UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ABBVIE INC., et al.,

Defendants.

Case Number: 2:14-CV-5151-HB

PLAINTIFF FEDERAL TRADE COMMISSION'S POST-TRIAL BRIEF

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KEY PERSONNEL

AbbVie Inc. / Abbott Laboratories / Solvay Pharmaceuticals, Inc.

1. **Carlos Alban**: Mr. Alban currently is AbbVie's Executive Vice President of Commercial Operations at AbbVie. In 2011, Mr. Alban was the Senior Vice President of Proprietary Pharmaceutical Products and Global Commercial Operations at Abbott.

2. **Adam Chiss**: Mr. Chiss currently is Division Counsel for Intellectual Property Litigation at AbbVie. In 2011, Mr. Chiss was a Senior Counsel at Abbott and was one of the in-house lawyers involved in the decisions to file the objectively baseless lawsuits against Teva and Perrigo.

3. **Johanna Corbin**: Ms. Corbin currently is AbbVie's Vice President of Intellectual Property. In 2011, Ms. Corbin was a Division Counsel at Abbott and was one of the in-house lawyers involved in the decisions to file the objectively baseless lawsuits against Teva and Perrigo.

4. **Kevin Dolan**: Mr. Dolan was Divisional Vice President & Controller for the Pharmaceutical Products Division at Abbott.

5. **Thomas Freyman**: Mr. Freyman was CFO of Abbott in 2011.

6. **Michael Gautsch**: Since 2014, Mr. Gautsch has been the Commercial Marketing Director for AndroGel at AbbVie. In 2011, Mr. Gautsch was a senior marketing manager for AndroGel who reported to Mr. Jaeger.

7. **Rick Gonzalez**: Mr. Gonzalez currently is AbbVie's CEO and Chairman. In 2011, Mr. Gonzalez was the COO of Abbott.

8. **Anat Hakim**: Ms. Hakim was Divisional Vice President and Associate General Counsel of Litigation at AbbVie. In 2011, Ms. Hakim was one of the in-house lawyers at Abbott involved in the decisions to file the objectively baseless lawsuits against Teva and Perrigo. In 2009, Ms. Hakim was a partner at Foley & Lardner LLP.

9. **Pablo Hernandez**: Mr. Hernandez currently is a Senior Product Manager, Men's Health Franchise at AbbVie. In 2011, Mr. Hernandez was one of several product managers on the marketing team for the AndroGel franchise who reported to Mr. Gautsch, who in turn reported to Mr. Jaeger.

10. **Jim Hynd**: Mr. Hynd currently is the Vice President of Endo, Metabolic, GI Care, and Institutional Accounts at AbbVie. Since 2000, he has been one of the principal executives responsible for the AndroGel franchise at Solvay, then Abbott, and now AbbVie.

11. **Frank Jaeger**: Mr. Jaeger currently is a Regional Sales Manager at AbbVie. From 2010 to 2014, Mr. Jaeger was the Director of Marketing for AndroGel at Abbott and then AbbVie.

12. **Murray Kay**: Mr. Kay was the Vice President of Finance and CFO at Solvay in 2009. In 2011, Mr. Kay was a Commercial Controller at Abbott.

13. **Shannon Klinger**: Ms. Klinger was General Counsel of Solvay Pharmaceuticals, Inc. in 2009.

14. **Jennifer Razor**: Ms. Razor currently is AbbVie's Director of Ethics and Compliance. In 2011, Ms. Razor was a Senior Counsel for Legal Regulatory and Compliance at Abbott.

15. **Jose Rivera**: Mr. Rivera was AbbVie's Chief Compliance Officer and Divisional Vice President of Intellectual Property. In 2011, Mr. Rivera was Divisional Vice President and Associate General Counsel at Abbott and was one of the in-house lawyers involved in the decisions to file the objectively baseless lawsuits against Teva and Perrigo.

16. **Laura Schumacher**: Ms. Schumacher currently is the Executive Vice President, External Affairs, General Counsel, and Corporate Secretary at AbbVie. In 2011, Ms. Schumacher was Abbott's General Counsel and was one of the in-house lawyers involved in the decisions to file the objectively baseless lawsuits against Teva and Perrigo.

17. **Perry Siatis**: Mr. Siatis currently is the Vice President of Biotherapeutics and Legal at Abbott. In 2011, Mr. Siatis was Divisional Vice President of IP Strategy at Abbott and one of the in-house lawyers involved in the decisions to file the objectively baseless lawsuits against Teva and Perrigo.

18. **Jeff Stewart**: Mr. Stewart currently is the President of U.S. Commercial Operations at AbbVie. In 2011, Mr. Stewart was Vice President of U.S. Commercial Operations at Abbott.

19. **Marianne Sutcliffe**: Ms. Sutcliffe currently is the Vice President of Women's Health at AbbVie. In 2009, Ms. Sutcliffe was General Manager of the Dyslipidemia Franchise for Abbott's Pharmaceutical Products Division and was responsible for due diligence conducted by Abbott before the acquisition of Solvay's pharmaceutical business, including AndroGel.

20. **Lisa Wortsmann**: Ms. Wortsmann is a Commercial Controller at AbbVie with responsibility for AndroGel. She has held this position since about August 2011.

Besins Healthcare, Inc.

21. **Jay Bua**: Mr. Bua is President and CEO of Besins Healthcare, Inc.

22. **Leslie Grunfeld**: Mr. Grunfeld is a member of the executive board of Besins Healthcare, Inc. and CEO of its parent company, Besins Healthcare S.A.

23. **Thomas MacAllister**: Mr. MacAllister was General Counsel for Besins Healthcare, Inc. as well as President and CEO of BHR Pharma, LLC. Mr. MacAllister was one of the in-house lawyers at Besins involved in both the decision not to sue Perrigo in 2009 and the decisions to file the objectively baseless lawsuits against Teva and Perrigo in 2011.

Teva Pharmaceuticals

24. **Maureen Cavanaugh**: Ms. Cavanaugh is Teva Pharmaceuticals' Senior Vice President of Trade Management and Generic Strategy and Chief Operating Officer, North America.

25. **Tim Crew**: Mr. Crew was Senior Vice President, Commercial Operations Officer for Teva Pharmaceuticals USA.

26. **William Marth**: Mr. Marth was President and CEO of Teva Pharmaceuticals.

Perrigo Company

27. **Andrew Solomon**: Mr. Solomon was Perrigo's Vice President and Assistant General Counsel.

Outside Lawyers

28. **Michele Bosch**: Ms. Bosch is a partner at Finnegan, Henderson, Farabow, Garrett & Dunner LLP. Ms. Bosch provided advice to Abbott and Unimed concerning the decision not to us Perrigo in 2009.

29. **Joseph Mahoney**: Mr. Mahoney is a partner at Mayer Brown LLP. He was responsible for prosecution of the '894 patent before the U.S. Patent and Trademark Office on behalf of Unimed Pharmaceuticals and Besins Healthcare, Inc.

The FTC has proven its case. The evidence shows that Defendants deliberately used objectively baseless patent infringement suits against Perrigo Company and Teva Pharmaceuticals to obstruct entry of lower-priced versions of their blockbuster drug, AndroGel. They were well aware of the AndroGel patent's prosecution history and the law on prosecution history estoppel. They knew that Teva and Perrigo had developed products using penetration enhancers that Defendants had surrendered to obtain that patent. Indeed, just two years earlier, after "a thorough evaluation," Defendants had determined "there was not a sufficient basis" to file a patent infringement claim against Perrigo and issued a press release announcing that decision to the world.

But in 2011 Defendants also knew: (1) generic AndroGel 1% entry would decimate the profits of a product rapidly approaching $1 billion dollars in annual sales; (2) filing infringement suits would automatically trigger a regulatory provision blocking FDA approval of the generic products for up to thirty months; and (3) gaining time to shift the market to their upcoming follow-on product, AndroGel 1.62%, would blunt the impact of eventual generic entry on the AndroGel franchise. Faced with the dilemma that "it would all be over" after a generic launched, Defendants decided to use litigation as an anticompetitive weapon to thwart competition and delay entry by their closest rivals.

The evidence also shows that Defendants possessed monopoly power when they filed their sham litigations. Entry of generic AndroGel substantially benefited consumers: the market price of AndroGel fell 45%. The detrimental effects Defendants' exclusion of generic AndroGel inflicted on consumers demonstrates both that branded and generic AndroGel are close economic substitutes, and that other testosterone replacement products were not close enough substitutes to meaningfully constrain AndroGel's price to a competitive level. Widely accepted economic analyses, contemporaneous business forecasts, and the testimony of AbbVie's top executives all support that Defendants possessed monopoly power in a relevant antitrust market consisting of branded and

generic AndroGel and refute Defendants' contention that AndroGel competed in a broader market with injectable testosterone products.

As a result of Defendants' exclusionary conduct, consumers continued to pay monopoly prices for AndroGel, resulting in over a billion dollars in ill-gotten profits for AbbVie and Besins. To remedy this antitrust violation, the Court should order Defendants to pay $1.47 billion in the form of equitable monetary relief to compensate injured consumers and deprive Defendants of their unlawful gains, along with an injunction to prevent similar unlawful conduct.

I. Defendants' objectively baseless lawsuits used the governmental process as an anticompetitive weapon

Defendants filed patent infringement lawsuits "against Teva and Perrigo [that] were without question objectively baseless." (Dkt. 300 at 31.) Once a lawsuit has been determined to be objectively baseless, the second prong of the Supreme Court's sham litigation test asks "whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor." *Prof'l Real Estate Inv'rs. v. Columba Pictures Indus., Inc.*, ("*PRE*") 508 U.S. 49, 60-61 (1993) (internal citation and quotation marks omitted). While *PRE*'s first prong analyzes the "lawsuit's *legal* viability," the second prong analyzes "the suit's *economic* viability." *Id.* at 61.

Defendants incorrectly claim this second prong of *PRE* requires proof of the litigants' actual knowledge that the case was baseless. But as the Federal Circuit has observed: "the [*PRE*] Court's subjective inquiry has nothing to do with what a litigant knew or should have known regarding the merits of its claim." *See Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1313-14 (Fed. Cir. 2013). Indeed, if the Supreme Court had meant to require proof of actual knowledge that the suit was baseless, it could easily have said so. Instead, the Court made clear that the second prong focuses on whether the litigant initiated the baseless lawsuit to "use [] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *PRE*, 508 U.S. at 60-61 (emphasis in original). Accordingly, this inquiry asks whether Defendants "sue[d] primarily for the

benefit of collateral injuries inflicted through the use of legal process." *Id.* at 65. (*See also* Dkt. 319 at 26-29; Dkt. 343 at 2-6.)

A. Defendants enjoyed substantial benefits from the collateral injuries their baseless lawsuits inflicted on Teva and Perrigo

By 2011, AndroGel was one of AbbVie's[1] most valuable and important products, with U.S. annual net sales exceeding $870 million. (FOF ¶ 16.) But AbbVie faced the near-term prospect of generic entry from Teva and Perrigo. AbbVie knew that entry by a generic competitor would be devastating, resulting in the loss of 90% of branded AndroGel 1% sales within a year. (FOF ¶¶ 100, 219-27.) Additionally, Abbott projected that generic entry would interrupt its plan to switch patients from the vulnerable AndroGel 1% product to its reformulated AndroGel 1.62% version, which would not face near-term generic competition. (FOF ¶¶ 102-06.) Generic AndroGel 1% products would not be automatically substitutable for AndroGel 1.62%, making it harder for them to compete if AndroGel 1.62% had already gained a large market share. (FOF ¶ 104.) But earlier introduction of a cheaper generic 1% product would dramatically limit AbbVie's ability to transition patients to the more expensive 1.62% product. (FOF ¶¶ 106, 630-33.)

Defendants knew there was a way to prolong their AndroGel franchise. By filing patent infringement suits against Teva and Perrigo, Defendants could trigger an automatic stay of FDA final approval—a prerequisite to generic entry—regardless of whether they had any realistic chance of prevailing. (FOF ¶¶ 97-98.) Defendants thus took advantage of this "unique opportunit[y] for gamesmanship" presented by Hatch-Waxman's "'non-refundable' 30-month stay." *See In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *20 (D.N.J. Aug. 28, 2009). They filed their baseless suits, triggered the automatic stays, and prevented FDA final approval of Teva's

[1] To avoid confusion, all references to AbbVie shall mean AbbVie, its associated entities, or the predecessor entity that existed at the time. The accompanying Plaintiff Federal Trade Commission's Proposed Findings of Fact and Conclusions of Law ("FOF") identifies the specific relevant entity.

and Perrigo's products for up to 30 months. (FOF ¶¶ 112-13, 172-73.) In short, they used the government process as an anticompetitive weapon by bringing "baseless claims in an attempt to thwart competition." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014). (*See also* Dkt. 319 at 26-27 n.20; Dkt. 343 at 3.)

B. The evidence at trial supports liability even under Defendants' erroneous view that *PRE* requires proof that Defendants knew their lawsuits were baseless

Defendants have erroneously argued that *PRE* requires "proving bad faith" by "show[ing] that Defendants knew at the time of the filing that the suits against Teva and Perrigo were baseless." (Dkt. 331 at 2.) This purportedly requires the FTC to establish that each Defendant's "decision-makers" had "direct knowledge" that the suits were baseless. (Dkt. 331 at 6.) Defendants are wrong on the law. Nowhere in *PRE* does the Supreme Court say "bad faith," "actual intent," and "direct knowledge" of the baselessness of a claim is needed to satisfy the second prong. Specific intent is not an element of the FTC's antitrust claim here. (Dkt. 343 at 2-4.) But even under Defendants' erroneous interpretation of *PRE*, the evidence at trial proves that Defendants knew they could not have realistically expected success on the merits of their lawsuits, and they instead used the process as an anticompetitive weapon to interfere with Teva's and Perrigo's business interests.[2]

1. As early as 2009, Defendants knew that Perrigo's product contained a different penetration enhancer than AndroGel

In 2009, Defendants considered and rejected a previous opportunity to sue Perrigo for infringing the AndroGel patent (the "'894 Patent") even though it would have triggered the automatic 30-month stay. (FOF ¶¶ 33-52, 54-62.) Despite strong financial incentives to protect their lucrative product, Defendants did not do so. (FOF ¶¶ 51-62.) Noting the "pleading requirements" for patent infringement litigation, Defendant Unimed and its then parent company Solvay explained

[2] Defendants also are wrong that clear and convincing evidence is required to prove the FTC's claim. (*See* Dkt. 343 at 4-6; Dkt. 319 at n.21 & accompanying text.) Even so, the evidence at trial satisfies this standard as well.

that Perrigo's proposed product had a different formulation (i.e., a different penetration enhancer) than AndroGel. (FOF ¶¶ 56-58, 61-62.) After a thorough analysis of Perrigo's paragraph IV notice and "the information available," including outside counsel's review of Perrigo's ANDA and legal research about prosecution history estoppel, Defendants "determined there was not a sufficient basis for filing patent infringement litigation" against Perrigo. (FOF ¶¶ 31-50, 54-62.) James Hynd—then a Solvay executive and later a senior executive at Abbott and AbbVie—helped develop and execute a communications plan explaining the decision not to sue. (FOF ¶¶ 58-59.) The same lawyers jointly represented Besins, the same information was available to Besins, and Besins decided that it was "standing down." (FOF ¶¶ 42-49, 54-55.)

Defendants' decision not to sue Perrigo was so potentially detrimental to their business that Murray Kay, then Solvay's CFO, identified the press release announcing the decision as a "significant subsequent event" and informed its auditors that FDA approval of Perrigo's product would risk a "significant reduction of [Solvay's] sales, profits, and cash flow." (FOF ¶¶ 63-66.) Indeed, when AbbVie was considering purchasing Solvay in 2009, it initially did not want the AndroGel franchise because it expected imminent generic entry. (FOF ¶¶ 67-72.)

2. Defendants sued Teva and Perrigo in 2011 even though they knew their generic products contained a different penetration enhancer than AndroGel

After purchasing the AndroGel assets, AbbVie got a second chance to protect the flagship product from generic competition by securing a 30-month stay. In 2010, AbbVie petitioned the FDA to make any applicant for generic testosterone 1% products referencing AndroGel that contained a different penetration enhancer than IPM conduct certain additional studies and re-file as an NDA. (FOF ¶¶ 81-83.) The FDA granted AbbVie's petition in part. (FOF ¶¶ 84-85.) In accordance with the FDA's decision, Teva and Perrigo filed 505(b)(2) NDAs for generic testosterone 1% gel products in January and July 2011, respectively. (FOF ¶¶ 90, 93.) Each

company informed Defendants that its product did not contain IPM. (FOF ¶¶ 91-92, 94.) Perrigo expressly warned that any patent infringement suit would be a sham. (FOF ¶ 95.)

But Defendants' economic motivations to trigger the 30-month stay had only increased since 2009. AndroGel 1% sales were soaring towards over $1 billion annually. (FOF ¶¶ 99-101.) In early 2011, Abbott was preparing for the imminent launch of AndroGel 1.62%, and planned to transition as many AndroGel patients as possible to 1.62% before generic 1% entry occurred to blunt the eventual impact on the AndroGel franchise. (FOF ¶¶ 102-107.) Faced with these incentives, Defendants filed baseless lawsuits against Teva and Perrigo in April and October 2011, respectively, and secured regulatory stays on FDA approval of the generic products. (FOF ¶¶ 108-14, 168-74.)

Defendants argue that they had a good-faith basis for the 2011 lawsuits because the 2011 decision-makers: (1) were different from those in 2009; and (2) did not know the precise penetration enhancers used in Teva's and Perrigo's products.[3] These arguments are not only legally flawed (*see* Dkts. 341 and 343), but also contradicted by the evidence.

First, Defendants' position contravenes well-settled agency principles. "Organizations are treated as possessing the collective knowledge of their employees and other agents, when that knowledge is material to the agents' duties, however the organization may have configured itself or its internal practices for transmission of information." Restatement (Third) Agency § 5.03, cmt. c (2018); *see generally In re Color Tile Inc.*, 475 F.3d 508, 513 (3d Cir. 2007) (gathering cases regarding imputation of knowledge). Thus, whether the specific executives with decision-making

[3] At the end of trial, Defendants asked the Court take judicial notice of the recent decision *Eli Lilly & Co. v. Dr. Reddy's Laboratories, Ltd.*, No. 1:16-cv-00308-TWP-MPB, 2017 WL 6387316 (D. Ind. Dec. 14, 2017) as relevant to the prosecution history estoppel issues in this case. It is not. *Lilly* analyzed a different drug, with its own unique prosecution history, which neither disclosed the alleged equivalent in the prior art cited by the examiner (like IPP here) nor specifically listed the alleged equivalent in the claim before it was dropped by amendment (like ISA here).

authority in 2011 were the same as those in 2009, the corporation was aware of the facts relevant to its previous decision not to sue. (*See* Dkt. 334 at 10-12; FOF ¶¶ 21-27, 31-50, 54-62, 115-18.)

Second, even if the identity of specific individual "decision-makers" mattered, the evidence at trial established that the 2011 decision-makers were in some cases either the same as those in 2009, or at least had access to the same information. For example:

- Thomas MacAllister was Besins's general counsel and was involved in Besins's decisions whether to sue for patent infringement in both 2009 and 2011. (FOF ¶¶ 34-36, 42, 136, 194, 197.) He reviewed and evaluated both the 2009 and 2011 paragraph IV notices, researched Perrigo's product composition in 2009, reviewed legal research regarding prosecution history estoppel in 2009, pursued new patent claims specifically targeted at testosterone formulations containing ISA (Perrigo's penetration enhancer) in 2009, received analysis of Teva's and Perrigo's products in 2011, and communicated with AbbVie's counsel prior to filing the baseless lawsuits in 2011. (FOF ¶¶ 33-36, 42-49, 55, 74-75, 136-41, 194-98.)

- Besins's outside counsel, Foley & Lardner LLP, reviewed and evaluated the paragraph IV notices in both 2009 and 2011, provided advice about the decision whether to sue for patent infringement in 2009 and 2011, had confidential access to Teva's and Perrigo's NDAs and shared the results of its review with in-house counsel. (FOF ¶¶ 44-45, 48, 109, 139-40, 195, 199.)

- AbbVie's lawyers (including Perry Siatis) and executives (including Jeffrey Stewart) conducted due diligence of Solvay before AbbVie acquired AndroGel. (FOF ¶¶ 67-69, 178, 191.) That due diligence included review of the '894 patent prosecution history and information about Solvay's 2009 decision not to sue Perrigo. (FOF ¶¶ 69, 117, 178, 191.) After AbbVie (then Abbott) signed an agreement to acquire Solvay, Mr. Siatis communicated with Solvay's former general counsel Shannon Klinger about the paragraph IV notice received from Perrigo in 2009. (FOF ¶ 179.) He also communicated with Mr. Mahoney, the intellectual property lawyer responsible for prosecuting the '894 patent. (FOF ¶ 179.) Mr. Siatis authored memoranda and presentations about—and communicated with inside and outside counsel about—the 2011 decisions to sue Teva and Perrigo. (FOF ¶ 121-24,176, 184-88.)

- Mr. Hynd was the principle senior executive responsible for AndroGel in 2009, and learned from Solvay in-house counsel that Perrigo's product contained ISA. (FOF ¶ 50.) He helped develop and execute a communications plan explaining the 2009 decision not to sue. (FOF ¶ 59.) In 2010, Mr. Hynd and Mr. Stewart had access to competitive intelligence stating that Perrigo's 505(b)(2) NDA product used ISA as a penetration enhancer and pursued defensive regulatory strategies specifically targeted at testosterone formulations containing ISA. (FOF ¶¶ 86-89, 182.) Both Mr. Hynd and Mr. Stewart communicated with Abbott's in-house counsel and other senior executives in 2011 about the paragraph IV notices received from Teva and Perrigo and the decisions to file the Teva and Perrigo patent suits. (FOF ¶¶ 130-33, 189-90.)

- Michele Bosch of Finnegan Henderson reviewed and evaluated Perrigo's ANDA in 2009 for Unimed, Solvay, and Besins. After AbbVie's acquisition of AndroGel, AbbVie consulted with her to obtain historical information about the 2009 decision not to sue Perrigo. (FOF ¶¶ 43-45, 47-49, 180.)

- AbbVie's in-house IP litigation team evaluated Teva's and Perrigo's paragraph IV notices. (FOF ¶¶ 119-23, 126, 176, 183-86.) One or two of AbbVie's in-house counsel had confidential access to Teva's and Perrigo's full NDAs, including information about their penetration enhancers, prior to filing the baseless lawsuits. (FOF ¶¶ 126, 183.) AbbVie's outside counsel, Munger Tolles & Olson LLP, also had confidential access to Teva's and Perrigo's NDAs and shared the results of their reviews with AbbVie's in-house lawyers prior to filing the baseless lawsuits. (FOF ¶¶ 126-28, 183-84.)

Third, it does not even matter whether Defendants knew the *specific* penetration enhancer used in Teva's and Perrigo's products. Rather, it is sufficient that Defendants simply knew that Teva's and Perrigo's products did not contain IPM before they filed the baseless lawsuits. (FOF ¶¶ 125-28, 136-41, 175-87, 194-99.) Defendants had access to and knowledge of the prosecution history of the '894 patent, (FOF ¶¶ 23-27, 115-18, 179, 187), which, "any reasonable person who reads the prosecution history of the '894 patent" would know resulted in the surrender of testosterone formulations that use any penetration enhancer other than IPM in particular concentrations. (Dkt. 300 at 30-31.) Indeed, attorney Joseph Mahoney jointly represented Defendants Unimed and Besins in prosecuting the '894 patent and had explicitly told both companies that the patent examiner would allow only claims focused on IPM. (FOF ¶¶ 21-26, 116, 179.)

Fourth, the evidence at trial shows that Defendants' executives knew they would lose the Teva and Perrigo litigations (but still realize benefits from delaying competition with the automatic stays of FDA approval of the generic products). (FOF ¶¶ 21-27, 98, 142-67, 201-02.) AbbVie's executives engaged in a months-long parallel process to evaluate the financial impact of losing the Teva Litigation and facing imminent generic entry. (FOF ¶¶ 146-58.) Immediately after Teva filed for summary judgment, in August 2011, AbbVie executives discussed a "lost case" scenario in which Teva prevailed at summary judgment and entered with an AB-rated product in April 2012.

(FOF ¶¶ 146-57.) After multiple meetings, AbbVie executives concluded that the April 2012 "lost case" date was the most likely generic entry scenario. (FOF ¶¶ 146-57.) They spent the fall of 2011 calculating AbbVie's losses from generic entry after the "lost case," cutting $20 million from AndroGel's marketing budget, and planning to rapidly accelerate the transition of patients from AndroGel 1% to AndroGel 1.62% to blunt the impact of expected generic entry in 2012. (FOF ¶¶ 146-66.) These efforts ceased, and the $20 million cut reversed, only after Defendants settled the Teva and Perrigo litigations. (FOF ¶¶ 158, 167.)

3. Establishing Defendants' relevant knowledge does not require the Court to make any inferences about the content of privileged communications

Defendants contend the FTC is asking the Court to draw inferences about the content of privileged communications to prove that Defendants used their baseless suits "as an anticompetitive weapon" under *PRE*. (Dkt. No. 335.) This is false.

The inference that Defendants knew the Teva and Perrigo litigations were baseless, which is only even relevant under Defendants' erroneous reading of *PRE*, is supported entirely by non-privileged facts and Defendants' undisputed knowledge: Defendants knew about the 30-month stay (FOF ¶ 98); Defendants knew generic entry would have significant negative impacts on AndroGel and had substantial economic incentives to file baseless litigations to obtain the automatic 30-month stays (FOF ¶¶ 99-107); Defendants knew the prosecution history of the '894 patent (FOF ¶¶ 21-27, 115-18, 179); Defendants knew that Perrigo's and Teva's products did not contain IPM (FOF ¶¶ 125-28, 136-41, 175-87, 194-99); Defendants' 2011 decision-makers communicated with individuals knowledgeable about the 2009 decision not to sue (and in some cases, were the same individuals) (FOF ¶¶ 41-44, 119-33, 136, 141, 178-87, 194, 198); and Defendants' actions were consistent with the belief they would lose the Teva and Perrigo litigations (FOF ¶¶ 146-67, 201-02). None of these facts requires any inference about the content of Defendants' privileged

communications.[4] But the Court can and should draw inferences based on non-privileged indirect or circumstantial evidence produced by Defendants. (*See* Dkt. 319 at 27-28.)

II. Defendants possessed monopoly power when they filed the sham lawsuits

Monopoly power is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). The touchstone of the monopoly power inquiry is consumer harm. *See FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (purpose of the inquiry is to "determine whether the particular conduct at issue has the potential for genuine detrimental effects"). The critical question is whether there is sufficient power "to force a purchaser to do something that he would not do in a competitive market." *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 464 (1992) (citations and quotation marks omitted). This power can be proven directly with proof of actual detrimental effects, or indirectly "from the structure and composition of the relevant market." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007).

Defining a relevant market is not an end in itself. Rather, the purpose is to assess the likely competitive effects of the conduct at issue. *See U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) (in defining the market, a key question is "*why* we are doing so: that is, what is the antitrust question in this case that market definition aims to answer?"). Market definition requires identifying "the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). This exercise involves more than simply identifying functional substitutes—i.e., those products that can be used for the same purpose as AndroGel. *Brown Shoe*

[4] For example, the information in AbbVie's privilege logs—subject matter, dates, senders and recipients, and descriptions of privileged communications—and non-privileged testimony of in-house counsel, establish non-privileged facts, including that (1) some of the lawyers and executives involved in the 2011 decisions to sue had also been involved in the 2009 decision not to sue Perrigo, and (2) others involved in the 2011 decisions communicated with those who had been involved in the 2009 decision. (FOF ¶¶ 123, 129, 131-33, 176, 179-80, 187, 189-90.)

Co. v. United States, 370 U.S. 294, 325 (1962) (functional substitutability provides only "[t]he outer boundaries of a product market").[5]

Instead, the market definition inquiry turns on whether products are economic substitutes, meaning they demonstrate "significant positive cross-elasticity of demand." *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063-64 (3d Cir. 1978) (market limited to cephalosporin antibiotics despite "a certain degree of interchangeability among all antibiotics").[6] Cross-elasticity "measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 438 n.6 (3d Cir. 1997). (FOF ¶¶ 256-57.) When cross elasticity between products X and Y is high, they constrain each other's prices because an increase in the price of product X will cause a large loss of sales to product Y. *See Mylan Pharm. Inc. v. Warner Chilcott Public Ltd.*, 838 F.3d 421, 437 (3d Cir. 2016) (finding Doryx and other oral tetracyclines that treat acne to be in the same market because they demonstrated a high degree of cross-price elasticity). Conversely, when cross elasticity is low, a small but significant price increase for product X will not cause sufficient sales to shift to product Y. *See Times Picayune Publ'g Co. v. United States*, 345 U.S. 594, 612 n.31 (1953).

The evidence at trial proved that Defendants possessed monopoly power in a properly defined relevant market consisting of branded and generic versions of AndroGel. First, the fact that Defendants' exclusion of generic AndroGel harmed consumers demonstrates that other testosterone replacement products had not meaningfully constrained AndroGel's price and therefore must be outside the relevant market. Second, the hypothetical monopolist test, which incorporates both

[5] *See also FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997) ("The Supreme Court did not stop after finding a high degree of functional interchangeability between cellophane and other wrapping materials in the *E.I. du Pont de Nemours* case.").

[6] *See also United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, No. 14-MD-02521-WHO, 2017 WL 5068533, at *15, *19 (N.D. Cal. Nov. 3, 2017) ("Lidoderm") ("Consistent with the bulk of the case law, something more than mere therapeutic equivalency is required to define the relevant antitrust product market. There must be some showing of cross-elasticity.").

functional interchangeability and cross elasticity of demand, confirms that branded and generic AndroGel comprise a distinct relevant market. *See Babyage.com v. Toys "R" Us, Inc.*, 558 F. Supp. 2d 575, 581 (E.D. Pa. 2008). Finally, the evidence demonstrates that injectable testosterone products are outside the relevant market because they are not close economic substitutes to AndroGel. Thus, even if the relevant market included all transdermal testosterone replacement products, Defendants' ability to maintain market share well above 60% for over a decade suffices to prove monopoly power.

A. Undisputed evidence of consumer harm from excluding generic AndroGel 1% proves that the relevant market is limited to branded and generic AndroGel

The evidence at trial showed that competition from generic versions of AndroGel made a profound difference to consumers. Every relevant player—including AbbVie, Teva, and Perrigo—independently and consistently projected that generic entry would provide consumers with a lower-priced alternative and take over 90% of branded AndroGel 1% sales within a year. (FOF ¶¶ 218-36, *see also* ¶¶ 237-38, 100.) AbbVie never forecasted that any other product would have a comparable impact. (FOF ¶¶ 221, 100.) The actual data confirms these forecasts: when Perrigo launched its lower-priced generic product in late 2014, it was a "significant boost to competition" and a "boon for consumers." (FOF ¶¶ 246, 237-38, 247-49.) Within 24 months, generics captured 85% of AndroGel 1% sales, and the average price for AndroGel 1% products dropped 45%. (FOF ¶¶ 237-38.) Thus, as Professor Shapiro explained, "the conduct at issue by delaying generic entry had a dramatic anticompetitive effect. . . . [I]t disrupted the competitive process and it harmed consumers." (FOF ¶ 249.)

In fact, both economists agree that Defendants' conduct harmed consumers. Defendants' economic expert, Dr. Cremieux, acknowledges that generic entry made available a lower-priced alternative to AndroGel 1%, took substantial sales from branded AndroGel 1%, and saved consumers money. (FOF ¶¶ 244-51.) He concedes that delaying generic entry could harm

"consumers who wanted to get a generic and could not get it because it was not available." (FOF ¶ 250.) As Dr. Cremieux explained:

> This is not about saying there is no harm, right? If you assume liability, I conclude *there is harm*. . . . we don't disagree on the principle that *there is harm*.

(FOF ¶ 251.)

Delaying generic entry could not harm consumers unless Defendants possessed monopoly power. "[I]f competitive prices were being charged before the patented drug had a generic competitor, then the entry of new competitors would not result in a substantial change in price." *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn. 2016). But the evidence shows that generic entry did result in a substantial change in the average price consumers paid for AndroGel. (FOF ¶¶ 237-38.) This means that other testosterone replacement products had not constrained AndroGel's price prior to generic entry. As Professor Shapiro explained, "[w]e know that generic entry forces prices down a lot more [than other testosterone products]." (FOF ¶ 241.) That tells us that the cross-elasticity of demand between AndroGel and its generics is far greater than between AndroGel and these other products. (FOF ¶ 241.) *See also Staples*, 970 F. Supp. at 1074, 1078 (finding relevant market of office "superstores" because pricing data showed Staples and Office Depot charge higher prices in the absence of competition from each other, demonstrating "low cross-elasticity of demand between [identical] consumable office supplies sold by the superstores and those sold by other [non-superstore] sellers"). Thus, other testosterone products are not close economic substitutes and are outside the relevant market for purposes of assessing the competitive effects of the sham lawsuits. *See Lidoderm*, 2017 WL 5068533, at *21 (finding that other pain relief drugs were not in same relevant market as Lidoderm absent evidence "those drugs *constrained* the price charged for Lidoderm").

B. The hypothetical monopolist test confirms that AndroGel and its generic counterparts comprise a distinct relevant antitrust market

Professor Shapiro's empirical analysis confirms that the relevant market is limited to branded and generic versions of AndroGel. Professor Shapiro performed the hypothetical monopolist test ("HMT"), a widely accepted methodology derived from Supreme Court precedent, *see E.I. du Pont*, 351 U.S. at 391-92, 400-01, adopted by the U.S. Department of Justice and the FTC in the Horizontal Merger Guidelines, and routinely applied by courts and economists in both merger[7] and non-merger cases across many industries.[8] (FOF ¶¶ 260-72.) The HMT incorporates "cross-elasticity of demand between in-market products" to systematically evaluate economic substitutability and determine whether an identified group of products comprises a relevant product market. *Babyage.com*, 558 F. Supp. 2d at 581.

The test starts with a narrow set of products (the candidate market) and asks whether a hypothetical monopolist selling all of those products could impose a small but significant non-transitory increase in price ("SSNIP," taken to be 5% or more) without losing too many sales to make the price increase unprofitable. (FOF ¶ 264.) If the answer is yes, then the market is correctly defined because products outside the candidate market are not effective price constraints. (FOF ¶ 264.) If not, then the candidate market is too narrow, and the relevant market includes other products. (FOF ¶ 264.) The test is analytically the same in a non-merger context involving exclusion of competition. (FOF ¶¶ 268-69.) In that context, the question is whether the hypothetical monopolist, by excluding a competitor, can prevent the price from falling by more than 5%. (FOF ¶ 269.)

[7] (*See* Dkt. 259 at 31 n.60 (collecting cases).)

[8] (*See* Dkt 259 at 31 n.61 (collecting cases); Dkt. 322 at 33 n.34 (same); Dkt. 377 at 2-3 (same).)

Here, Professor Shapiro started with a candidate market of branded and generic AndroGel.[9] (FOF ¶ 281.) Using AbbVie's data and assumptions, he calculated the change in AndroGel market price (using a weighted average price of branded and generic AndroGel) before and after generic AndroGel 1% entry. (FOF ¶¶ 273-92.) Dr. Shapiro concluded that entry of an AB-rated and a BX-rated generic AndroGel 1% product would cause market prices to decline by at least 41% and 11%, respectively. (FOF ¶¶ 285-92.) This means that a hypothetical monopolist selling the products in the candidate market could profitably impose a price increase that exceeds the competitive price by far more than the 5% SSNIP threshold. (FOF ¶¶ 285-92.) Under the HMT, therefore, AndroGel and its generic counterparts constitutes a properly defined antitrust market. Professor Shapiro confirmed these results using actual market data following generic entry in 2014 and 2015. (FOF ¶¶ 237-38.)

Defendants offer three reasons why this Court should ignore the results of Professor Shapiro's HMT analysis.[10] None has merit.

First, Defendants incorrectly assert that use of the HMT is inconsistent with the Third Circuit controlling *Mylan* decision. But *Mylan* did not reject the HMT: the opinion does not

[9] Defendants' criticism of Professor Shapiro for including AndroGel 1.62% and BX-rated generics in the candidate HMT market makes no sense. Whether Professor Shapiro's candidate market includes all branded and generic AndroGel products or only branded AndroGel 1% and AB-rated generics, the result is the same: AbbVie had 100% of the market when it filed its sham litigations.

[10] Dr. Cremieux also complains that Dr. Shapiro analyzed the effect of generic AndroGel 1% entry on the overall market price of AndroGel products, rather than focusing only on what happened to the price of branded AndroGel. (FOF ¶ 279.) But, as Professor Shapiro explained, "that is the best way to measure the impact on customers when we have this situation where the impact is very different for some customers than others." (FOF ¶¶ 274-81.) When generic entry occurs, the vast majority of the customers will choose the generic and receive a substantial discount. Some customers, however, will continue to pay the higher branded price. Focusing exclusively on the small number of customers that continue to buy the branded product, as Dr. Cremieux suggests, would miss the large price-lowering impact of generic entry on the class of customers as a whole. (FOF ¶¶ 273-81.) It would also ignore the fact that cross elasticity focuses on a company's ability to charge a higher price *without* losing sales. *Package Shop, Inc. v. Anheuser-Busch, Inc.*, 675 F. Supp. 894, 942 (D.N.J. 1987) (market power is ability to "effect unilateral price increases above competitive levels without suffering an offsetting decline in consumer demand").

reference the HMT, and plaintiffs in that case do not appear to have presented it. The Third Circuit has, however, accepted the HMT where it has been relied on, including in *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016), decided the day before *Mylan*. Nor did *Mylan* create a special approach for defining relevant markets in the pharmaceutical industry. Instead, the Third Circuit reaffirmed that traditional market definition principles—functional interchangeability and cross-elasticity of demand—apply in the pharmaceutical industry. *Mylan*, 838 F.3d at435-36; *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *8 (D. Mass. Jan. 25, 2018) ("Even in the pharmaceutical market [] cross-elasticity must be demonstrated between products to establish a market definition that includes them."). The HMT incorporates these principles. *See Babyage.com*, 558 F. Supp. 2d at 581.

Second, Defendants contend that use of the HMT in this specific context must be inappropriate because it always will result in a market that is limited to the branded and generic drug. But the HMT is not rigged for a pre-determined outcome. Rather, it is designed to answer the critical market power inquiry: whether the excluded competition matters to consumers. If, for example, the generic were to enter at the same or higher price than the brand, the generic's entry would make little difference to consumers, and the HMT would conclude that the relevant market must include other drugs. (FOF ¶ 267.) But if generic competition would benefit consumers by making available a lower-priced alternative, then the HMT correctly defines the relevant market as the brand and its generic counterparts. (FOF ¶ 267.) This result does not prove too much. As Judge Posner observed long ago, "[i]t would not be surprising. . . if *every* manufacturer of brand name prescription drugs had some market power." *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 787 (7th Cir. 1999).

Finally, Defendants suggest that Professor Shapiro's HMT analysis is somehow invalid because the regulatory structure encourages generic substitution. But "[a]ntitrust analysis must

sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). That "admonition is particularly relevant in an industry, like the pharmaceutical industry, that is subject to extensive regulation in which Congress has balanced the protection of intellectual property and the need for competition." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 216-17 (3d Cir. 2012), *vacated and remanded on other grounds*, *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., Inc.*, 570 U.S. 913 (2013). The Hatch-Waxman Act and state substitution laws were "designed to correct for [a] price disconnect by shifting drug selection, between brand drugs and their corresponding generics from doctors, to pharmacists and patients, who have greater financial incentives to make price comparisons." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645-46 (2d Cir. 2015). This regulatory structure creates a uniquely close competitive role for generics that "cannot be seriously debated." *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003).

Defendants simply ignore this inconvenient fact. Their economic expert does not consider the competitive effects of generic entry. Nor does he assess whether generics are closer economic substitutes to AndroGel than other TRTs. Indeed, Dr. Cremieux's entire analysis focuses on the period *prior* to generic entry and ignores the *impact of* generic entry—the very competition that was excluded by Defendants' conduct. (FOF ¶¶ 457-61.) But the regulatory reality that makes generic AndroGel a more effective competitor is critically important in defining the relevant market in this case. *See United States v. Archer-Daniels-Midland, Co.*, 866 F.2d 242, 246 (8th Cir. 1988) (finding sugar and high fructose corn syrup, though functionally interchangeable, are in separate markets due to government program that artificially inflated the sugar price).

C. Injectable testosterone products are not in the relevant market

Even if the relevant market included not just AndroGel but *all* transdermal testosterone replacement products (TTRTs), Defendants still possessed monopoly power. Professor Shapiro demonstrated that Defendants had market shares of 71.5% in April 2011 and 63.3% in October 2011 (when they filed sham litigation against Teva and Perrigo, respectively). (FOF ¶¶ 356, 354-55, 408-17, 393.) Defendants' ability to maintain market shares well in excess of 60% until generic entry in late 2014, coupled with significant barriers to entry (FOF ¶¶ 358-61), suffices to infer monopoly power.[11] Defendants do not dispute Professor Shapiro's calculations. Instead, they contend that the relevant market must also include injectables. But the record adduced at trial shows that injectables had low cross elasticity with AndroGel and did not constrain Defendants' ability to charge a high price.

1. The *Brown Shoe* factors support excluding injectable testosterone products

The Supreme Court has recognized that within a broad market, "well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes." *Brown Shoe*, 370 U.S. at 325. The boundaries of such a market "may be determined by examining such practical indicia 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 prices changes, and specialized vendors." *Id.* at 325. A well-defined submarket may exist even if only some of these factors are present. *Gen. Food Corp. v. FTC*, 386 F.2d 936, 941 (3d Cir. 1967), *cert. denied*, 391 U.S. 919 (1968). Courts routinely rely on the *Brown Shoe*

[11] *See Mylan*, 838 F.3d at 437-38; *see also In re Mushroom Direct Purchaser Antitrust Litig.*, 514 F. Supp. 2d 683, 700-01 (E.D. Pa. 2007) (§ 2 case where 60% market share sufficient to present factual issue regarding monopoly power). In addition to its predominant share, other factors demonstrate AndroGel's market power in a TTRT market. No other TTRT products had a market share near AndroGel's, and Defendants were able to consistently increase AndroGel's WAC price for years without losing meaningful share to other TTRT products. (FOF ¶¶ 358-61.)

factors to define the relevant product market.[12] In this case, even though injectables are indicated for treating hypogonadism, the *Brown Shoe* factors overwhelmingly support a TTRT submarket that excludes them.

Product's Peculiar Characteristics and Uses. AndroGel and other TTRTs "are the optimal form for delivering testosterone to men with hypogonadism." (FOF ¶ 314.) They are the "simplest and most convenient way of both restoring and maintaining testosterone levels in the normal range, and they do so with minimal side effects, ease of use, and favorable pharmokinetics and offer flexible dosing options." (FOF ¶ 314.) AndroGel is painless to apply, easy to administer, has convenient application sites, and produces steady testosterone concentration levels over a 24-hour period. (FOF ¶¶ 314, 311, 315, 379, 386.)

In contrast, injectable testosterone products are painful and cause discomfort. They are administered with a "wide bore needle" that must be "inserted completely into the muscle [typically the buttocks] until the [1 ½ inch] tip of the needle is no longer visible," and inserted carefully to avoid the sciatic nerve and any blood vessels. (FOF ¶¶ 367-71.) Injectables also have an unfavorable pharmacokinetic profile characterized by significant fluctuations in testosterone levels that cause "peaks and troughs" resulting in undesirable swings in mood, libido, energy level, and aggression. (FOF ¶¶ 376-78.)

Distinct Customers. Because of the substantial differences in use and application, AndroGel and injectables appeal to very different patient types. AndroGel patients typically like the "daily routine" of "put[ting] on a small amount of gel every single day" and just want "to get back into the normal range and not try to be on the super ordinary range of testosterone." (FOF ¶¶ 381, 386.)

[12] *See, e.g., TransWeb, LLC v. 3M Innovative Props. Co.*, 16 F. Supp. 3d 385, 409 (D.N.J. 2014), *aff'd*, 812 F.3d 1295 (Fed. Cir. 2016); *United States v. Mrs. Smith's Pie Co.*, 440 F. Supp. 220, 228 (E.D. Pa. 1976) (applying *Brown Shoe* factors to define a relevant submarket of frozen dessert pies); *United States v. Am. Tech. Indus., Inc.*, No. 73-246, 1974 WL 823, at *4 (M.D. Pa. Jan. 8, 1974) (applying *Brown Shoe* factors to define a relevant submarket of artificial Christmas trees).

Injectables patients struggle with compliance issues and would rather not apply a gel daily, or prefer the "superman like high" associated with peak testosterone levels achieved at the start of a dosing cycle. (FOF ¶ 380.)

Specialized Vendors. AndroGel is prescribed in doctors' offices and applied at home. Injections are often administered in "Low-T centers," which promise a quick fix service in a "man-cave" environment. (FOF ¶ 382.) Low-T centers are designed to appeal to men by promoting a fun, sports-themed, "Hooter's-like" atmosphere, often with "female only support staff between the ages of 20-25" "dressed not as you want in a healthcare office" and "hired with strong consideration of their physical appearance." (FOF ¶ 383.) These centers typically emphasize the lifestyle aspect of treatment, not the clinical importance of the hypogonadal medical condition. (FOF ¶ 384.)

Industry or Public Recognition of a Submarket. AbbVie did not consider injectables to be an AndroGel competitor during the relevant period. For example, AndroGel's marketing director from 2010 to 2013, Mr. Jaeger, testified that, although AbbVie tracks data on injectables, he did not consider them competitors because injectables patients are "in general different, they have different insurance, they have [a] different set of expectations." (FOF ¶¶ 381, 387.) Indeed, sometime around 2010, Mr. Jaeger decided to stop trying to switch injectables patients to AndroGel. (FOF ¶¶ 380-81, 388-89.) He analyzed market research and internal patient-level prescription trends and concluded that injectables patients simply are "not our [AndroGel] patient type." (FOF ¶¶ 380-81, 388-89.) Mr. Hynd, a senior executive with "P&L" responsibility for AndroGel, similarly believed that "the injectable patient was not the same type of patient as AndroGel 1% patients." (FOF ¶ 390.) In response to direct questions from the Court, Mr. Hynd confirmed that he held this view for over thirteen years, until 2014—well after Defendants filed their sham litigation. (FOF ¶¶ 390-91.)[13]

[13] Testimony from two lower-level employees (Messrs. Gautsch and Hernandez) that they viewed injectables as competitors to AndroGel during the relevant time period is inconsistent with the overwhelming weight of the evidence. (FOF ¶¶ 392-93.)

Like AbbVie, payors also considered "injectable TRTs" to be in "a different class from topical TRTs." (FOF ¶¶ 403-05.) Teva likewise believed that generic AndroGel would compete only against branded AndroGel—not injectables or even other gels. (FOF ¶¶ 234-35.)

Distinct Prices. AndroGel and injectables do not meaningfully compete on price. When AndroGel launched in 2000, injectables had been on the market for almost fifty years, were genericized, and were generally available at the lowest-cost formulary tier. (FOF ¶¶ 395-402.) Injectables consistently were priced at a significant discount to AndroGel. (FOF ¶¶ 395-402.) Nonetheless, Defendants raised AndroGel's list price—never once lowering it—and AndroGel sales soared. (FOF ¶¶ 395-402.) According to AndroGel's marketing director, AbbVie did not look at the price of injectables when making AndroGel pricing decisions. (FOF ¶¶ 395-402.)

Sensitivity to Price Changes. Economic analysis demonstrates that AndroGel and injectables prescriptions are not sensitive to relative price changes. Professor Shapiro analyzed the change in injectables prescription volumes in response to two generic TTRT entry events—the June 2014 entry of generic Testim, and the late 2014 entry of generic AndroGel. (FOF ¶¶ 419-24.) Because of this change in relative price, patients would have been expected to switch from injectables to the gel (Testim or AndroGel) if the products were close competitors with high cross-elasticity. (FOF ¶¶ 419-24.) But the evidence shows that a decrease in the price of Testim and AndroGel had no discernible impact on injectables sales. (FOF ¶¶ 419-24.) Professor Shapiro similarly found that there was no meaningful decline in growth of injectables when the market price of AndroGel and its generic counterparts fell significantly in late 2014. (FOF ¶¶ 419-24.) Professor Shapiro also ran a regression analysis confirming that the overall upward trend in injectables sales continued unabated after the introduction of generic Testim and generic AndroGel 1%. (FOF ¶¶ 419-24.) Based on these analyses, Professor Shapiro concluded that the cross elasticity between AndroGel and injectables was relatively low. (FOF ¶¶ 419-24.)

2. Defendants' purported evidence of competition between AndroGel and injectables does not establish high cross-elasticity of demand

Despite this evidence, Defendants contend that the relevant market necessarily includes a wide range of testosterone drugs (including injectables) because they treat the same broad medical condition as AndroGel. (Dkt. 322 at 20-22.) Defendants' approach to market definition, however, confuses the notion of functional interchangeability with the antitrust analysis of "reasonable interchangeability." The relevant market does not include all functionally interchangeable products. Instead, it must be "drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small." *Times Picayune*, 345 U.S. at 612 n.31. In the pharmaceutical context, courts have routinely excluded functionally interchangeable drugs from a relevant market when they exhibit low cross-elasticity of demand.[14]

None of Defendants' purported examples of economic competition between AndroGel and injectable testosterone products actually demonstrates high cross elasticity.

a. AbbVie's internal business documents do not establish high cross-elasticity between AndroGel and injectables

Defendants point to certain internal AbbVie business documents as evidence that AbbVie viewed the market as consisting of all testosterone products. It is not surprising that AbbVie can find *some* documents that track injectables and identify AndroGel's share of all TRT products.

[14] *See, e.g.*, *SmithKline*, 575 F.2d at 1064 (cephalosporin antibiotics did not demonstrate "significant positive cross-elasticity of demand" with other antibiotics and thus were in a separate relevant market despite "a certain degree of interchangeability among all antibiotics"); *Lidoderm*, 2017 WL 5068533, at *17-21 (market limited to Lidoderm and its generic equivalents, excluding other pain relief drugs where there was "no significant cross-elasticity of demand" between them); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 388 (D. Mass. 2013) (Nexium would need to have significant positive cross elasticity of demand with other drugs to be in the same relevant market); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005) (market limited to branded and generic terazosin hydrochloride, excluding other hypertension drugs); *In re Ciprofloxacin Hydrocholoride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005) (market limited to ciprofloxacin, excluding other antibiotics in same family).

(FOF ¶¶ 474-76.) AbbVie, like any brand company, regularly conducts market research to better understand the overall marketplace. (FOF ¶¶ 329, 380-81, 384, 389, 407.) But when the brand team reported AndroGel market shares to senior management, it reported shares only of the TTRT market—without injectables. (FOF ¶ 393.) Similarly, when senior management reported market shares to the Board of Directors, it too reported shares only of the TTRT market—without injectables. (FOF ¶¶ 408-12.) And when senior management prepared for the company's quarterly earning calls with shareholders, analysts, and investors, they reviewed reports that discussed AndroGel's share of the TTRT market—once again, without injectables. (FOF ¶¶ 413-17.) This evidence confirms that AbbVie viewed injectables as far more distant competitors than generic AndroGel or even other testosterone gels.

In any event, "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes." *Staples*, 970 F. Supp. at 1075. Rather, an antitrust market includes only those products that demonstrate a high cross elasticity of demand between them. The documents Defendants cite merely use the words "TRT" or "injectables"; they do not show that patients are actually switching between AndroGel and injectables for price reasons. These documents make clear that clinical factors, such as efficacy, ease of use, patient compliance, and low side effects are the most important reasons why a physician prescribes a particular TRT product. (FOF ¶ 476.)

b. AbbVie's "co-pay" analysis does not establish high cross-elasticity between AndroGel and injectables

Defendants rely heavily on a 2010 document entitled "TRT Market: Injection Growth Analysis" to support its broad market definition in this case. Defendants did not identify who created this document. (FOF ¶¶ 425-26.) Nor is there any evidence that AbbVie relied on it to make any business decisions about the pricing or sale of AndroGel. (FOF ¶ 427.) To the contrary, the

AbbVie executives responsible for AndroGel in 2011 testified that they did not view testosterone injectables as a competitive threat at that time, or for many years thereafter. (FOF ¶¶ 387-91.)

Nonetheless, Defendants contend that this document provides proof that AndroGel and injectables exhibit high cross-elasticity of demand. (FOF ¶ 428.) It does not. The underlying analysis notes only that the increase in injectable market share is *correlated* with the change in AndroGel's co-pay. It does not purport to find any *causal* relationship between the two events. Correlation is not causation, as Defendants' economic expert acknowledges. (FOF ¶¶ 430-33.) As late as 2013, AbbVie had no idea why injectables usage was increasing. An analysis circulated to senior management, including Messrs. Stewart and Hynd, hypothesized a variety of possible non-price factors, including compliance, convenience, comfort, perceived efficacy, as well as mitigation of transference risk. (FOF ¶¶ 434-36.) In short, AbbVie's "co-pay" analysis does not establish that AndroGel and injectables are close economic substitutes.

c. AbbVie's purported evidence of formulary competition does not establish high cross-elasticity between AndroGel and injectables

Defendants also provide anecdotal evidence that AbbVie offered rebates to secure exclusive or preferred formulary placement. This evidence, however, does not prove high cross elasticity between AndroGel and injectables. First, none of these rebates responded to competition from injectables. (FOF ¶¶ 397-98, 402, 453-56.) Second, offering a lower price to increase sales is neither unusual nor inconsistent with the exercise of market power. For "[e]ven a complete monopolist can seldom raise his price without losing some sales; many buyers will cease to buy the product, or buy less, as the price rises." *Fortner Enters., Inc. v. U.S. Steel Corp.*, 394 U.S. 495, 503 (1969). As another court recently explained in concluding that a brand drug and its generic counterpart comprised the relevant market, notwithstanding similar rebating activity:

> [E]vidence that physicians and MCOs were concerned about the 'high' price of Lidoderm and prescribed more or made more available where prices were lower or significant rebates were provided does not mean that the *other* products on the

> market . . . constrained the price of Lidoderm. It simply shows that, in order to grow the market for what defendants repeatedly characterized as a unique product, price concessions and rebates for Lidoderm were necessary.

Lidoderm, 2017 WL 5068533, at *20. The fact that AbbVie may have discounted AndroGel to sell more of it provides no insight into whether AndroGel's price was already elevated due to monopoly power, or the degree of cross elasticity between AndroGel and injectables.

d. Dr. Cremieux's patient-switching study is not evidence of cross-elasticity between AndroGel and injectables

Finally, Defendants cite Dr. Cremieux's patient-switching analysis to support its broad product market. This analysis, however, shows that: (1) a majority of the 46,000 AndroGel patients in his study took only AndroGel and did not switch to any other testosterone product, and (2) among those that switched from AndroGel to another testosterone product, most chose a different testosterone gel, not an injectable. (FOF ¶ 444.) Dr. Cremieux's own study shows that only about one in five patients used both AndroGel and an injectable during the five-year period covered by his analysis. (FOF ¶¶ 437-44.) Even when there was a switch from AndroGel to an injectable, Dr. Cremieux cannot identify the *reason* for the switch. For example, Dr. Cremieux has no idea whether the patient switched because of an allergic reaction, an insurance change, undesirable side effects, pain or discomfort from an injection, or a relative price change. (FOF ¶¶ 437-42.) Without a way to determine whether price changes drove switching, Dr. Cremieux's analysis provides no insight into the degree of economic substitution between AndroGel and injectables.[15] *See Lidoderm*, 2017 WL 5068533, at *17 ("Defendants' analysis—essentially ignoring cross-elasticity—creates a vastly overbroad market."). At most, his analysis shows that *some* AndroGel patients switched to a different testosterone replacement product for *some* unidentified reason.

[15] Dr. Cremieux also concedes that his analysis does not purport to adopt any particular threshold level of substitution that must be met in order to conclude that two products are in the same relevant market. (FOF ¶¶ 446-50.)

III. This court should award $1.47 billion in equitable monetary relief and a prospective injunction to prevent similar conduct

"It is well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 170-71 (2004) (quotation omitted). The FTC seeks (1) equitable monetary relief to compensate victims of Defendants' unlawful conduct, deprive Defendants of their ill-gotten gains, and deter future similar conduct; and (2) injunctive relief to restore competitive conditions and prevent future violations.

A. Section 13(b) of the FTC Act authorizes courts to order equitable monetary remedies

Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides that "in proper cases, the Commission may seek, and after proper proof, the court may issue, a permanent injunction." Since 1982, every court to address the issue, including eight circuit courts of appeals (*see* Dkt. 319 at 22 n.12), has concluded that this general grant of authority to issue injunctions gives district courts the power to award equitable monetary relief. The Third Circuit endorsed these decisions in *FTC v. Magazine Sols., LLC*, 432 Fed. App'x 155, 158 n.2 (2011), and more recently in *FTC v. Cephalon, Inc.*, 100 F. Supp. 3d 433, 437-39 (E.D. Pa. 2015), this court reached the same conclusion.

This uniform body of precedent rests on a straightforward application of *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946) and *Mitchell v. Robert DeMario Jewelry Inc.*, 361 U.S. 288 (1960). As the Third Circuit explained in *United States v. Lane Labs-USA, Inc.*, 427 F.3d 219, 223-226 (3d Cir. 2005), these cases establish that a general statutory grant of authority to award equitable relief in government suits to enforce a regulatory enactment—such as the authority to issue an injunction—invokes all the inherent equitable powers of the district court, including the power to order monetary remedies such as restitution and disgorgement.

Defendants urge this Court to dismiss *Porter* and *Mitchell* as "outmoded" and "supplanted"

by cases rejecting implied private rights of action. (*See* Dkt. 322 at 39 (citing *Alexander v. Sandoval*, 532 U.S. 275 (2001)).) But *Lane Labs* expressly rejected the contention that *Sandoval* supplants *Porter*. *See* 427 F.3d at 235. And the Supreme Court has continued to cite *Porter* with approval. *See, e.g.*, *Kansas v. Nebraska*, 135 S. Ct. 1042, 1053 (2015); *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496 (2001).

Defendants' oblique reference to *Lane Labs*'s discussion of *Meghrig v. KFC Western, Inc.*, 516 U.S. 479 (1996), fares no better. (*See* Dkt. 322 at 39-40.) While Defendants try to analogize Section 13(b) to the citizen suit provision in *Meghrig*, *Lane Labs* clearly distinguished that citizen suit remedy from a government enforcement action brought in the public interest. 427 F.3d at 230-32; *see also Cephalon*, 100 F. Supp. 3d at 438-39.[16]

B. The record supports the FTC's calculation of Defendants' ill-gotten gains

Defendants deliberately used sham litigations to prevent generic competition to their lucrative AndroGel franchise until they could shift the market to their follow-on product, AndroGel 1.62%. Their contemporaneous documents show they expected this strategy to protect billions in revenue. Their scheme succeeded, and equitable monetary relief is necessary to compensate injured consumers and to "deprive the defendants of any of the benefits of the illegal conduct." *United States v. Grinell Corp.*, 384 U.S. 563, 577 (1966). As in previous cases, the FTC would place this money in a consumer relief fund and consumers harmed by Defendants' violation could seek compensation, with any money remaining after five years to be deposited in the U.S. Treasury.[17]

[16] Defendants also incorrectly suggest that the uniform precedent that Section 13(b) of the FTC Act authorizes equitable monetary relief is inconsistent with criminal and private remedies provided in other statutes. These remedies have coexisted with Section 13(b) for over three decades. Moreover, Section 13(b) applies equally to FTC antitrust and consumer protection suits. *See FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25, 35-37 (D.D.C. 1999) (rejecting argument that 13(b) does not apply to antitrust cases).

[17] *See, e.g.*, *FTC v. Zuccarini*, No. 01-cv-4854, 2002 WL 1378421, at *5 (E.D. Pa. Apr. 9, 2002) (awarding equitable monetary relief to be placed into consumer redress fund administered by FTC).

Courts determine the appropriate amount of equitable monetary relief using a two-step burden-shifting framework. As the Third Circuit explained in *SEC v. Teo*, 746 F.3d 90, 107 (3d Cir. 2014), at the first step the government must only "establish[] a reasonable approximation of the profits tainted by the violation." The burden then shifts to the defendant to provide "evidence that the [government's] approximation of profits was unreasonable." *Id.* at 107-08.[18]

Defendants suggest this two-step framework should not apply in government antitrust cases, pointing instead to *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017). (Dkt. 322 at 43-45.) But *Wellbutrin* addressed the distinct injury requirements applicable in antitrust suits brought by *private parties*. *Id.* at 149. *Teo* explained at length why private-damages actions are subject to a more demanding causation standard. 746 F.3d at 101-05 (rejecting direct causation standard). And the reasoning in *Teo* applies equally to a government antitrust case.[19] In either context, the fundamental causation question is "whether it is proper and fair to regard [the defendant's] profits as tainted by the wrongdoing." *Teo*, 746 F.3d at 108.

Defendants likewise err when they attempt to distinguish securities law enforcement on the grounds that such cases requires "predicting [] market responses to alternative variables," which is "at best speculative, making separating legal from illegal profits exactly a near-impossible task." (Dkt. 322 at 43) (internal citations omitted).) The same is true in antitrust enforcement suits, which

[18] *See also FTC v. Commerce Planet, Inc.*, 815 F.3d 593, 603-04 (9th Cir. 2016) (expressly adopting two-step burden-shifting framework); *FTC v. Bronson Partners, LLC*, 654 F.3d 359, 369 (2d Cir. 2011) (same); *FTC v. Febre*, 128 F.3d 530, 535 (7th Cir. 1997) (same); *FTC v. NHS Sys., Inc.*, 936 F. Supp. 2d 520, 537 (E.D. Pa. 2013) (same).

[19] Like the SEC: "the FTC as government enforcer stand[s] in different shoes" from private plaintiffs (*In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016)); the "basis of liability . . . is statutory," and so there is "no need to rely on common law theories of unjust enrichment," (*Bronson Partners*, 654 F.3d at 371); and the FTC "need not identify specific victims to whom payment is due" because it seeks "to deter violations of the laws by depriving violators of their ill-gotten gains." *Id.* at 373 (quotation omitted); *see also* 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶¶ 303a, 303e (4th ed. 2017) (noting distinctions between private and government suits).

require making assumptions about how the market would have looked absent the anticompetitive conduct. In both contexts, the well-established principle in equity applies: "the risk of uncertainty should fall on the wrongdoer whose illegal conduct created that uncertainty." *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1231-32 (D.C. Cir. 1989); *see also* 3 AREEDA, *supra* note 20, ¶ 653f ("[T]he monopolist bears the risk of the uncertain consequences created by its exclusionary acts.").

1. Contemporaneous documents provide a reasonable basis for estimating Defendants' ill-gotten gains

The evidence at trial shows that Defendants' sham lawsuits and resulting settlements kept cheaper generic competition out of the market until December 27, 2014. The foreseeable outcome was that Defendants made additional profits by avoiding generic competition, and gained time to transition many more patients to AndroGel 1.62%, producing higher AndroGel 1.62% profits even after generic AndroGel 1% entered. Indeed, the contemporaneous documents show that this is precisely what Defendants predicted.

Professor Shapiro calculated that a conservative estimate of these additional profits is $1.35 billion.[20] To arrive at this estimate, he considered the contemporaneous documents and the generic's economic incentives absent the violation to model: (1) the timing of Teva's entry; (2) the timing of Perrigo's entry; and (3) the resulting effect of those estimated entry dates on Defendants' AndroGel sales and profits.

Timing of Teva's entry. Professor Shapiro determined that, but for the sham lawsuit, it was reasonable to expect that Teva would have launched a BX-rated product in June 2012. (FOF ¶¶ 487, 505-83.) Teva would have been legally authorized to enter as early as February 14, 2012, but

[20] Professor Shapiro estimated Defendants' financial gain to be $1.23 billion as of August 2017 based on actual data, with a projected ongoing gain of $17 million per month. (FOF ¶¶ 489-98.) The total gain through March 2018 is $1.35 billion. Professor Shapiro calculated these profits by deducting revenues attributable to the sham litigation and resulting settlement from actual revenues, and then deducting incremental costs incurred due to the additional sales.

Professor Shapiro conservatively added four months for Teva to manufacture commercial launch quantities. (FOF ¶¶ 487, 512-20, 537.) At the time of the sham lawsuit, Teva and its manufacturing partner had developed a 12-13 month manufacturing timeline, leading to a May or June 2012 launch. (FOF ¶¶ 512-20.)

Professor Shapiro recognized that Teva did not launch BX-rated AndroGel 1% at its settlement entry date in December 2014. But he explained that, by that time, Teva's market incentives had changed dramatically. (FOF ¶¶ 570-83.) In 2012, Teva would have been the only generic AndroGel product on the market, and branded AndroGel 1% still would have represented 49% of the AndroGel franchise mix. (FOF ¶¶ 572-79.) By December 2014, however, Teva faced immediate competition from Perrigo and near-term entry from two other AB-rated generic AndroGel 1% products. (FOF ¶¶ 577-79.) And the remaining branded AndroGel 1% share was only a fraction of what it was in 2012. (FOF ¶¶ 573, 576.)

Timing of Perrigo's entry. Professor Shapiro determined that, but for the sham lawsuit, it was reasonable to expect that Perrigo would have launched an AB-rated generic in June 2013. (FOF ¶¶ 487, 584-613.) Perrigo could have entered the market upon FDA approval on January 31, 2013, but Professor Shapiro conservatively allotted four months for Perrigo to obtain its AB-rating from FDA (TE ratings for 505(b)(2) NDA products typically take no longer than a month). (FOF ¶¶ 487, 584-613.)

Effect on AndroGel sales. Examining contemporaneous documents and real-world data, Professor Shapiro concluded that generic AndroGel 1% entry would have had two relevant effects. First, it would have quickly eliminated most of Defendants' sales of branded AndroGel 1%. (FOF ¶ 238.) As a result, nearly all of Defendants' profits on branded AndroGel 1% after June 2012 are attributable to delay from the lawsuits and settlements. (FOF ¶¶ 477-82.) Second, as AbbVie well knew, once a cheaper generic version of AndroGel 1% was available, AbbVie would no longer be

able to convince patients to switch to the more expensive AndroGel 1.62%. AbbVie consistently forecasted that generic 1% entry would erode its 1.62% sales and market share. (FOF ¶¶ 616-22.) As one employee observed, "[o]nce the 1% generic comes out, we will no longer have the opportunity to transition that business—it will be gone." (FOF ¶ 640.) And the real-world data from generic AndroGel 1% entry confirms that it caused the 1.62% product's market share not only to flatten out, but in fact decrease slightly. (FOF ¶¶ 628-29.) Thus, Professor Shapiro conservatively concluded that, had generic AndroGel 1% launched in June 2012, AndroGel 1.62%'s market share would have frozen at its then current level—51%. (FOF ¶ 614.) Defendants' profits on AndroGel 1.62% sales beyond this 51% threshold are thus attributable to the sham lawsuits and resulting settlements. The unjust profits on these additional sales of 1.62% will continue until generic versions of AndroGel 1.62% enter the market. (FOF ¶¶ 496, 651.)

Finally, consistent with Third Circuit precedent, the FTC also seeks $122 million in prejudgment interest. *See Teo*, 746 F.3d at 109-10. An explanation of the FTC's methodology for calculating the applicable prejudgment interest is set forth in Appendix A.

2. Defendants have not shown the FTC's approximation is unreasonable

Defendants' burden to show that the FTC's estimate of the unlawful gain is unreasonable is "not simply one of carrying the ball back across the fifty-yard line by presenting a merely plausible alternative explanation for the profit." *Teo*, 746 F.3d at 107. Instead, Defendants must provide "specific evidence" and "credibly demonstrate the unreasonableness of the government's proposed disgorgement." *Id.* at 108.[21] Defendants have not met that burden.

First, Defendants suggest there were no unlawful gains whatsoever because "the allegedly sham litigation cannot be said to have caused any delay in generic competition." (Dkt. 322 at 45.)

[21] *See also SEC v. Patel*, 61 F.3d 137, 140 (2d Cir. 1995) (affirming disgorgement award of full avoided losses as "eminently reasonable" in spite of specific evidence that other events besides inside information were responsible for the losses that defendant avoided).

But Defendants' own economist testified that the conduct delayed Perrigo's generic entry and harmed consumers. (FOF ¶¶ 250-51, 484.) In any event, Defendants' "no delay" argument rests on the untenable premise that the restrictions on Teva and Perrigo's generic entry are attributable to their "voluntary" settlements, not the sham lawsuits. But Defendants cannot escape the simple fact that, but for the sham litigations, there would have been no settlements.

Second, Defendants' arguments that intervening events precluded earlier generic entry are contradicted by the evidence and are—at best—"merely plausible alternative explanations" and thus insufficient to meet their burden to show the FTC's approximation is unreasonable. *See Teo*, 746 F.3d at 107-08.[22]

Teva's entry. In the face of a wealth of contemporaneous documents, and Teva's incentives to launch its BX-rated generic AndroGel 1% product in 2012, Defendants point to testimony—years after the fact—from Senior Vice President of Trade and Generic Strategy, Maureen Cavanaugh, that *she* would not have launched a BX-rated product in June 2012. She conceded, however, that her boss at the relevant time, Tim Crew, would have been a key decision maker about whether to move forward with a BX launch and that he strongly believed a BX-rated AndroGel 1% product could be "very successful." (FOF ¶¶ 550-52, 554.) Indeed, Teva had planned for a possible BX-rated launch from the day it filed its application. (FOF ¶¶ 505-08, 553.) One of Teva's top executives explained that, while the company "hope[d] for an AB rating," it had a plan to launch and market a non-AB product. (FOF ¶¶ 554.) Teva's forecasts, including those sent to the highest levels of the company and used to create Teva's official annual work plan, consistently included scenarios for both an AB-rated and non-AB-rated product. (FOF ¶¶ 510, 524, 532.) And the contemporaneous documents

[22] *Teo* rejected an analogous argument that a tender offer "was the direct, intervening cause" of defendants' profits. *Teo*, 746 F.3d at 101, 107. The Third Circuit explained that (1) "if the issue of intervening cause is to be raised, it will normally be the defendant's burden to do so," and (2) profits can be "directly attributable to the underlying wrong" whether or not "the defendant's wrong is the exclusive or even the predominant source of the defendant's profit." *Teo*, 746 F.3d at 105-06.

from Teva's files indicate that in 2012, Ms. Cavanaugh herself had expressed a vastly different view about launching a BX-rated product. (FOF ¶¶ 545 (stating that "MC supports strongly" a BX-rated launch). Defendants' suggestion that Teva would have been unable to launch in June 2012 is similarly flawed: they rely on timelines developed long after any relevant manufacturing decisions would have been made absent the sham litigation, rather than the relevant contemporaneous documents. (*See* FOF ¶¶ 512-20.)

Perrigo's entry: Defendants argue that, even absent the sham lawsuit, Perrigo would not have entered before July 2014—the date it actually obtained an AB-rating following Perrigo's lawsuit against the FDA. But, as Perrigo's Vice President and Assistant General Counsel, Andrew Solomon, explained, Perrigo did not move more quickly in pursuing the AB-rating because the sham litigation settlement barred its entry until December 2014. (FOF ¶¶ 600-01.) Otherwise, Perrigo would have had a strong incentive to press the FDA more aggressively for an AB-rating upon receiving approval in January 2013 and would have sued the FDA sooner. (FOF ¶¶ 598-604.) Perrigo was well aware that the more time that passed, the more the overall market opportunity for generic AndroGel 1% declined. (FOF ¶¶ 602-04.) Defendants provide no evidence that the FDA would have acted *more slowly* on Perrigo's lawsuit for a TE-rating in 2013 than it did in 2014, when it knew that Perrigo could not launch its product due to the settlement. (FOF ¶¶ 595-96, 605.) Indeed, it typically takes no more than a month for FDA to award a TE rating to a 505(b)(2) product such as Perrigo's. (FOF ¶ 587.)

Conversion to 1.62%: As noted, AbbVie expected that generic AndroGel 1% entry would blunt further conversion of patients to AndroGel 1.62%, and in fact it did. (FOF ¶¶ 616-22, 628-29, 633, 640.) Defendants assert that AndroGel 1.62% would have grown at the same rate despite earlier generic entry, but neither the contemporaneous evidence nor economic data support this claim.

In sum, Defendants lack any persuasive evidence that the FTC's estimate of the unlawful gains is unreasonable. Indeed, that is why they seek to place a new, heightened causation burden on the FTC. But *Teo* explains that "whether the Appellants' profit resulted directly—from a causal perspective—from the wrongdoing or from the operation of dumb luck is not dispositive on the question of whether it is proper and fair to regard those profits as tainted by the wrongdoing." 746 F.3d at 108. Thus, while the Third Circuit acknowledged that a subsequent event was "likely one cause of the Appellants' profits" in addition to the violation, it nonetheless affirmed the district court's disgorgement order, because it "rightly judged the enforcement objectives to weigh decisively in favor of disgorgement." *Id.* at 108-09.[23] Equity supports a similar result here.

C. The Court should issue an injunction

A permanent injunction is justified when there is a "cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). While past misconduct does not automatically establish a cognizable danger of future violations, it "is highly suggestive of the likelihood of future violations and the court should therefore look at the totality of the circumstances." *In re Nat'l Credit Mgmt. Grp., L.L.C.*, 21 F. Supp. 2d 424, 440 (D.N.J. 1998). Courts consider the following factors, among others: (1) the degree of scienter involved on the part of the defendant; (2) the isolated or recurrent nature of the infraction; (3) the defendant's recognition of the wrongful nature of his conduct; (4) the sincerity of the defendant's assurances against future violations; and (5) the nature of the defendant's occupation. *See, e.g., id.* (FTC enforcement action), *citing, inter alia, SEC v. Bonastia*, 614 F.2d 908, 912 (3d Cir.1980).

The injunction proposed by the FTC is warranted here. Defendants intentionally used a

[23] *Teo* cites extensively to the Restatement of Restitution, which explains this principle: "To take an obvious example, a trustee who makes a profit from the personal use of trust assets could not escape liability in restitution by proving that he could have (and would have) made the same profit legitimately . . . ." Restatement (Third) of Restitution and Unjust Enrichment, § 51, cmt. f (2018).

baseless lawsuit as an anticompetitive weapon to keep competitors out of the market: their conduct caused hundreds of millions of dollars in consumer harm; they are well-positioned to engage in similar conduct with regard to other drugs; and they have offered no assurances against future similar actions.

Moreover, injunctions in government antitrust suits are not limited to "a simple proscription against the precise conduct previously pursued." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 698 (1978). And an appropriate order can bar conduct that would otherwise be legal. *See FTC v. Nat'l Lead Co.*, 352 U.S. 419, 431 (1957). Thus, as set forth more fully in the FTC's Pretrial Memorandum (Dkt. 319 at 17-21), injunctive relief is warranted both to prevent a similar violation in the future and, to the extent possible, to restore competitive market conditions.

Dated: March 23, 2018

Respectfully submitted,

/s/ Patricia M. McDermott

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Appendix A: Defendants' Financial Gain - Prejudgment Interest

Prejudgment interest on Defendants' financial gain is calculated by applying the IRS underpayment interest rate compounded quarterly to Defendants' financial gain total from June 2012 through March 2018.[1]

- A 3% interest rate is used for years 2013, 2014, and 2015, a 3.75% interest rate for 2016, and a 4% interest rate for 2017 and 2018.[2]
- Compounded quarterly, these rates equate to an annual percentage yield of 3.03% for 2013, 2014, and 2015, 3.80% for 2016, and 4.06% for 2017.
- The interest rate used for the first quarter of 2018 was 1%.
- Defendants' additional annual financial gain is added to the principal at the end of each calendar year.

Prejudgment Interest *(all amounts in millions of dollars)*								
	2012 (June - Dec.)	**2013**	**2014**	**2015**	**2016**	**2017**	**2018 (Jan. - Mar.)**	**Total**
Financial Gain	$79	$192	$303	$264	$252	$209	$51	$1350
Principal for Interest Calc.	--	$79	$273	$584	$866	$1151	$1407	--
Interest	--	$2.41	$8.29	$17.73	$32.92	$46.72	$14.07	$122

Total Financial Gain (including prejudgment interest): $1.472 billion

Financial gain through August 2017 is based on actual revenue data. (*See* FOF ¶¶ 489-90; PLX428 (financial gain calculation).) Financial gain beyond August 2017 is based on an ongoing rate of financial gain of $17 million per month. (*See* FOF ¶¶ 496-97.)

Alternative Scenario 1 (including $117 million in prejudgment interest)[3]: $1.426 billion

Alternative Scenario 2 (including $39 million in prejudgment interest)[4]: $529 million

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[1] *See, e.g.*, *S.E.C. v. Antar*, 97 F. Supp. 2d 576, 588-92 (D.N.J. 2000) (awarding prejudgment on disgorgement based on IRS underpayment rate compounded quarterly); *S.E.C. v. Teo*, 2011 WL 4074085, at *12 (D.N.J. Sept. 12, 2011) (awarding prejudgment interest on disgorgement), *aff'd*, 746 F.3d 90 (3d Cir. 2014).

[2] *See* IRS Rev. Rule 2017-25, at 13 (3rd column from right) (specifying IRS underpayment interest rate), available at https://www.irs.gov/pub/irs-drop/rr-17-25.pdf. For 2016, the first quarter of the year had a 3.00% rate and the other 3 quarters had 4.00%. The average of these rates is 3.75%.

[3] This scenario is based on Teva entering in June 2012 and Perrigo entering in August 2013. (*See* FOF ¶ 500.) Prejudgment interest is calculated as described above.

[4] In this scenario, Teva does not enter and Perrigo enters in June 2013. (*See* FOF ¶ 501.) Prejudgment interest is calculated as described above.

Certificate of Service

I hereby certify that on March 23, 2018, I caused Plaintiff Federal Trade Commission's Post-Trial Brief to be filed with the United States District Court for the Eastern District of Pennsylvania using the Court's ECF system.

/s/ Patricia M. McDermott
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