UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff, v. ABBVIE INC. et al., Defendants.	CIVIL ACTION Case No. 14-cv-5151 **PUBLIC VERSION**

DEFENDANTS' POST-TRIAL BRIEF

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INTRODUCTION

FTC seeks to brand Defendants as monopolists, and to extract a billion-dollar penalty, because Defendants filed suits involving complex patent-law questions and obtained settlements that provided most of the relief Defendants sought. For multiple independent reasons, judgment should be entered for Defendants.

First, FTC has not carried its burden to show subjective baselessness. The evidence does not show that Defendants sued Teva or Perrigo with an improper "subjective motivation"; it shows that Defendants believed in the merits of their suits and not only sought but obtained favorable outcomes through settlement. Under those circumstances, the Court should not conclude that Defendants' intent was to use the litigation process, as opposed to the outcome of the process, as an anticompetitive weapon. FTC's claim thus fails at the threshold.

Second, FTC has not carried its burden to show that Defendants possessed and willfully maintained monopoly power—*i.e.*, the ability to control prices and exclude competition—in the relevant market. Monopoly power can be proven by "direct" or "indirect" evidence; Third Circuit precedent establishes that FTC here has proven neither. There is no evidence of an abnormally high price-cost margin or that Defendants restricted their output—each an essential element of a direct evidence showing. With respect to indirect evidence, the only market definition asserted by FTC's economic expert is based on a legal test that is inconsistent with the law of this Circuit and is unsupported by the kind of evidence that the court of appeals has said is required. While FTC has alluded to an alternative market of just topical testosterone gels, it has provided no economic analysis supporting that alternative (or any other). Nor would the evidence support the existence of a topicals-only market, or show that Defendants had monopoly power within any such unsupported market. Moreover, although Defendants bear no burden to establish a relevant market, the evidence at trial dictates the conclusion that a properly defined

market includes all FDA-approved testosterone replacement therapies, which are all reasonably interchangeable and competed with each other on price. In that market, Defendants indisputably lacked power; indeed, the use of injectables surged through the entirety of the relevant period, causing injectables to dominate other testosterone therapies, including AndroGel. FTC's failure to establish monopoly power is a separate basis for judgment in Defendants' favor.

Finally, FTC has not carried its burden to show that it is entitled to disgorgement, let alone in the extraordinary amount that FTC requests. As a matter of law, disgorgement is not available. But even if it were, FTC has failed to prove that but for the filing of the Teva and Perrigo litigation any of the extremely speculative assumptions underpinning its disgorgement request is even reasonable, let alone would have come to pass.[1]

ARGUMENT

I. The Court Should Enter Judgment for Defendants on *Noerr-Pennington* Grounds

Because the First Amendment protects the right to petition the courts, "[a] plaintiff claiming that a lawsuit is, by its very existence, anticompetitive and unlawful faces an uphill battle." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 147 (3d Cir. 2017). Here, FTC's claim must be rejected unless FTC carries the burden of showing that the suits in question were "a mere sham" because they were both subjectively and objectively baseless. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51, 60-61 (1993) (*PRE*) (citation omitted). The evidence is not sufficient to establish the "subjective component[]." *Id.* at 61. In addition, Defendants are separately requesting that the Court reconsider objective baselessness in light of new authority and rule that a litigant could have had "a reasonable belief that there [wa]s

[1] Pursuant to the Court's direction, this brief does not address FTC's request for a traditional injunction or any procedural issues relating to disgorgement. Defendants understand that those issues will be briefed further as necessary. In addition, as the Court requested, this brief attempts to avoid duplication by cross-referencing arguments in prior briefs. Defendants also respectfully preserve legal arguments made at earlier stages, as well as evidentiary objections asserted at trial.

a chance that [the patent] claims" might have been "held valid." *Id.* at 62-63 (internal citations, quotation marks, and alterations omitted); *see Wellbutrin*, 868 F.3d at 148. Either ruling would independently dictate judgment for Defendants.

A. FTC Has Not Carried Its Burden of Proving Subjective Motivation (Findings of Fact ("FF") 19-187, Conclusions of Law 1-16)

The "subjective component[]" of the *PRE* test requires a court to "examine the litigant's subjective motivation" to decide whether a lawsuit conceals "an attempt to interfere *directly* with the business relationships of a competitor . . . through the use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60-61 (internal quotation marks omitted). Only litigation undertaken in "bad faith" can meet this standard. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368-69 (Fed. Cir. 1998) (en banc). An infringement suit that a patentee believes has some chance of success is not brought in bad faith because it is "genuinely aimed at procuring favorable government action." *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991) (citation omitted); *see* Dkt. 324 at 1-2, 17-19, 49-56; Dkt. 331 at 1-5. FTC has the burden to establish bad faith by clear and convincing evidence. *See In re Wellbutrin XL Antitrust Litig.*, 2012 WL 1657734, at *4-5 (E.D. Pa. May 11, 2012) (weight of authority suggests that standard), *aff'd on other grounds*, 868 F.3d 132 (3d Cir. 2017); *see also* Dkt. 324 at 49-51.[2]

Under the correct standards, as well as under the lesser standards for which FTC argues, FTC has failed to present evidence sufficient to carry its burden on subjective baselessness.[3]

[2] Those standards are justified by the need to avoid chilling protected First Amendment activity and, in a patent case, by the "presumption that the assertion of a duly granted patent is made in good faith." *C.R. Bard*, 157 F.3d at 1368-69.

[3] At trial, FTC proffered circumstantial rather than direct evidence. Defendants have not raised an advice-of-counsel defense; rather, they have maintained attorney-client and work product privilege. There is nothing inappropriate about Defendants' doing so in a case in which subjective intent is directly at issue. *See Rhone-Poulenc Rorer Inc. v. Home Indem. Co.*, 32 F.3d

1. Under the Correct Standards, FTC Has Not Carried Its Burden

FTC has not shown that Defendants had the subjective motivation that *PRE* requires for a finding of sham litigation—let alone made such a showing by clear and convincing evidence.[4]

a. *Favorable outcome through settlement.* The evidence at trial shows that Defendants obtained favorable outcomes, by settlement, in the Teva and Perrigo cases. In settlement negotiations in each case, Abbott's Perry Siatis initially offered an entry date of January 1, 2015, and held firm when Teva countered with dates of September 2013, December 1, 2014, and December 15, 2014, ultimately agreeing to an extremely favorable entry date of December 27, 2014. That is approximately 15½ months after the expiration of the longest possible Hatch-Waxman stay, more than 2½ years after the scheduled trial in the Teva case (in which a Teva victory would have ended the stay), and only 8 months before the entry of generic AndroGel under prior agreements with Watson and Par. FF 81-91; Siatis Demonstrative 1. Similarly, Abbott rebuffed Perrigo's proposals for a March 2014 entry date and limited-volume entry. The Perrigo entry date ultimately agreed on, December 27, 2014, was 9 months after the end of the longest possible Hatch-Waxman stay and over 2½ years after the scheduled trial in the Teva case. FF 95-104; Siatis Demonstrative 2.

In light of those favorable outcomes, the Court should not conclude that Defendants had the subjective motivation to use the litigation process, as opposed to the outcome of that process, in an anticompetitive manner. *PRE*, 508 U.S. at 60-61; *see In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1357-58 & n.13 (S.D. Fla. 2004). The up-to-30 month

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851, 863-64 (3d Cir. 1994). And "it is improper to draw an inference of bad faith from the assertion of the attorney-client privilege." *Freedom Card, Inc. v. JPMorgan Chase & Co.*, 432 F.3d 463, 479-80 n.25 (3d Cir. 2005); *see* FF n.1.

[4] Several Defendants were not plaintiffs in the suits against Teva and Perrigo. References to "Defendants' suits" (or the like) are for convenience and do not waive the argument that no Defendant is liable for the acts of a separate corporate entity. *See* Dkt. 324 at 4-7; FF 1-18.

stay automatically triggered by the filing of the suits against Teva and Perrigo would have expired long before December 2014—particularly if it were true that the suits were legally weak. FTC has no plausible—let alone compelling—explanation for why Defendants would have insisted on such a late date if they believed the infringement suits lacked merit or if they otherwise were motivated only to use the litigation process to obtain the maximum possible Hatch-Waxman stay.

FTC has suggested (without evidentiary support) that Defendants might have been bluffing, as in poker. But that analogy fails. There can be no bluff when all of the cards are on the table, and that was the case here: Teva and Perrigo had full access to the information necessary to decide whether the infringement suits had merit. After all, the applicability of prosecution history estoppel was to be determined based on the public record of the patent prosecution history, not based upon information to which Defendants had sole access. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727, 736 (2002). The settlement negotiations must therefore be considered an indicator of Defendants' belief about the merits of the suits.[5] *See* Dkt. 250 at 36-37; *see also, e.g.*, Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, Antitrust, Summer 2003, at 70, 75 ("as anyone who negotiates licenses will tell you, . . . licensing negotiations reflect the underlying strength of the patent").

b. ***Abbott planning processes.*** Abbott's motivation to obtain favorable outcomes from filing the patent suits is also reflected in the official annual and long-range plans that Abbott worked on and finalized while the suits were pending. The company relied on those plans to guide its business. FF 106-108, 111-113. When a loss of exclusivity was expected as to a certain product, that expectation was noted in the plans, as demonstrated in those documents with

[5] FTC did not present any evidence that the AndroGel settlement agreement with Teva was linked to the separate agreements that were concurrently negotiated, and the evidence shows that no such linkage existed. *See* 2/26 Tr. 135:2-140:1 (Siatis).

respect to products not at issue in this case. *See* 2/20 Tr. 91:13-24 (Hynd); DX66-0004; FF 108-110, 114, 116, 120, 123. Had an early 2012 loss of the Teva litigation been expected, that would have been reflected in the plans—but it was not. FF 109-110, 115, 119, 122, 126-127. And had the expectation been that Defendants' suits would result in no more than a temporary stay of FDA approval of Teva's and Perrigo's products, that also would have been reflected in the plans—but it was not. *See id*.

In addition, after Teva filed its "early" summary judgment motion but before the litigation settlements, Abbott substantially increased its marketing budget for AndroGel for 2012 (by 23%) and projected a comparably large increase in 2012 sales (a 25.1% increase), both actions that are inconsistent with a belief that the suits against Teva and Perrigo were meritless or that Teva's generic product would be on the market in 2012. FF 122, 124. FTC has mistakenly fixated on a $20 million cut to the tentative 2012 marketing budget, ignoring that even with that cut the budget still *increased* by over $37 million compared to 2011. FF 150. Had Abbott actually expected that Teva would win the patent suit and enter the market with a generic product in 2012, Abbott would have reduced the 2012 AndroGel marketing budget by over $100 million. *See* 2/21 Tr. 168:12-26, 169:19-22 (Wortsmann); FF 154.

FTC has suggested that the Court should infer that Abbott did not believe it could win the suits because of an AndroGel scenario exercise conducted from August to October 2011 that looked at what might happen if a generic 1% product entered the market on various dates. In fact, the scenario exercise shows just the opposite, because it demonstrates that the company did not change the expectation in its 2012 Annual Plan for when generic entry would occur, despite having specifically evaluated the *possibility* of earlier generic entry—and having presented that evaluation to its most senior executives during the 2012 annual planning process. FF 126-147. In finalizing its long-range plan and 2012 Annual Plan in Fall 2011, the company continued to

project revenues and expenses based on an expectation that generic entry would not occur until 2015. FF 126-128, 147. The evidence also shows that the company runs scenario exercises "for every litigation," as well as for other business uncertainties. It is a prudent business practice when risk exists, as Abbott has never denied was true here. FF 110, 127, 129-134; 2/26 Tr. 117:9-11 (Siatis); *see, e.g.*, 2/14 Tr. 155:18-25 (Kay); 2/22 Tr. 127:20-129:25 (Stewart); 2/20 Tr. 110:22-111:7 (Hynd).

FTC has also argued that Abbott attempted to accelerate the transition of patients from AndroGel 1% to AndroGel 1.62% because of developments in the Teva litigation in Summer 2011. FTC initially argued that the acceleration plan began as a panicked reaction to Teva's filing its early summary judgment motion on August 1, 2011. FTC shifted positions after Abbott pointed to a June 27, 2011 email identifying the need for an acceleration plan and evidence that substantial work was done on the acceleration plan in July 2011. FF 159; DX296. FTC then speculated that the email was a response to Teva's submission to the Court on June 26, 2011 of a non-docketed letter discussing the possibility of an early summary judgment motion. But the email says nothing of the sort and there is no evidence that news of the scheduling issue was immediately (or ever) transmitted to the business team. FF 159. More generally, the evidence shows that since Fall 2010—months before Teva served its paragraph IV certification and half a year before Defendants filed suit against Teva—a rapid uptake of 1.62% was the centerpiece of Abbott's plan for introducing the product in light of the early 2011 launch of two competing "low volume" 2% gels, Axiron and Fortesta. FF 156-157. Once 1.62% did launch in late May 2011, Abbott closely tracked the weekly prescription data, and saw almost immediately that it was disappointing. FF 158. That is what spurred the 1.62% acceleration planning. FF 159-163. The evidence also shows that discussions of 1.62% acceleration predated the June 27, 2011 email. *See* 2/20 Tr. 132:5-133:2 (Hynd); 2/23 Tr. 15:22-18:15 (Gautsch); FF 158-159.

While additional tactics were identified in August 2011, many of those never got past initial discussions; this and other evidence shows that there was not the sort of hysteria that FTC posits resulted from the August 1, 2011 summary judgment filing. *See, e.g.*, 2/20 Tr. 151:22-160:19 (Hynd); 2/23 Tr. 27:1-43:12 (Gautsch); PLX145; DX103.

c. *FTC theories ungrounded in evidence*. FTC has also argued that some inference of bad faith should be drawn—apparently with respect to both the Perrigo litigation filed on October 31, 2011 and the Teva litigation filed on April 29, 2011—from the July 2009 decision of Solvay not to sue Perrigo based on an ANDA that was subsequently withdrawn. That 2009 decision is not relevant to Defendants' subjective intent in bringing the 2011 litigation.

Even assuming that the situation in 2011 in all respects mirrored the situation in July 2009, the 2011 Abbott decision-makers were not bound by the conclusion of the 2009 Solvay decision-makers. In addition, the trial evidence established that the 2011 Abbott decision-makers could not know that Perrigo's 2011 NDA product was the same product that Solvay assessed in Perrigo's 2009 ANDA. FF 19-36, 42-45. The trial evidence confirmed that the Abbott legal department had no involvement in Solvay's election not to sue Perrigo and did not have access to the confidential contents of Perrigo's 2009 ANDA. 2/26 Tr. 110:24-112:9; *see id.* at 112:14-25, 113:15-114:1 (Siatis) (Abbott in-house counsel who evaluated Perrigo's 2011 paragraph IV notice, who were sole actors at Abbott "responsible for determining whether to bring a patent litigation case," were not former Solvay employees, and no former Solvay lawyers were employed in Abbott's legal department at the time); FF 35, 44, 75.[6] Indeed, Perrigo's in-

[6] In addition, knowledge in Solvay's possession in 2009 may not be imputed to Abbott, which later became Solvay's parent—and even if it could, that would not be sufficient to show bad faith. *See* Dkt. 331 at 6-9. The parent/subsidiary relationship does not give rise, without more, to a principal/agent relationship permitting such imputation. *See, e.g.*, *Transamerica Leasing, Inc. v. La Republica de Venezuela*, 200 F.3d 843, 849 (D.C. Cir. 2000). Even as to a principal and agent, no imputation is appropriate for information—like that in the 2009 ANDA—under

house counsel Mr. Solomon testified that Perrigo's 2011 NDA formulation did differ from the formulation disclosed in Perrigo's 2009 ANDA. 2/12 Tr. 162:3-6. While Mr. Solomon retrospectively characterized the differences as minor, the 2011 NDA did not identify the specific differences or allow the 2011 Abbott decision-makers to make a comparison. 2/14 Tr. 92:12-16, 93:17-94:6.

Finally, at trial FTC used generalized phrasing on a privilege log to speculate that Defendants created a bad-faith plan to sue Perrigo, regardless of the merits, more than a year before receiving and evaluating Perrigo's paragraph IV notice and NDA in 2011 (or even knowing that Perrigo would be filing an NDA). FTC's speculation was rejected by Perry Siatis, who testified that Abbott did not evaluate—let alone determine—whether to bring either 2011 suit before receiving the associated paragraph IV notice. *See* 2/26 Tr. 243:18-24; FF 50-51.[7]

d. ***No bad faith.*** In light of the evidence described above, FTC has not established that Defendants had the bad-faith "subjective motivation" that *PRE* requires for a finding of sham litigation. That conclusion is cemented by looking to the specific factors that *PRE* mentioned as relevant to the subjective motivation inquiry: "whether [the plaintiff] was indifferent to the outcome on the merits of the . . . suit, whether any damages for infringement would be too low to justify [the plaintiff's] investment in the suit, or whether [the plaintiff] had decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process." *PRE*, 508 U.S. at 65. FTC did not present any evidence in this case that Defendants were indifferent to

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confidentiality restrictions. *See* Restatement (Third) of Agency § 5.03(b) & cmt. e ("[W]hen an agent is subject to a duty . . . not to disclose a fact . . . , the agent's knowledge is not imputed.").

[7] The citizen petitions that Abbott filed in 2010 and 2011 cannot be considered part of some overarching bad-faith plan; they were meritorious requests to FDA to apply certain agency regulations and procedures to testosterone products. FF 173-183. Given that FDA granted both petitions in part, and specifically recognized that the 2011 citizen petition "raise[d] significant, complex, and evolving scientific and legal issues," DX21-0008, nothing about those petitions can possibly raise any inference of bad faith.

the outcome on the merits—and the successful resolution of the suits through settlement, by which Defendants obtained greater relief than they could possibly have gotten through application of the up-to-30-month stay, demonstrates that they were not. Nor did FTC present any evidence that the relief Defendants could have obtained if they were successful in their suits—injunctions barring the Teva and Perrigo products for the duration of the patent term—did not justify the cost of the suits. Indeed, FTC presented affirmative evidence that this relief, which would prevent generic entry for a period after the expiration of any maximum stay, was worth hundreds of millions of dollars or more. *See, e.g.*, DX5-010 (2011 LRP projecting AndroGel sales of approximately $1 billion in 2014). Finally, the evidence does not support the conclusion that Defendants decided to sue "primarily for the benefit of collateral injuries inflicted through the use of legal process"—that is, to obtain the temporary stay of FDA approval of Teva's and Perrigo's NDAs. *PRE*, 508 U.S. at 65. Here, the evidence establishes that Defendants' motivation was to obtain *greater* relief than the Hatch-Waxman stay—and that they in fact did so via settlement.

e. *Recent judicial decision reinforces conclusion of no subjective intent to file baseless litigation*. FTC has suggested that a finding of subjective bad faith can be reached directly from the Court's pretrial finding of lack of objective merit in the patent suits. But the objective and subjective prongs of *PRE* are separate elements that must be independently proven. On top of that, the recent district court decision in *Eli Lilly & Co. v. Dr. Reddy's Laboratories, Ltd.*, 2017 WL 6387316 (S.D. Ind. Dec. 14, 2017), illustrates that a finding of subjective bad faith should not flow from the Court's pretrial finding.[8] As set forth in the concurrent motion for

[8] Defendants discussed this case with the Court at the post-trial conference, and also requested during trial that the Court take judicial notice of it. *See* 3/1 Tr. 93:19-21. Also, in *In re Lantus Direct Purchaser Antitrust Litig.*, 2018 WL 355372 (D. Mass. Jan. 10, 2018), a case that post-dates the pre-trial ruling, the court dismissed a sham litigation monopolization claim for lack of

reconsideration, the facts of the prosecution history in *Eli Lilly* are strikingly similar to the facts of the '894 patent prosecution history—and *Eli Lilly* expressly found that the presumption of prosecution history estoppel had been rebutted (not just that there was a reasonable argument that the presumption had been rebutted). If an Article III judge can reach the conclusion that an argument so analogous to Defendants' argument was meritorious, it certainly cannot be the case that this Court's pretrial ruling—even if, contrary to Defendants' separate motion, it were not worthy of reconsideration—shows that Abbott brought its suits in subjective bad faith.

2. Under FTC's Mistaken Position on What the Subjective Prong of *PRE* Requires, FTC Still Cannot Prevail

Even were the Court to disregard *PRE*'s repeated references to "subjective intent" or "subjective motivation" and conclude that *PRE*'s subjective prong does not require bad faith, and even were the Court to apply a preponderance standard, the Court should find for Defendants.

As a threshold matter, it is not clear what FTC interprets *PRE*'s subjective prong to mean in the context of a patent suit that, if successful, would by definition block a competing drug. It is true that *PRE* refers to a defendant's "economic motivation," 508 U.S. at 61, 65-66, but in the context of intellectual property litigation with the very purpose of excluding an allegedly infringing product, that cannot mean that the subjective prong is asking whether the defendant was actually motivated by the economic benefits of exclusion. *Id.* at 60-61; *see id.* at 69 (Stevens, J., concurring in the judgment) (even in a "doubtful case," "[a]ccess to the courts is far too precious a right for us to infer wrongdoing from nothing more than using the judicial process to seek a competitive advantage"). That would reduce the subjective prong to a tautology. Instead, the prong must be calling for an inquiry into whether the defendant was primarily motivated by the collateral consequences of instituting litigation—inflicting litigation cost on the

objective baselessness in part because "[t]he fact of . . . settlement helps defeat a finding that the litigation was objectively baseless." *Id.* at *13.

counterparty or obtaining benefits of the litigation process—rather than by the prospect of obtaining a favorable outcome. Here, the only possible conclusion, and certainly the better conclusion, is that the suits against Teva and Perrigo were "sincerely and honestly felt and experienced" by Defendants as a means of obtaining substantive relief, *id.* at 61 (majority opinion)—even if, by statute, those suits also automatically triggered stays under Hatch-Waxman.

To the extent that FTC is arguing that the subjective prong of *PRE* is satisfied any time that there is an adverse finding on the objective prong, FTC is simply wrong. *PRE* sets forth separate objective and subjective components. *See id.* at 60-61. And a defendant's recognition that it could benefit from the Hatch-Waxman stay cannot alone be enough to satisfy the subjective prong. *See Wellbutrin*, 868 F.3d at 157-58 ("We are not inclined to penalize a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman.' Doing so would punish behavior that Congress sought to encourage." (citation omitted)).

II. Judgment Should Be Entered for Defendants on the Ground that FTC Has Not Established that Defendants Possessed Monopoly Power (FF 188-348, Conclusions of Law 25-37)

FTC cannot prevail unless it carries its burden to establish the elements of a monopolization claim. *See Wellbutrin*, 868 F.3d at 149. That requires proof of Defendants' "possession of monopoly power in the relevant market" and the willful maintenance of that power. *Mylan Pharm. Inc. v. Warner Chilcott plc*, 838 F.3d 421, 433-34 (3d Cir. 2016).[9] Monopoly power is "the ability to control prices and exclude competition in a given market." *Id.* Simply having a patent does not mean that the patentee has monopoly power. *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 45-46 (2006) ("a patent does not necessarily

[9] In light of the nature of this element of FTC's claim, the appropriate period for which to evaluate monopoly power is the period in which the Court finds that a generic actually would have entered the market but for any predatory conduct that the Court finds. Dkt. 324 at 57.

confer market power upon the patentee" and does not obviate requirement of "proving that [patentee] possess[es] power within" relevant market); *see also* 2/28 Tr. 56:10-58:7 (Crémieux).

The Third Circuit explained in *Mylan* that monopoly power can be proven in two ways: through "direct evidence" or "indirect evidence." *Id.* at 434-35.[10] FTC has proven neither. During the period when FTC says Defendants caused anticompetitive harm, Defendants did not have the ability to control prices and exclude competition. Rather, they operated in a highly competitive atmosphere—one in which products competed fiercely for patients on price and other bases, new and improved products were entering the market with substantial resources behind them, and Defendants' share of prescriptions continuously declined. FTC's failure to carry its burden on monopoly power independently warrants judgment in Defendants' favor.

A. FTC Has Failed to Prove Monopoly Power Through Direct Evidence

The Third Circuit has emphasized that direct evidence of monopoly power is "rarely available." *Mylan*, 838 F.3d at 434. A plaintiff must prove that a defendant set supracompetitive prices, which generally includes proof "both that the defendant had an 'abnormally high price-cost margin' and that the defendant 'restricted output.'" *Id.*

FTC has presented no direct evidence of monopoly power. Its only claim to have done so was the testimony of its expert Dr. Shapiro, who expressed the view that *any* brand pharmaceutical manufacturer has monopoly power before a generic enters the market, regardless of any other facts, because once a generic enters its price will be lower than the brand price and the brand will lose market share. *See* 2/15 Tr. 68:20-71:1; 2/16 Tr. 91:1-19, 123:18-25; FF 286. Under binding precedent, that testimony is plainly insufficient.

First, Dr. Shapiro expressly acknowledged that he did not conduct any analysis of

[10] *See also, e.g.*, *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 201-02 (3d Cir. 1992); *Weiss v. York Hosp.*, 745 F.2d 786, 827 & n.72 (3d Cir. 1984); Dkt. 250 at 12-19; Dkt. 324 at 19-26; Dkt. 383 at 1-6..

Defendants' "price-cost margin" and that Defendants did not restrict their output. 2/16 Tr. 102:7-103:6, 103:14-24; *see id.* at 101:21-102:6 (stating his view that inquiring whether "a price [was] above competitive levels" is "not helpful"); FF 274-275. The Third Circuit definitively ruled in *Mylan* that an expert opinion devoid of any such analysis is not proof of monopoly power by direct evidence. *See Mylan*, 838 F.3d at 435 ("Mylan's expert reports are devoid of any substantiated quantitative analysis showing that Defendants maintained high price-cost margins or that Defendants markedly restricted output. . . . Accordingly, Mylan has failed to provide direct evidence of monopoly power."); *id.* at 434 n.53 ("Mylan contends that we should look to its proffered expert testimony to conclude that Defendants exercised monopoly power even in the absence of clear evidence of supracompetitive prices or restricted output. We disagree.").[11]

Second, the law is clear that in the pharmaceutical context the fact that a generic's price will be lower than a brand's price does not establish that the brand has monopoly power. If the rule were otherwise, a brand manufacturer would always have monopoly power prior to generic entry—but in *Mylan* the Third Circuit reached the opposite conclusion. *See Mylan*, 838 F.3d at 434-35; *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 682 (D.N.J. 2005) (plaintiffs cannot "merely rely on the fact that later generic manufacturers could enter the market more cheaply than [the brand's] price in order to establish monopoly power").[12] As Dr. Crémieux testified, higher brand pharmaceutical prices say nothing about monopoly power; they merely reflect the fact that brand manufacturers must invest huge sums in research, development,

[11] *See also, e.g.*, *URL Pharma, Inc. v. Reckitt Benckiser, Inc.*, 2015 WL 5042911, at *5 (E.D. Pa. Aug. 25, 2015); *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 681 n.10 (D.N.J. 2005).

[12] *See also, e.g.*, *Kaiser Found. v. Abbott Labs.*, 2009 WL 3877513, at *9 (C.D. Cal. Oct. 8, 2009) (same); *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 500 (2d Cir. 2004).

and marketing, whereas generic manufacturers make no such investment and rely on state-mandated automatic substitution to generate sales. *See* 2/28 Tr. 54:16-56:7; FF 276; *see also Remeron*, 367 F. Supp. 2d at 682 & n.13.

B. FTC Has Failed to Prove Monopoly Power Through Indirect Evidence

Proof of monopoly power through indirect evidence requires properly defining the relevant market by assessing "the reasonable interchangeability of use between a product and its substitute" and whether "a price change for one product affects the price of the other." *Mylan*, 838 F.3d at 435. It also requires proof that there were barriers to entry or expansion into that market. *See id.*; *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1441 (9th Cir. 1995) (barriers to expansion of current competitors as well as barriers to entry of new competitors necessary to exercise monopoly power). FTC has the burden of proof on all of those requirements, *see, e.g.*, *Tunis Bros. v. Ford Motor Co.*, 952 F.2d 715, 724 (3d Cir. 1991), but has not carried its burden as to any of them.

1. FTC's Only Proposed Market Definition Is Inconsistent with the Law and the Evidence

FTC has purported to present evidence of only one proposed relevant market: a market limited to AndroGel 1%, its AB-rated (generic) equivalents, B-rated products that use AndroGel 1% as the reference drug, and AndroGel 1.62%. *See* 2/15 Tr. 34:6-12; 2/16 Tr. 152:13-18, 142:22-143:7. FTC supports its proposed market not with any analysis of other testosterone replacement therapies, but instead solely based on Dr. Shapiro's adaptation of the so-called "Hypothetical Monopolist Test" (HMT), which is supposed to look to the smallest group of products for which a hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price. FF 281, 291-292. As Defendants have previously explained in extensive briefing, the HMT is not the test in this Circuit for defining the relevant market in a non-merger pharmaceutical case. *See* Dkt. 250 at 12-19; Dkt. 272 at 6-9 & n.2; Dkt. 324 at 24-

26; Dkt. 383. In that context, the Third Circuit has definitively *rejected* the premise that market definition can be based on anything other than rigorous econometric analysis of drug products that are reasonably interchangeable with each other. *See Mylan*, 838 F.3d at 435-38. Accordingly, the circumscribed market definition that FTC has proposed should not be accepted, and FTC has failed to show monopoly power.

Mylan involved a claim that manufacturers of a brand acne drug violated the antitrust laws by excluding generic competition. The plaintiff argued that the market should be defined through use of the HMT, application of which led to a market that consisted of *only* the brand acne drug manufactured by the defendants and that drug's generic equivalents. *See* Appellant Reply Br. at 28-29, *Mylan*, 2016 WL 539005 (stating that "market definition is properly focused on the smallest relevant market satisfying the hypothetical monopolist test" and arguing that the "market in this case" consists of the brand drug "and its generic equivalents").[13] Indeed, as the evidence at trial in the current case showed, that highly limited market definition would be the result under the HMT in *every single pharmaceutical case*, because of state automatic substitution laws. *See* 2/15 Tr. 92:12-16; 2/16 Tr. 88:7-90:8; *see also* 2/28 Tr. 125:9-18; 144:4-23.[14]

The Third Circuit disagreed. Observing that "the pharmaceutical market functions in a

[13] *See also, e.g.*, Appellant Opening Br. at 24, *Mylan*, 2015 WL 5665735 (claiming that argument that the HMT was inapplicable was "departure[] from standard economics"); No. 12-cv-3824 Dkt. 553 at 33-34 (E.D. Pa.) (arguing brand drug "satisfies the Hypothetical Monopolist Test" because company controlling brand production "could impose a small but significant nontransitory" price increase).

[14] Before Dr. Shapiro testified, FTC asserted to the Court that the "initial fact pattern in *Mylan* . . . would not satisfy the HMT" because "the generic entered—at least initially—at a higher (not lower) price than branded Doryx." Dkt. 378 at 4. But FTC presented no testimony from Dr. Shapiro or other evidence supporting this assertion and Defendants showed it to be wrong in their responsive bench brief. Dkt. 383 at 4 ("This was not a situation in which there was at any time—even for a single day—an AB-rated generic drug that was priced higher than an equivalent brand drug.").

unique way," 838 F.3d at 428, the court rejected the contention that the market consisted of only the brand and its generic equivalent, and instead concluded that "the market was much broader and consisted of all oral tetracyclines prescribed to treat acne." *Id.* at 436. The court arrived at that definition by adopting and applying a legal test very different from the HMT—one that looks to (1) "reasonable interchangeability of use between a product and its substitute" and (2) whether "a price change for one product affects the price of the other." *Id.* at 435-36.

FTC filed an amicus brief supporting a petition for rehearing *en banc* in *Mylan*. FTC described what the court of appeals said about how to define a market as a "misstatement[] of law." FTC Amicus Br. at 2-3. FTC said that the court's ruling on market definition was "contrary to" using the HMT to "define[] the relevant market." *Id.* at 9. And FTC asked the court to rehear the case to make clear that "market definition can be shown not only through evidence of interchangeability and cross-price elasticity of products" but also through the HMT. *Id.* The Third Circuit declined to rehear the case. 15-2236 Order (3d Cir. Nov. 30, 2016).

The Third Circuit's ruling in *Mylan* is binding. It is also correct.[15] The HMT improperly disregards real competition among pharmaceutical products that patients, doctors, and other health-care actors consider reasonably interchangeable and that affect each other's prices. FF 287-288. The HMT also, as Dr. Shapiro admitted, often disregards real competition in situations involving high gross margins, of which pharmaceuticals are an example. FF 284.

At trial, Dr. Shapiro admitted that the HMT excludes pharmaceutical products from the scope of the market even though they are reasonably interchangeable and compete on price. *See* 2/16 Tr. 114:24-115:24; FF 287. He also agreed that, in circumstances like those presented here,

[15] FTC's assertion that the HMT has been applied in other pertinent cases in the Third Circuit is wrong. Those cases all pre-date *Mylan*, do not arise in a non-merger pharmaceutical context, and are otherwise distinguishable. *See* Dkt. 383; *see also* 2/28 Tr. 89:3-5 (Crémieux testimony that in economics the HMT is not commonly used outside the merger context).

courts have rejected use of the HMT on the ground that it would define the market too narrowly. *See* 2/16 Tr. 116:22-120:5 (discussing Dr. Shapiro's article reporting on such cases).

Dr. Shapiro nevertheless clung to the HMT and failed to present the kind of analysis that the Third Circuit said in *Mylan* was the correct way to define a market in a case like this one. *See* 838 F.3d at 435.[16] Most notably, Dr. Shapiro did not look at whether AndroGel competed on price with other testosterone replacement therapies. FF 293-295, 297. After Defendants pointed this out, Dr. Shapiro repeatedly used the term "cross-elasticity" in his testimony, but his only purported analysis of cross-elasticity is a simplistic chart of the numbers of prescriptions over a limited time period of injectables and generic topical products (and not any of the many other testosterone products on the market during the relevant time). That chart does not account for key events other than generic entry (such as negative medical studies and resulting lawyers' product liability advertisements that disproportionately impacted gels) that affected prescription levels. *See* PLX425; 2/28 Tr. 106:16-123:10 (Crémieux); FF 298-302; p. 24, *infra*.

In sum, Dr. Shapiro's market definition opinion is unsupported by the types of analyses that *Mylan* requires. It is also based on a methodology that the Third Circuit rejected in *Mylan* and that cannot be squared with *Mylan*'s holding that the market in that case was not limited to the brand drug and its generic alternatives. Accordingly, FTC has failed at the threshold in attempting to prove monopoly power by indirect evidence. FF 303.

[16] Dr. Shapiro did not even correctly perform an HMT analysis. He had no coherent explanation for why he included AndroGel 1.62% in his market definition, even though the HMT would have been satisfied by a market of just AndroGel 1% and its AB-rated generic equivalent and the HMT should not go beyond the narrowest group of products for which the test will be satisfied. *See* 2/15 Tr. 95:12-96:3; 2/16 Tr. 149:8-150:14; *see also* 2/28 Tr. 101:17-103:2 (Crémieux); FF 292. The only apparent (and illegitimate) reason for that deviation is that FTC seeks relief with respect to AndroGel 1.62% under theories premised on AndroGel 1.62%'s inclusion in the relevant market.

2. FTC Has Not Carried Its Burden with Respect to Any Alleged Topicals-Only Market

FTC suggested before trial, as a last-ditch strategy, that the Court could alternatively define the market as topical (or "transdermal") testosterone products—that is, those that are applied to the skin. The evidence does not come close to supporting such a market definition. And even were the market defined that way, FTC has not carried its burden to show that Defendants had monopoly power in such a market.

a. *Insufficient evidence on market definition*. Definition of a market requires economic analysis. But FTC's economic expert *specifically disclaimed* the opinion that the market here should be defined to include only topical products. 2/16 Tr. 152:13-18 (Shapiro testimony, referring to PLX445, that "[i]t is not my opinion that this group of [topical] products is the relevant market that the Court should use in this case"). FF 304. Not surprisingly, then, he did not provide any economic analysis supporting such a market definition. FF 304. For example, he provided no econometric analysis that would distinguish price elasticity among topicals from price elasticity among a broader group of testosterone replacement therapies that includes injectables. 2/16 Tr. 152:19-22 ("I have not done such econometric analysis"); 2/28 Tr. 87:1-8 (Crémieux testimony that Shapiro did not do such analysis); *see Mylan*, 838 F.3d at 434; *FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1037 (D.C. Cir. 2008) ("[i]t is incumbent on the parties to shape a case").

Abbott and AbbVie documents typically discuss competition among all testosterone replacement therapies. It is true that there are some documents, or entries in documents, that look specifically at topical products, but the existence of such documents is far from sufficient to limit the relevant market to "topicals" alone. As Dr. Crémieux explained, "you would expect your marketing people and your finance people" not only "to focus on the entire market" but also

"to focus on subsets of the market." 2/28 Tr. 48:1-6; *see* 3/1 Tr. 15:13-23 (Crémieux) (same).[17] The documents that focus on topicals do not purport to contain the economic analysis that would be required under *Mylan* to support a market definition that excluded injectables.

b. ***Insufficient evidence on monopoly power*****.** Even if the evidence supported a topicals-only market definition, there would be insufficient evidence of monopoly power in such a market. All FTC presented at trial in this regard was AndroGel's share of topical prescriptions. While a high market share is generally necessary for a finding of monopoly power, it is not sufficient. There must also be barriers to entry (for new competitors) or expansion (for current competitors). *See Fineman*, 980 F.2d at 201-02; *Weiss*, 745 F.2d at 827 & n.72; *Mylan*, 838 F.3d at 434; *see also* 2/28 Tr. 85:18-86:9 (other pertinent factors). Here, there was no evidence of either.

First, FTC has not demonstrated that there were barriers to entry of other topical testosterone products, and the evidence shows that there were not. Since early 2011, four new topical testosterone products have launched: Axiron (in April 2011), Fortesta (in late February 2011), AndroGel 1.62% (in May 2011), and Vogelxo (in 2014), resulting in numerous FDA-approved topical testosterone therapies. FF 247, 251, 257, 259; *see also* FF 262, 264 (Aveed, a long-lasting injection, and Natesto, a nasal product, also launched during this period or shortly therafter). Entry of these competitors demonstrates the absence of meaningful barriers and, more broadly, the absence of monopoly power. *See Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 113-14 (3d Cir. 1992) (insufficient evidence of market power where "six new products received FDA approval").

Second, FTC has not presented evidence showing barriers to expansion of existing

[17] In particular, while the quarterly summaries on which FTC focused at trial discuss only topical products, those documents simply provide truthful information about a market subset in which the company was performing well. See 3/1 Tr. 29:3-30:9.

competitors. "If rivals . . . can quickly respond to any predator's attempt to raise prices above competitive levels, the predator will suffer an immediate loss of market share to competitors. In that instance, the predator does not have market power." *Rebel Oil*, 51 F.3d at 1441. There was substantial evidence at trial of intense competition among topicals that would not have made sense if the topicals were supply-constrained.[18] In an effort to convince insurers to make the products available to customers, topicals competed fiercely on rebates and formulary placement. Abbott and AbbVie gave insurers hundreds of millions of dollars in rebates—that is, price discounts— representing [redacted] of total AndroGel sales, but AndroGel nevertheless lost formulary placement to topical competitors, thereby also losing very significant revenue. *See* FF 309-312. AndroGel also competed with other topicals on the patient copay, which was affected not just by rebates designed to ensure better formulary tier placement but also by copay assistance programs. FF 313. In addition, AndroGel competed with other topicals with respect to tens and even hundreds of millions of dollars in marketing and promotion that would not have made sense if there were supply constraints rather than intense competition for additional prescriptions. FF 316. That intense competition for market share is the antithesis of supply-constrained market participants who are not in a position to make enough product to take share from others if those others raise prices above competitive levels. *See Mylan*, 838 F.3d at 434; *Weiss*, 745 F.2d at 827 & n.72; *Rebel Oil*, 51 F.3d at 1441; 2/28 Tr. 66:20-68:20, 85:11-87:8

3. The Evidence Shows that a Properly-Defined Market Encompasses Injectables and that Defendants Did Not Have Monopoly Power

Having failed to prove a relevant market, FTC has by definition failed to establish monopoly power through indirect evidence. Defendants have no burden to establish the bounds of a relevant market, and the Court need not identify one either. Still, the evidence presented at

[18] There was also competition between AndroGel and non-topical products such as injectables. *See* pp. 22-25, *infra*.

trial proves that the relevant market in which AndroGel 1% competed includes injectable testosterone products (as well as all other FDA-approved testosterone products).[19] The evidence also shows that AndroGel's share of that market was never more than about 50% and was falling consistently and precipitously before, during, and after the relevant period. It is therefore clear that Defendants did not possess monopoly power in a properly defined market.

a. ***Definition of relevant market.*** The overwhelming weight of the evidence at trial shows that injectables and AndroGel 1% competed in the same market, because those products are reasonably interchangeable and the price of one affected the price of the other.

First, the evidence establishes that AndroGel and injectables (as well as the other FDA-approved testosterone replacement therapies) are reasonably interchangeable. The test is whether the products are "roughly equivalent" to another and "work effectively" from a therapeutic perspective. *Mylan*, 838 F.3d at 436 (quoting *Allen-Myland, Inc. v. IBM Corp.*, 33 F.3d 194, 206 (3d Cir. 1994)). It is undisputed that injectables and AndroGel have the same medical indication and work effectively to increase testosterone to normal levels. FF 192-197. Indeed, FTC's own medical expert testified that applicable medical guidelines treat injectables as one of many viable testosterone replacement options and that when practicing in Ireland she frequently prescribed injectables to her own patients. *See* 2/14 Tr. 62:25-64:3. Defendants' medical expert, Dr. Ritenour, concurred that "any of the approved options are reasonable for most patients" and "generally do the same thing . . . in the same way." 2/26 Tr. 258:5-7; 2/27 Tr. 9:19-10:1; *see* 2/27 Tr. 10:2-18 ("it's fairly simple to switch between different formulations").

Moreover, the evidence shows that patients frequently switched between AndroGel and injectables. FF 201. Analyzing a large body of patient data from insurance companies, Dr.

[19] All parties agree that the only available oral testosterone products have health risks that exclude them from the relevant market. FF 190. References herein to testosterone products (and the like) should be read to exclude such oral products.

Crémieux found that 21.8% of patients who were prescribed AndroGel sometime between December 1, 2009, and November 30, 2014, also received a prescription for injectables at some point in time. *See* DX111; 2/28 Tr. 33:9-34:8, 35:20-21. In addition, Dr. Crémieux found that many patients used a different testosterone product in the year before or after their last AndroGel prescription, and that the products that patients who were prescribed AndroGel most frequently switched to or from were injectables. *See* DX112; 2/28 Tr. 38:12-40:12.

During that same period, more and more patients chose to use injectables rather than AndroGel or some other testosterone replacement product. In April 2011, approximately 30.6% of patients undergoing testosterone replacement used injectables. FF 265. That percentage climbed throughout 2011 and 2012, matched and exceeded AndroGel's market share at the end of 2013 and the beginning of 2014, and then continued to rise sharply in the following years. *See* FF 265. As of the week before trial, it was 68%. FF 265. This evidence is definitive proof of reasonable interchangeability. *See Mylan*, 838 F.3d at 436.

Of course, some patients may prefer not to use a testosterone delivery method that involves a needle (while others may prefer injections because they are not administered daily and do not require precautions against transference). But the law is clear that reasonable interchangeability of use exists for antitrust purposes despite "some degree of preference for . . . one [product] over the other," so long as "either would work effectively." *Mylan*, 838 F.3d at 436 (quoting *Allen-Myland*, 33 F.3d at 206); *see also* 2/27 Tr. 240:22-241:5 (Crémieux). Here, data about the extensive and consistently growing use of injectables shows that patients are willing to use them (instead of other testosterone products), that doctors are willing to prescribe them, and that insurance companies are willing to cover them.

Second, the evidence establishes that AndroGel and injectables competed on price. Dr. Ritenour and others testified, and documents show, that the large amount of patient switching

from AndroGel to injectables was driven by price. *See* 2/27 Tr. 21:11-25; FF 288-289. The evidence also shows that Abbott concluded in 2010, based on its own cross-elasticity analysis, that higher AndroGel-to-injectable copay differentials were associated with higher use of injectables, and Abbott therefore developed a copay "assistance" program to keep the amount that patients would pay for AndroGel within range of the amount that patients would pay for injectables. *See* 2/26 Tr. 53:21-55:5 (Hernandez); *see also* DX201 (study concluding that "[a]s AndroGel co-pays increase Injection Share Increases"); DX197-006. That competition on price decreased revenues, but it was important to the company because cost plays a significant role in physician and patient decisions about which testosterone product to use. 2/27 Tr. 12:13-14:15; DX190-0010.

Although Dr. Shapiro created a single, simplistic chart of prescription levels over a limited period of time that purported to show a lack of cross-elasticity, Dr. Crémieux explained why the chart showed no such thing. FF 298-302. The chart does not look at price; it looks only at number of prescriptions, which is insufficient to evaluate cross-elasticity. *See* PLX425; 2/28 Tr. 114:2-16 (Crémieux). The chart also concentrates on the wrong moments in time, since the price effects of generic entry are not seen until several months after entry. *See id.* Most importantly, the chart does not account for an event that "swamped" the effects the chart purports to measure: negative publicity about the health effects of testosterone that disproportionately affected branded topical products (because they were pictured in negative ads). *See id.*; DX102-0002. The chart therefore has no probative value, and certainly does not undermine the conclusion that "a price change for one product affects the price of the other." *Mylan*, 838 F.3d at 435.

Finally, confirming what the expert economic analysis demonstrates, the AbbVie Defendants regularly tracked injectables' share of the testosterone replacement market and

analyzed the reasons for patients' choice to use injectables. *See, e.g.*, DX16-0012, -0013, -0017; DX98-0004, -0007; DX196-0005, -0007; DX280-0008, -0009; DX282-0016; DX297-0004, -0010, -0012; 2/28 Tr. 45:11-47:2 (discussing DX279); Tr. 48:7-49:23 (discussing DX284); FF 331. For instance, a July 2010 study by Abbott concluded that "[a]s AndroGel co-pays increase [i]njection [s]hare [i]ncreases." DX201; *see* DX197-0005 (analyzing reasons for "increases in injectable use"). Thus, as Dr. Crémieux concluded, "when you look at how they are thinking about the market, it's very clear that injectables is one of the questions they are thinking of" and "those documents are consistent with exactly what you observe in the data."[20] 2/28 Tr. at 50:22-51:3.

b. ***Defendants' lack of monopoly power.*** In a properly defined market that includes injectables, Defendants lacked a high market share and there were no significant barriers to entry or expansion. Thus, no indirect evidence of monopoly power exists. *See Mylan*, 838 F.3d at 434. First, Defendants' share of the testosterone replacement market was at all relevant times below the minimum level of 55% at which market power generally can be found. *See Mylan*, 838 F.3d at 437. Specifically, AndroGel's share of that market declined continuously from a high of 50.3% in January 2011 to a low of 20.8% in November 2016. *See* DX121; DX122; FF 340. No other factors indicate that Defendants nevertheless exercised some dominant power to control prices and exclude competition. *See Fineman*, 980 F.2d at 202. Rather, Defendants were *themselves* being steadily squeezed out of the market as the popularity of injectables surged. *See* 2/28 Tr. 64:25-66:19; DX121; *United States v. Syufy Enters.*, 903 F.2d 659, 666 (9th Cir. 1990).

[20] Some company sales executives did not immediately understand the competition posed by injectables. As Mr. Hynd testified, that was a blind spot contrary to the actual data. *See* 2/13 Tr. 269:18-270:2. Dr. Crémieux observed that it took certain individuals "a while to realize" the extent of injectable competition because AndroGel sales did not start plateauing until 2012 and those individuals "focused on 1.62," but that they recognized "after the fact that this was a mistake, that in fact the market was broader." 3/1 Tr. 57:5-24.

Second, no significant barriers to entry or expansion existed. *See* pp. 20-21, *supra*.

III. FTC's Request for Disgorgement Should Be Denied (FF 349-528, Conclusions of Law 38-62)

A. Disgorgement Is Not Legally Authorized Here

The statutory provision under which FTC brought this case, section 13(b) of the FTC Act, authorizes only one form of relief if liability is established: issuance of a "permanent injunction" to "enjoin [an] act or practice." 15 U.S.C. § 53(b). Section 13(b) does not refer to disgorgement or other monetary relief—or even to any "appropriate" relief, in contrast to other provisions of the same statute not applicable here. *See* 15 U.S.C. § 57b(b); 15 U.S.C. § 45(*l*). Thus, nowhere does the statute provide the "'affirmative' evidence of congressional intent" necessary to create an implied disgorgement remedy. *Alexander v. Sandoval*, 532 U.S. 275, 288, 293 n.8 (2001).

FTC nevertheless seeks more than $1.23 billion in disgorgement by arguing that section 13(b) implicitly authorizes "equitable monetary awards" as a form of "ancillary equitable relief." Dkt. 321 at 21-23. The Third Circuit has never accepted that argument in a precedential decision, and FTC has not pointed to the required affirmative evidence of congressional intent. The argument also cannot survive *Kokesh v. SEC*, 137 S. Ct. 1635 (2017), in which the Supreme Court held that disgorgement is a "penalty"—that is, a "punishment"—because it "is not compensatory" and "is imposed for punitive purposes." *Id.* at 1644-45; *see id.* at 1642 n.3. A penalty is the opposite of an equitable remedy, and Congress's authorization of an "injunction" cannot be distorted so as to permit infliction of punishment. *See, e.g.*, *Marshall v. City of Vicksburg*, 82 U.S. 146, 149 (1872) ("Equity never, under any circumstances, lends its aid to enforce a forfeiture or penalty, or anything in the nature of either.").[21]

[21] *See also, e.g.*, *Hecht v. Bowles*, 321 U.S. 321, 329 (1944) (equitable remedies are not designed "to punish"); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 433-35 (1945) ("relief in equity is remedial, not penal"); *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 293-94

Kokesh was about the SEC's disgorgement remedy, but there is no basis for distinguishing the disgorgement that FTC seeks here. *See* Dkt. 321 at 21-23 (relying on SEC cases). Although FTC has told this Court that it will set up a consumer-claims procedure, disgorgement amounts in FTC cases (as in SEC cases) often go to the Treasury. That could well happen here, because it is unclear whether FTC will be able to identify or locate affected consumers and because FTC's disgorgement request covers profits made on sales of AndroGel 1.62% at a time when a patient was free to choose an AndroGel 1% generic, and therefore was not in any sense injured in purchasing AndroGel 1.62%. *See Kokesh*, 137 S. Ct. at 1644; *see also, e.g., FTC v. Bronson Partners*, 654 F.3d 359, 373 (2d Cir. 2011) (disgorgement not "restitutionary"; no obligation to return funds to consumers and amounts can go to Treasury).

B. FTC Has Not Carried Its Burden to Prove Any of Its Requested Disgorgement Amounts

1. FTC has the burden to establish causation, and speculation is not sufficient. FTC has asserted that it need show only a "reasonable approximation" of what the world would have looked like if Defendants had not sued Teva and Perrigo. Even were FTC correct,[22] the cases are clear that when FTC seeks disgorgement it has the burden to establish but-for causation. Speculation is not enough to meet that burden. *See SEC v. Teo*, 746 F.3d 90, 105 (3d Cir. 2014); *SEC v. Posner*, 16 F.3d 520, 522 (2d Cir. 1994) (disgorgement covers income that would not have been earned "[b]ut for . . . illegal conduct"); Dkt. 324 at 40-46; *cf. Wellbutrin*, 868 F.3d at 149, 152-53, 165. The "reasonable approximation" language in the cases, which is mainly about situations in which exact amounts affected by fraud are unknowable, does not diminish FTC's

(1960) (remedy that is "punitive" is "outside the function of equity"); *Stevens v. Gladding*, 58 U.S. (17 How.) 447, 455 (1855); *Smith v. Maryland*, 10 U.S. (6 Cranch) 286, 296 (1810).

[22] The cases FTC has cited (Dkt. 321 at 22-23) predate the Supreme Court's 2017 decision recognizing disgorgement as a punishment, which should not be inflicted without solid proof.

burden to establish the foundational fact that but for the patent suits Teva or Perrigo would actually have entered the market at the times that FTC posits.

2. All of FTC's disgorgement scenarios rely on assumptions that FTC has not adequately proven. FTC has not established that, but for the Teva litigation, Teva would have entered with a BX-rated product in June 2012; that but for the Perrigo litigation, Perrigo would have received an AB rating and entered in Summer 2013; or that in either scenario the "franchise mix" between AndroGel 1.62% and AndroGel 1% would have been frozen at the moment of BX or AB product entry. Accordingly, FTC's requested disgorgement should be denied.[23]

a. Unsupported Teva assumption. The evidence at trial does not establish FTC's assumption about Teva entry. Indeed, the evidence shows that the assumption is wrong.

As Maureen Cavanaugh, a Teva executive, testified at trial, testosterone gel is a retail pharmaceutical product (not a product administered in hospitals), and Teva's generics division has *never once* actually launched a BX-rated retail pharmaceutical product. 2/9 Tr. 109:13-115:25; *see* FF 381. That is because Teva's generics business model relies on automatic substitution at pharmacies under state law. 2/9 Tr. 112:20-113:12, 114:6-115:14. Because a BX-rated product may not be automatically substituted, Teva would have to "create demand" for it—for instance, by hiring a sales force. 2/9 Tr. 99:17-21, 112:20-113:12, 113:22-114:25. For a retail pharmacy product with no perceived marketplace advantage—*i.e.*, a "me-too" product—the generics division at Teva was not equipped to do that. *Id.*; *see id.* at 118:23-120:5 ("From a marketing perspective, [Teva] did not see anything that would give [it] an advantage, a perceived

[23] For all of the reasons set forth in the text, the Court should not order any disgorgement. But, in any event, FTC's failure of proof means that the maximum amount of disgorgement here is $39.8 million, as Dr. Crémieux testified. *See* FF 521-527. That is the amount of profits attributable to any delay in Perrigo entry following its late July 2014 receipt of an AB rating. *See id.*

advantage in the market."); FF 378-380.[24] And there is no evidence that any other Teva division could or would have launched this particular product, or that Teva at any time considered transferring the testosterone gel product to any other division.

Teva also faced obstacles to profitable launch of a generic testosterone gel. First, in July 2011, Teva was forced to withdraw its request for FDA approval of a pump version of its product, which FDA said "does not appear to be approvable." DX46; DX47. Teva believed that this setback cut its sales opportunity by over half and would have put any Teva product at a significant competitive disadvantage with respect to pharmacies. 2/9 Tr. 124:4-12; *see* 2/8 Tr. at 171:1-172:8 (Phelps) (testifying that to gain approval of the pump Teva would have had to reformulate over a lengthy period, if possible, and then go through another long FDA process); FF 384-387.

Second, Teva's manufacturing partner, Cipla, demanded that [redacted] for construction of manufacturing facilities. 2/9 Tr. 127:8-15; FF 388-392. As Ms. Cavanaugh testified, "[a]ny time we have [capital expenditure] requirements, it really kind of stops things and we have to really take a look at the revenues," particularly where money would be provided to a partner. 2/9 Tr. 128:11-23. In negotiations, Cipla never retreated from its demand for [redacted]. 2/9 Tr. 127:8-15, 128:25-129:6, 129:16-24. (Cipla at one point suggested obtaining the payment through royalties but only to the extent that the royalties would cover [redacted]; together with other royalty obligations of third parties, that royalty rate would have amounted to approximately [redacted] of any Teva revenues. FF 390-391.)

As Ms. Cavanaugh testified, those factors—not the short-lived patent litigation or the

[24] Ms. Cavanaugh recognized that Teva had brainstormed about whether it could somehow create demand for a BX-rated product by partnering with managed care organizations, but stated that it "was just a concept" and unlikely to succeed. 2/9 Tr. 116:11-117:24. Ms. Cavanaugh also explained that Teva's investment of resources in seeking FDA approval and making sales projections did not indicate that product launch was likely. 2/9 Tr. 133:4-14; 2/28 Tr. 179:15-24.

settlement of that litigation—led to Teva's decision not to make testosterone gel its very first ever BX-rated retail product. In mid-2012, Teva underwent a leadership overhaul that resulted in the replacement of Tim Crew and William Marth with leaders who had different philosophies. 2/9 Tr. 131:7-14, 163:15-22, 164:16-19. At the same time, the Chief Financial Officer of Teva Americas expressed skepticism about the project. *See* PLX320-002. Ms. Cavanaugh made the recommendation to her new supervisor not to proceed with testosterone gel, and he agreed. 2/9 Tr. 132:10-18, 163:6-9; *see* DX153-0001 (Teva never paid Cipla [redacted]); FF 402.

As Ms. Cavanaugh testified at trial, her recommendation had nothing to do with the patent litigation or the settlement of that litigation. She would have made the same recommendation and expected the same result without them. FF 404-405. Dr. Crémieux, applying his economic expertise, also concluded that in the "but for" world Teva would not have incurred financial risks and used its finite resources to pursue an unprecedented business strategy of entering the market with a BX-rated "me-too" product, especially given the manufacturing and other problems specific to testosterone gel that Teva faced. *See* 2/28 Tr. 124:20-130:8.

The evidence to which FTC's Dr. Shapiro has pointed is wholly insufficient to support a different conclusion. That evidence consists principally of a handful of confusing and often contradictory Teva emails and spreadsheets, the reliability of which was not endorsed by any witness and which do not support the notion that Teva would have entered with a BX-rated product in June 2012. *See* FF 363-364, 383, 394-398. For instance, a Teva spreadsheet on which Dr. Shapiro heavily relied (PLX301) does not account for any of the setbacks Teva suffered in 2011 (such as withdrawal of the pump) and does not align with the official work plans that Teva developed in late 2010 and 2011, which projected that a product could not launch until at least 2013. *See* PLX318-004, -006; PLX35-015, -017, -019; PLX310; FF 359-362. Dr. Shapiro also relied on a handful of exchanges between Teva and Cipla about how quickly Cipla

could produce—but those do not account for the fundamental problem that Teva was unwilling to commit the [redacted] that Cipla required to begin. Moreover, the timelines are inconsistent (including 12 months, 18 months, and 26 months until market readiness), and FTC presented no testimony from Cipla that would support a finding that the quickest estimate was reliable or realistic. *See* PLX18-006; PLX314-017; DX59. That is especially problematic given Ms. Cavanaugh's uncontroverted testimony that Cipla was not always reliable, "did not necessarily meet dates[,]" and "overpromised and underdelivered a bit." 2/9 Tr. 61:18-20; FF 389.

This Court should not accept FTC's invitation to impose more than *half a billion* dollars in disgorgement, which is the amount that FTC says flows from its Teva assumption, based on the extraordinarily slim reed of inferences FTC would draw from a cherry-picked group of documents that are on their face unreliable—inferences that also are unsupported by testimony of any of the numerous people actually involved in the relevant events and decisions. FTC has not carried its burden.

b. Unsupported Perrigo assumption. FTC likewise has not proven that but for Defendants' suit, Perrigo would have received an AB rating and entered the market in Summer 2013. The evidence shows that no such entry would have been possible, for reasons having nothing to do with the litigation against Perrigo. *See* 2/28 Tr. at 139:13-142:21.

In the real world, FDA did not award (and would not have awarded) any therapeutic equivalence (TE) rating until it had ruled on the legitimate citizen petitions regarding the propriety of such a rating. *See* DX21-0008 (FDA statement that "it is critical to resolve [the citizen petitions] in order to make a decision regarding Perrigo's TE rating"); PLX288-009 to -012; *see also* DX21-008 and DX245 (FDA statements that citizen petitions raised "significant" and "complex" issues). FDA did not resolve those petitions until July 2014, and its consideration of them was not slowed in any way by the fact, then unknown to FDA, that Perrigo

had in its settlement agreed not to enter until the end of 2014. *See* FF 436-450, 462

FTC's contrary contention rests on the wholly implausible assertion that Perrigo would have sued FDA for unreasonable delay at a point when no delay had occurred and almost immediately gotten a favorable result. The evidence refutes that. *See* FF 459-466; 2/28 Tr. at 139:13-142:21 (Crémieux).

FDA does not begin considering whether to award a TE rating to a 505(b)(2) drug until the drug obtains marketing approval, which in Perrigo's case did not occur until January 31, 2013. 2/8 Tr. 136:9-13. In the real world, following that approval Perrigo diligently pressed its request for an AB rating with FDA in detailed letters. *See* FF 426-435. Then, more than a year after receiving marketing approval, Perrigo filed suit against the agency for "unreasonable delay" in issuing the rating. *See* FF 456. Perrigo obtained no judicial relief, although FDA did inform the court that it would issue the rating by a future date (the date when the citizen petitions were ultimately resolved). *See* FF 458; PLX288-002, -009 to -011.

FTC posits that in the "but for" world Perrigo might have filed suit against FDA for unreasonable delay in Spring 2013 and that Perrigo would have obtained an AB rating within a few months after that suit commenced. FTC presented no evidence that there would have been any factual or legal basis for such a suit when so little time had elapsed. FTC likewise presented no evidence that Perrigo would have decided to take the drastic step of suing its own regulator at such an early date and before its less drastic steps were unsuccessful. *See* 2/12 Tr. 206:11-13, 206:24-207:2 (testimony by Perrigo lawyer that filing suit against FDA is rare and "a tactic of last resort"); *see, e.g.*, *Mallinckrodt Inc. v. FDA*, 2015 WL 13091366, at *9 (D. Md. July 29, 2015) (change in TE rating not judicially reviewable); 2/27 Tr. 151:24-153:25 (Mathers); *see also City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998) (the "presence of the regulatory scheme and need for approval . . . cuts the causal chain and converts

what might have been" an "injury in a free market into only a speculative exercise"). And FTC presented no evidence that FDA would have acted more quickly if Perrigo had filed its unreasonable delay claims a year earlier, at a point when no unreasonable delay existed. FF 460-461, 466.

Instead, FTC's argument in this regard is based on pure speculation that cannot support hundreds of millions of dollars in disgorgement. In basing his disgorgement scenarios on the assumption that Perrigo would have sued FDA immediately upon obtaining its AB rating, or just 30-60 days thereafter, Dr. Shapiro, who admittedly has no expertise in FDA regulatory matters, relied only on the testimony of FTC's regulatory expert, Kenneth Phelps, and Perrigo's Mr. Solomon. *See* 2/16 Tr. 66:11-12, 67:9, 68:12-69:8, 80:4-14. But neither Phelps nor Solomon testified that Perrigo would have sued earlier in the but-for world—let alone that it would have sued (and obtained relief) in the immediate time frame that Dr. Shapiro assumed.

Phelps testified only to the vague conclusion that in the but-for world Perrigo "could have sued the FDA earlier perhaps." 2/8 Tr. 84:4-5. But Phelps did not state that he had any degree of certainty in this conclusion, and it was, by its very terms, halting and tentative. Phelps also admitted on cross-examination that Perrigo had an equally strong incentive to push for a TE rating as soon as possible in the real world. 2/8 Tr. 187:8-13 (company never knows what obstacles FDA will raise and how long they will take to resolve). Phelps also admitted that FDA would not rule on the TE rating until it resolved the pending citizen petitions, that the petitions were complex, that it can take a long time for FDA to resolve citizen petitions, and that FDA is under no obligation to assign a TE rating or do so within any particular timeframe. 2/8 Tr. 138:12-24, 138:25-139:4, 140:21-141:1. As for Solomon, he never testified that, absent the patent suit, Perrigo would have sued FDA immediately after obtaining marketing approval or within 30 or 60 days. 2/12 Tr. 208:18-209:9. In fact, he *twice* described any hypothesis of an

earlier suit as mere "speculation." *Id.* And Solomon's speculation about "30 or 60 days" was not—as Dr. Shapiro inaccurately portrayed it—30 or 60 days after marketing approval, but "maybe the first time [FDA] said we'll get back to you in 60 days or 30 days . . . . [and] they failed to do so." *Id.* FTC presented no evidence whatsoever of when that would be. Dr. Shapiro's opinion on Perrigo's entry thus lacks any underpinning.

c. Unsupported assumption regarding freeze in 1.62% sales. The evidence at trial also does not support the third assumption underlying Dr. Shapiro's disgorgement calculations: that sales of AndroGel 1.62% as a percentage of total AndroGel business would freeze upon the entry of a BX-rated generic 1% product, because customers would no longer "convert" from using a 1% product to using the 1.62% product in that circumstance. *See* 2/15 Tr. 137:22-138:4. Even apart from reliance on the incorrect proposition that Teva would have entered the market with a BX-rated product in June 2012, Dr. Shapiro's assumption is fatally flawed.

First, AndroGel 1.62% sales as a fraction of total AndroGel business did not flatten on *actual* entry of a generic 1% product. *See* FF 486-491. Second, the vast majority of AndroGel 1.62% sales came not from "converting" patients who had previously been using AndroGel 1% to the new 1.62% offering, but rather from patients who had previously been untreated or using a competing testosterone product. FF 481-484. For instance, Dr. Crémieux examined patient prescription data and found that over 55% of AndroGel 1.62% patients did not use a testosterone replacement therapy in the year before starting AndroGel 1.62%, while another 16.3% used only non-AndroGel products. *See* DX124; *see also* DX98-0043 (percentage of AndroGel 1.62% patients who had switched from AndroGel 1% was only 25.3% in July 2012 and declined to 12.8% by June 2014). Thus, as Dr. Crémieux explained, AndroGel 1.62% sales as a fraction of total AndroGel business would have continued to grow upon generic entry of a 1% product in the "but for" world as well—particularly if that entry was by a BX-rated product that was not

substitutable for AndroGel 1% at the pharmacy. *See* 2/27 Tr. 230:24-232:3; 2/28 Tr. 143:10-153:3; DX306 (AndroGel 1.62% prescriptions ceased growing by late 2012). Indeed, the whole idea of a static group of patients who were waiting to be "converted" from one product to another is totally contrary to the evidence of extensive patient turnover among testosterone replacement therapies. 2/28 Tr. 148:21-153:3; FF 200-201, 305-306, 322-326.

Dr. Shapiro did not rely on data of actual prescription patterns. He relied principally on an Abbott scenario planning document (PLX32) that made projections about the future that turned out to be completely inaccurate. *See* PLX32-013; 2/28 Tr. 195:1-11; *see also* PLX180 (additional inaccurate projections). Dr. Shapiro's opinion on the subject is therefore entitled to no weight, and certainly lacks sufficient probative value to support the disgorgement that FTC seeks. As the Third Circuit has ruled, "expert testimony based on prior predictions of sales for a given period when actual performance data for that same time span are available" is not probative. *Tunis*, 952 F.2d at 738-39 (quoting *Advent Systems, Ltd. v. Unisys Corp.*, 925 F.2d 670, 682 (3d Cir. 1991)).

More fundamentally, the evidence establishes that, given the freedom to choose between AndroGel 1.62%, AndroGel 1%, and generic versions of AndroGel 1%, patients have overwhelmingly chosen 1.62%, which offers benefits that 1% and generic 1% do not. FF 488-491, 501; *see* FF 472-478. Nothing about AbbVie's marketing of AndroGel 1.62% has been shown (or even alleged) to have been wrongful, and there is no reason whatsoever to conclude that patients presented with a choice among the products in the but-for world would have chosen differently. Defendants therefore should not be subject to disgorgement for profits on any 1.62% sales. *See* Dkt. 324 at 46.[25]

[25] Dr. Shapiro's analysis is further flawed because he failed to deduct the cost of the royalties paid by Abbott/AbbVie when he calculated his disgorgement amounts. It is a stipulated fact that

CONCLUSION

Judgment should be entered in Defendants' favor.

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Respectfully submitted,

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all such royalties are paid to non-parties LBI SAS or BHL SARL. Dr. Shapiro admitted at trial that the amount of the royalties were "financial gain to the party that is receiving [the] royalties, but not to AbbVie because they had to pay them." Trial Tr. 2/16 at 203:20-204:11, 204:20-208:1, 208:12-209:1 (Shapiro); FF 505-513.

Counsel for Defendants AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals, LLC, and Besins Healthcare, Inc.

CERTIFICATE OF SERVICE

I certify that, on March 23, 2018, the foregoing document was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. The document is available for viewing and downloading.

/s/ Adam R. Lawton