control and insurance initiatives pool.

The commissioner shall assist such pool administrators, as necessary, in the fulfillment of this requirement.

(b) Reports filed pursuant to paragraph (a) of this subdivision shall, at a minimum, for each quarterly period

(i) profile, as of the end of each quarter and based on the available data, all revenue collected pursuant to each source specified in subparagraphs (i), (ii), (vi) and (vii) of paragraph (a) of this subdivision, as well as revenue collected for deposit into the pools specified in subparagraph (viii) of such paragraph, further reported, as applicable, according to each category of payer, including, but not limited to, medical assistance, private insurance, employer benefit plans, workers' compensation, no-fault, cigarette taxes, tobacco settlement funds, and the public asset established pursuant to sections four thousand three hundred one and seven thousand three hundred seventeen of the insurance law;

(ii) profile, as of the end of each quarter and based on the available data, aggregate revenue, by source, deposited for the quarter, into each pool specified in subparagraphs (iii), (iv), (v), and (viii) of paragraph (a) of this subdivision as well as the fund balances for each such pool as of the end of each quarter; and

(iii) profile, as of the end of each quarter and based on the available data, every disbursement from each pool specified in subparagraphs (iii), (iv), (v) and (viii) of paragraph (a) of this subdivision, further reported, as applicable, according to and indicative of each allocation specified for such pool, and further reported according to and indicative of each recipient of funds from each such allocation, except allocations made pursuant to subparagraph (iii) of paragraph (c) of subdivision one of section twenty-eight hundred seven-l of this chapter, and further indicative of the status of funding for each such recipient.

(c) The reports required by paragraph (a) of this subdivision shall cover the periods January through March, April through June, July through September and October through December and shall be submitted no later than forty-five days following the last day of the quarterly period covered by the report. Reports shall be submitted in both written and electronic form.

(d) The commissioner shall also ensure that any such contracts require such entities, beginning August first, two thousand three and no later than the twelfth day of each month thereafter, to report to the comptroller in an electronic and written format the beginning pool balances, receipts collected by source, the disbursements made by purpose, the amount and nature of any transfers made among such pools, and the ending pool balances for the pools described in subparagraphs (i), (ii) and (iii) of

paragraph (b) of this subdivision and at the same level of specificity required by such paragraph. The comptroller shall include such information in the monthly report required by subdivision nine-a of section eight of the state finance law. Any additional expenses incurred by the entity as a result of this paragraph shall be borne by the department of health.

20. The commissioner shall, in consultation with the superintendent of state police, promulgate, by regulation, a list of "select chemical agents" which shall consist only of those toxic chemicals which have been identified, as of the effective date of this subdivision, for the application of verification measures under article VI of the convention on the prohibition of the development, production, stockpiling and use of chemical weapons and on their destruction, opened for signature on January thirteenth, nineteen hundred ninety-three, in schedules contained in the annex to said convention. The commissioner may, from time to time, promulgate regulations amending said list in the event that the schedules contained in the annex to the convention are amended, revised, modified or repealed, so that the list of select chemical agents promulgated pursuant to this subdivision conforms in whole or in part to any such amended, revised, modified or repealed list, if the commissioner determines that any such amendment, revision, modification or repeal is consistent with the purposes of this chapter.

21. [As added by L.2004, c. 1, pt. A. See, also, subd. 21, below.] The commissioner shall, in consultation with the superintendent of state police, promulgate, by regulation, a list of "select biological agents" which shall consist only of those select biological agents which have been identified, as of the effective date of this subdivision, by the United States Secretary of Health and Human Services and placed on the select agent list established pursuant to section 511 (d) of the Anti-terrorism and Effective Death Penalty Act, Pub. L. 104-132 at 42 C.F.R. Part 72. The commissioner may, from time to time, promulgate regulations amending said list in the event that the list of select biological agents promulgated by federal regulations is amended, revised, modified or repealed, so that the list of select biological agents promulgated pursuant to this subdivision conforms in whole or in part to any such amended, revised, modified or repealed list, if the commissioner determines that any such amendment, revision, modification or repeal is consistent with the purposes of this chapter.

21. [As added by L.2004, c. 58, pt. B. See, also, subd. 21, above.] The commissioner shall make the information developed pursuant to section five hundred forty-four of the executive law available through, but not limited to, the department's website and written materials available to the public.

22. The commissioner shall provide information and technical assistance concerning the drug discount program authorized by section 340B of the federal public health service act (42 U.S.C § 256b) to:

(a) covered entities, as defined in section 340B of the public health service act, to facilitate their participation in such drug discount program; and

(b) local government officials, regarding the benefits of the drug discount program and the process of accessing discounted drugs under the program on behalf of individuals whose prescription drug costs are borne by local government, including but not limited to residents of county-operated nursing homes.

23. Pursuant to subdivision six of section two hundred two of the state administrative procedure act, on an emergency basis and upon a finding by the commissioner of an immediate threat to the public safety, the commissioner is authorized to remove a drug, procedure or supply whose primary purpose is to enhance or facilitate sexual performance from: (a) the definition of medical assistance established pursuant to section three hundred sixty-five-a of the social services law, (b) the definition of health care services covered by the family health plus program established pursuant to section three hundred sixty-nine-ee of the social services law, (c) the definition of covered health services established pursuant to subdivision seven of section twenty-

five hundred ten of this chapter, or (d) the list of prescription drugs covered by the program for elderly pharmaceutical insurance coverage (EPIC) established pursuant to title three of article two of the elder law, or to otherwise restrict the criteria for payment for such drug, procedure or supply, by the medicaid, family health plus, child health plus, or EPIC programs, for those persons required to register as sex offenders pursuant to article six-C of the correction law.

24. [As added by L.2008, c. 58. See, also, subd. 24 below.] Notwithstanding any inconsistent provision of law to the contrary, the commissioner is authorized to receive applications and to determine initial and continuing eligibility for enrollment under the child health plus program established under title I-A of article twenty-five of this chapter, the medical assistance program established under title eleven of article five of the social services law, and the family health plus program established under title eleven-D of such article. The commissioner may exercise such authority with respect to all residents, or a subset of residents, of one or more local social services districts. The commissioner is authorized to enter into one or more contracts, which contracts shall be procured on a competitive basis pursuant to a request for proposal process, for the purpose of exercising his or her authority under this subdivision. State employees shall supervise and provide oversight and quality assurance monitoring of contract staff activities. Provided further, the department shall endeavor to use state employees in exercising the commissioner's authority under this subdivision.

24. [As added by L.2008, c. 174. See, also, subd. 24 above.] The commissioner shall have the authority to correct errors on marriage certificates maintained by the department pursuant to paragraph (e) of subdivision one of this section upon request of any applicant whose name appears thereon for a certificate of marriage where:

(a) such error was not the result of any intended fraud, deception or attempt to avoid the effect of any valid law, regulation or statute; and

(b) either party to the marriage provides proof, satisfactory to the commissioner, of the accuracy of the facts presented in support of correcting the error.

To effectuate such correction and provide certified copies of the amended certificate, the commissioner shall be entitled to a fee not exceeding ten dollars. The commissioner shall forward a copy of such amended certificate to the clerk of the town or city which issued such certificate.

25. (a) [Eff. until March 31, 2016, pursuant to L. 2008, c. 563, § 8.] In assessing and reporting on the impact of section sixty-eight hundred one of the education law, pursuant to subdivision four of such section the commissioner may use: (1) influenza vaccine supply data from the federal centers for disease control and prevention; (2) pneumococcal vaccine supply data provided by manufacturers and distributors of such vaccine; and (3) data from a third party entity that engages in the collection of data and tracking of pharmaceutical sales and distribution. Manufacturers and distributors of pneumococcal vaccine shall provide or arrange for the timely provision to the commissioner of such data as the commissioner may reasonably request to complete the report. Provider and customer identifiable information submitted pursuant to this paragraph shall be confidential, unless the information provider consents to its release or the commissioner determines disclosure is necessary to respond to an imminent public health emergency.

(b) Notwithstanding the provisions of paragraph (a) of this subdivision, the commissioner may require reporting by entities licensed pursuant to article twenty-eight or thirty-six of this chapter, pharmacies registered pursuant to article one hundred thirty-seven of the education law, manufacturers and distributors of adult immunizing agents doing business in this state, and others possessing such adult immunizing agents of additional information needed to respond to an imminent public health emergency.

26. The commissioner is hereby authorized and directed to review any policy or practice instituted in facilities operated by the department of corrections and community supervision, and in all local correctional facilities, as defined in subdivision sixteen of section two of the correction law, regarding human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), and hepatitis C (HCV) including the prevention of the transmission of HIV and HCV and the treatment of AIDS, HIV and HCV among inmates. Such review shall be performed annually and shall focus on whether such HIV, AIDS or HCV policy or practice is consistent with current, generally accepted medical standards and procedures used to prevent the transmission of HIV and HCV and to treat AIDS, HIV and HCV among the general public. In performing such reviews, in order to determine the quality and adequacy of care and treatment provided, department personnel are authorized to enter correctional facilities and inspect policy and procedure manuals and medical protocols, interview health services providers and inmate-patients, review medical grievances, and inspect a representative sample of medical records of inmates known to be infected with HIV or HCV or have AIDS. Prior to initiating a review of a correctional system, the commissioner shall inform the public, including patients, their families and patient advocates, of the scheduled review and invite them to provide the commissioner with relevant information. Upon the completion of such review, the department shall, in writing, approve such policy or practice as instituted in facilities operated by the department of corrections and community supervision, and in any local correctional facility, or, based on specific, written recommendations, direct the department of corrections and community supervision, or the authority responsible for the provision of medical care to inmates in local correctional facilities to prepare and implement a corrective plan to address deficiencies in areas where such policy or practice fails to conform to current, generally accepted medical standards and procedures. The commissioner shall monitor the implementation of such corrective plans and shall conduct such further reviews as the commissioner deems necessary to ensure that identified deficiencies in HIV, AIDS and HCV policies and practices are corrected. All written reports pertaining to reviews provided for in this subdivision shall be maintained, under such conditions as the commissioner shall prescribe, as public information available for public inspection.

27. The commissioner shall promulgate regulations to require that a manufacturer or other entity selling, leasing, or otherwise providing any drug, device, or health care service shall not, directly or indirectly, establish as a condition for the use by a dentist of such drug, device, or health care service that the dentist meet any quota for the number of patients on whom the dentist uses the drug, device, or health care service and that a dentist shall not, directly or indirectly, request or receive from any manufacturer or other entity a drug, device, or health care service having a condition that the dentist meet any quota for the number of patients on whom the dentist uses the drug, device, or health care service.

28. The commissioner shall assist the commissioner of education in developing rules and regulations, relating to pupils who suffer mild traumatic brain injuries, in accordance with subdivision forty-two of section three hundred five of the education law, and provide for the posting on the department's internet website of such information as shall be required pursuant to such subdivision.

Credits

(L.1953, c. 879. Amended L.1957, c. 193; L.1961, c. 317; L.1962, c. 879, § 1; L.1963, c. 326; L.1964, c. 193; L.1965, c. 988; L.1966, c. 966; L.1967, c. 274, § 1; L.1967, c. 275, § 1; L.1968, c. 323; L.1968, c. 967, § 2; L.1969, c. 95; L.1970, c. 388, § 2; L.1971, c. 626, § 4; L.1971, c. 1144; L.1972, c. 189, § 1; L.1972, c. 918, § 1; L.1973, c. 1007, § 1; L.1976, c. 571, § 11; L.1977, c. 776, § 1; L.1978, c. 716, § 1; L.1978, c. 717, § 1; L.1978, c. 783, § 1; L.1981, c. 719, § 15; L.1983, c. 83, §§ 1, 2; L.1983, c. 822, § 3; L.1983, c. 823, § 1; L.1984, c. 805, §§ 51, 52; L.1986, c. 913, § 5; L.1988, c. 703, § 10; L.1989, c. 244, § 2; L.1989, c. 712, § 6; L.1990, c. 190, § 269; L.1992, c. 293, § 2; L.1993, c. 267, § 2; L.1993, c. 362, § 1; L.1993, c. 432, § 4; L.1993, c. 703, § 3; L.1993, c. 731, § 62; L.1994, c. 135, § 1; L.1994, c. 255, § 52; L.1995, c. 694, § 3; L.1996, c. 16, § 4; L.1996, c. 474, § 239; L.1997, c. 187, § 1, eff. July 8, 1997; L.1997, c. 443, § 2, eff. Aug. 20, 1997; L.1998, c. 2, § 32, eff. Sept. 24, 1998; L.1998, c. 553, § 1, eff. Feb. 1, 1999; L.1999, c. 395, § 3, eff. Jan. 1, 2000; L.1999, c. 595, § 1, eff. Nov. 1, 1999; L.2001, c. 562, § 2; L.2003, c. 62, pt. A3, § 38, eff. May 15, 2003; L.2004, c. 1, pt. A, § 12, eff. July 23, 2004; L.2004, c. 58, pt. B, § 24, eff. Aug. 20, 2004; L.2004, c. 58, pt. C, § 5, eff. Aug. 20, 2004, deemed eff. April 1, 2004; L.2004, c. 207, §

6, eff. July 20, 2004; L.2004, c. 703, § 5, eff. Jan. 1, 2005; L.2005, c. 58, pt. B, § 74, eff. April 12, 2005; L.2005, c. 645, § 7, eff. Aug. 30, 2005; L.2007, c. 602, § 1, eff. Aug. 15, 2007; L.2008, c. 58, pt. C, § 39, eff. Oct. 1, 2008; L.2008, c. 174, § 2, eff. July 7, 2008; L.2008, c. 563, § 6, eff. Dec. 3, 2008; L.2008, c. 638, § 2, eff. Sept. 25, 2008; L.2009, c. 58, pt. C, § 69, eff. April 7, 2009, deemed eff. April 1, 2009; L.2009, c. 419, § 1, eff. Sept. 16, 2009; L.2009, c. 419, § 2, eff. Sept. 16, 2011; L.2010, c. 58, pt. A, § 11, eff. July 2, 2010, deemed eff. April 1, 2010; L.2010, c. 77, § 3, eff. May 12, 2010; L.2010, c. 504, § 1, eff. Sept. 17, 2010; L.2011, c. 59, pt. H, § 38-a, eff. March 31, 2011, deemed eff. April 1, 2011; L.2011, c. 62, pt. A, § 104, eff. Oct. 3, 2011; L.2011, c. 62, pt. C, subpt. B, § 127-s, eff. March 31, 2011; L.2011, c. 62, pt. C, subpt. B, § 127-t, eff. Sept. 16, 2011; L.2011, c. 496, § 3, eff. July 1, 2012; L.2013, c. 56, pt. D, § 33-a, eff. March 28, 2013, deemed eff. Jan. 1, 2013; L.2013, c. 56, pt. E, § 112, eff. Jan. 1, 2014; L.2014, c. 60, pt. A, § 16, eff. March 31, 2014, deemed eff. April 1, 2014; L.2014, c. 60, pt. C, § 34-a, eff. March 31, 2014, deemed eff. April 1, 2014; L.2014, c. 132, § 1, eff. July 22, 2014.)

Notes of Decisions (16)

Footnotes

1 21 USCA § 301 et seq.

2 Pub.L. 111-5, Feb. 17, 2009, 123 Stat. 115.

McKinney's Public Health Law § 206, NY PUB HEALTH § 206

Current through L.2014, chapters 1 to 479.

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