IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION	:	CIVIL ACTION
	:	
v.	:	
	:	
ABBVIE INC., et al.	:	NO. 14-5151

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Bartle, J. June 29, 2018

The Federal Trade Commission ("FTC") has sued defendants AbbVie Inc., Abbott Laboratories, and Unimed Pharmaceuticals LLC (collectively, "AbbVie"), as well as Besins Healthcare, Inc. ("Besins"), for violation of section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a), which prohibits "[u]nfair methods of competition in or affecting commerce."

AbbVie and Besins together own U.S. Patent No. 6,503,894 ("'894 patent") for a brand-name testosterone replacement drug, AndroGel 1%. In Count I of the complaint, the FTC alleges that AbbVie and Besins maintained an illegal monopoly through the filing of sham patent infringement lawsuits against two potential competitors, Teva Pharmaceuticals USA, Inc. ("Teva") and Perrigo Company ("Perrigo"), to delay entry into the market of their generic versions of AndroGel.[1]

1. In count II of the complaint, the FTC alleged that the settlement between Teva and the other defendants constituted an

To prevail in this antitrust litigation, the FTC must prove that defendants possessed monopoly power in the relevant market and that defendants willfully acquired or maintained that power. See Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 433 (3d Cir. 2016). Here, the FTC asserts that defendants maintained their AndroGel monopoly through the filing of sham litigation against Teva and Perrigo. To prove its case, the FTC must establish: (1) the lawsuits filed by defendants against Teva and Perrigo were objectively baseless; (2) defendants subjectively intended to file such lawsuits; and (3) that defendants possessed monopoly power in the relevant market. See Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993) ("PRE"); In re Wellbutrin XL Antitrust Litig., 868 F.3d 132, 148-49 (3d Cir. 2017).

On September 15, 2017, this court ruled that defendants' infringement lawsuits against Teva and Perrigo were objectively baseless and entered summary judgment in favor of the FTC on this issue. See FTC v. AbbVie Inc., No. 14-5151, 2017 WL 4098688, at *11 (E.D. Pa. Sept. 15, 2017) (Doc. # 300).

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improper restraint of trade in violation of the FTC Act. On May 6, 2015, this court granted the motion of defendants to dismiss count II of the complaint, as well as count I to the extent it was premised on the settlement agreements with Teva. As a result, Teva was dismissed as a defendant in this action and only the claim involving sham lawsuits in Count I remains.

Thereafter the court held an approximately three-week nonjury trial on the issues of subjective intent and monopoly power. The court now makes the following findings of fact and conclusions of law.

I

To understand the claim presented in this action, we first set forth the regulatory scheme that governs the testing and approval of new drugs in the United States. That framework is governed by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, which is commonly known as the Hatch-Waxman Act, 21 U.S.C. § 355 and 35 U.S.C. § 271. See Pub. L. No. 98-417, 98 Stat. 1585.

A drug manufacturer seeking to market a new drug must obtain approval from the U.S. Food and Drug Administration ("FDA"). See 21 U.S.C. § 355(a). There are three pathways established by the FDCA and Hatch-Waxman: (1) a section 505(b)(1) New Drug Application ("NDA"); (2) a section 505(b)(2) NDA; and (3) a section 505(j) Abbreviated New Drug Application ("ANDA").

An NDA is a full-length application containing information on the drug's safety and efficacy, an explanation of the drug's ingredients, a description of the methods used in the manufacture and packaging of the drug, samples of the proposed

labeling, and samples of the drug itself. See id. § 355(b)(1). The NDA must also contain a list of any patents covering the drug. Id.

Once the FDA has approved a new brand-name drug, an applicant with a generic version of that drug can obtain approval through the use of abbreviated procedures. See 21 U.S.C. § 355(j). Most commonly, the applicant will file a section 505(j) ANDA stating, among other things, that the generic has the same active ingredients and is biologically and pharmacologically equivalent to the brand-name drug. Id. § 355(j)(2)(A). The applicant may then rely on the safety and efficacy data contained in the NDA for the brand-name drug. Id.

In the alternative, the applicant with a generic drug may file a section 505(b)(2) NDA, which is a hybrid between an ANDA and a full NDA. A section 505(b)(2) NDA is used for generics that have slight modifications from the brand-name drug. See 21 C.F.R. § 314.54. The applicant must submit additional data to the FDA demonstrating that any differences between the brand-name drug and the generic will not affect safety and efficacy but can otherwise avoid the other studies necessary for a full NDA application. Id.; see also Ethypharm S.A. France v. Abbott Labs., 707 F.3d 223, 227 (3d Cir. 2013). Because the Hatch-Waxman Act allows the applicant to "piggy-back" on the efforts for the approval of the brand-name

drug, its provisions "speed the introduction of low-cost generic drugs to market" and thereby promote drug competition. FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013) (quoting Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012) (alteration omitted)).

Once the FDA approves a generic drug, the applicant may request from the FDA a therapeutic equivalence ("TE") rating. A TE rating is a code that reflects the FDA's determination regarding whether a generic product is pharmaceutically and biologically equivalent to the reference-listed brand-name drug. Products that are determined to be therapeutically equivalent are assigned an "A" or "AB" rating. Generic products for which therapeutic equivalence cannot be determined are assigned a "B" or "BX" rating.[2] An "A" or "AB" rating is extremely desirable. Every state in the

2. "A" and "B" are the two general categories into which the FDA sorts drugs when evaluating therapeutic equivalence. Within these two categories are various subcategories depending on the type of product (i.e., oral, injectable, solution, or powder) and other factors. For our purposes we will focus on "AB," which means "actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence," and "BX," which is "specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence." See U.S. Food & Drug Admin., Center for Drug Evaluation & Research, Approved Drug Products with Therapeutic Equivalence Evaluations, at xiii, xx (38th ed. 2018), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#_ftn4.

United States has generic substitution laws. See Mylan Pharm. Inc., 838 F.3d at 428. These laws "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written." Id. (internal quotation marks and citations omitted).

The Hatch-Waxman Act also provides specialized procedures for parties to resolve intellectual property disputes. In submitting an ANDA or section 505(b)(2) NDA, an applicant must certify that any patent currently in force for the referenced brand-name drug "is invalid or will not be infringed by the manufacture, use, or sale" of the proposed generic. 21 U.S.C. § 355(j)(2)(A)(vii). This certification is commonly referred to as a paragraph IV notice. Actavis, 570 U.S. at 143.

The paragraph IV notice "automatically counts as patent infringement" and thus often leads to an infringement suit by the patentee. Id. (citing 35 U.S.C. § 271(e)(2)(A)). Upon receiving the paragraph IV notice, the patentee has 45 days to determine whether to file suit for infringement. 21 U.S.C. § 355(j)(5)(B)(iii). The notice often includes an offer of confidential access whereby outside counsel for the patentee may review the application submitted to the FDA by the generic

applicant to facilitate a determination regarding infringement litigation. If the patentee files an infringement suit against a generic entity within this 45-day period, the FDA is required to withhold approval of the generic drug for 30 months from receipt of the paragraph IV notice or until the infringement action is resolved in the district court, whichever occurs first. Id.

II

AndroGel is a brand-name transdermal testosterone gel product approved by the FDA for the treatment of hypogonadism, a clinical syndrome that results from failure of a man's body to produce adequate amounts of testosterone. It is estimated that this condition affects 2-6% of the adult male population in the United States. Hypogonadism is a lifelong condition which causes decreases in energy and libido, erectile dysfunction, and changes in body composition including decreased bone density. Patients with hypogonadism are typically treated with testosterone replacement therapy ("TRT") whereby exogenous testosterone is administered.

The first TRTs approved by the FDA were injectables in which testosterone is dissolved in a liquid and then injected into a muscle of the body. Injectable testosterones were introduced in the 1950s and have been available in generic form for decades. They are administered every one to three weeks.

While many patients receive injections at their doctors' office, some patients opt to self-administer injections at home or visit clinics specializing in TRT commonly known as "Low-T" centers. Because they are available in generic form, injectables generally require a five to ten dollar patient copay on most insurance plans and thus are the least expensive treatment method for hypogonadism.

Testosterone injections typically require two needles: a withdrawal needle and an injection needle. The withdrawal needle is typically a 20-gauge wide bore and 1-inch long needle required to withdraw the testosterone from the glass vial. After withdrawal, the patient must switch to a 21- or 22-gauge narrow bore and 1.5-inch long needle to administer the injection. This needle must then be inserted deep into a muscle, typically the buttocks or thigh, until the needle is no longer visible. Because a deep intramuscular injection is required, this treatment method may cause pain and discomfort which will vary from patient to patient. Injectables generally provide an initial peak in testosterone level at the time of injection followed by troughs or valleys as the injection wears off. This variation in testosterone level may cause swings in mood, libido, and energy.

TRTs may also be administered through a gel or patch which is applied to the skin and thereby absorbed into the

bloodstream. This group of products is known as topical testosterone replacement therapies or transdermal testosterone replacement therapies ("TTRTs"). Androderm, the first testosterone patch, was released in the 1990s. It is applied once a day to the back, abdomen, thighs, or upper arms. The patch formulation delivers a steady level of testosterone without the peaks or valleys associated with injectables. It is relatively easy to apply, although the patch may cause skin irritation in some patients and may be visible depending on where it is applied. Testoderm, a testosterone patch worn on the scrotum, was also introduced in the 1990s.

AndroGel was launched in 2000 as the first FDA-approved testosterone gel. It is applied once a day to one or more application sites, including the upper arms, shoulders, and abdomen. AndroGel comes in two strengths: (1) 1%, which was the original formulation launched in June 2000; and (2) 1.62%, which was first sold in May 2011. At the time AndroGel 1% came on the market in 2000, it was available only in sachets. In 2004 it became available in a metered-dose pump. AbbVie discontinued manufacture of the AndroGel 1% pump in December 2013.

AndroGel 1% was developed through a collaboration between Unimed and various subsidiaries of Besins' parent company. At the time of its launch, AndroGel 1% was marketed

and distributed by Solvay Pharmaceuticals, Inc. ("Solvay"), the parent company of Unimed. Abbott Laboratories acquired Solvay and Unimed in February 2010. At that time Solvay was renamed Abbott Products Inc. In January 2013, AbbVie assumed all of Abbott's proprietary pharmaceutical business, including AndroGel 1%.

As the first gel in the market, AndroGel achieved great commercial success and quickly became one of Solvay's "flagship" products. In 2009, AndroGel's U.S. net sales were approximately $604 million and in 2010, that number grew to $726 million. After AbbVie[3] acquired Solvay and Unimed in 2010, sales of AndroGel continued to grow, and AndroGel became one of AbbVie's blockbuster drugs. In 2011, U.S. net sales for AndroGel reached $874 billion and in 2012, U.S. net sales surpassed $1.15 billion. In 2013, AndroGel's U.S. net sales were approximately $1.035 billion while in 2014, net sales totaled $934 million. After entry of generic versions of AndroGel 1%, AndroGel U.S. net sales fell to $694 million in 2015. Throughout this time, AbbVie maintained a high profit margin of approximately 65% on AndroGel.

Transdermal gels have several advantages over the other forms of TRTs. A gel is relatively easy for a patient to

3. As stated above, AbbVie acquired all of Abbott's proprietary pharmaceutical business in 2013. Hereafter we will refer to Abbott as "AbbVie."

apply without the potential for pain or discomfort associated with an injection. It also allows the patient to maintain a steady testosterone level without peaks and troughs. As compared to the patch form of testosterone, it has a lower rate of irritation and is not visible.

Gels such as AndroGel, however, are not without some drawbacks. There is a serious but rare risk of secondary exposure associated with gels, whereby testosterone may be transferred from a patient to others, including women and children, through skin-to-skin contact. Precautions such as washing hands after application and covering the application site with a t-shirt can prevent such exposure. Gels may also cause skin irritation in some patients. Finally, some patients may dislike having to apply the gel daily.

After AndroGel was released in 2000, several other brand-name TTRTs were launched by competing pharmaceutical companies. Testim, a 1% gel available in a five gram tube, was approved in 2002. In 2011, two brand-name testosterone 2% gels were brought to market: (1) Fortesta, a metered-dose pump product applied to the thighs; and (2) Axiron, a solution that is dispensed from a metered-dose pump and is applied to the underarms using a silicon applicator. And in 2014 Vogelxo, another brand-name low-volume testosterone gel, was launched along with an authorized generic version of the same product.

In addition to injectables and TTRTs, several other forms of TRT have been approved by the FDA. Striant, a buccal testosterone tablet that is applied twice daily to gums, was released in 2003. Testopel, a pellet that is surgically inserted in the hip, buttocks, or thigh every three to six months, was approved in 2008. And in 2014 the FDA approved Natesto, a nasal testosterone spray that is administered three times a day.

AndroGel 1% is protected by the '894 patent. That patent is owned by Besins and by Unimed, which as discussed above, was a wholly-owned subsidiary of Solvay until 2010. Laboratoires Besins Iscovesco SA, a subsidiary ultimately owned by Besins' parent company and now known as Laboratoires Besins Iscovesco SAS ("LBI SAS"), licensed to Unimed certain intellectual property rights to AndroGel. In return, Unimed was obligated to pay a royalty on net sales of AndroGel. Under a separate supply agreement, LBI SAS agreed to manufacture and to sell to Unimed AndroGel products for sale and distribution by Unimed in the United States.[4]

We have previously discussed the prosecution history of the '894 patent in our September 15, 2017 Memorandum

4. AbbVie and Besins later amended the license and supply agreements to include AndroGel 1.62%. Royalties on U.S. sales of AndroGel 1.62% are paid to LBI SAS or Besins Healthcare Luxembourg SARL ("BHL SARL").

(Doc. # 300) and therefore need not restate it in detail here. See AbbVie, 2017 WL 4098688, at *1-4. In summary, the initial patent application that resulted in the '894 patent claimed a pharmaceutical composition of a testosterone gel including a penetration enhancer, which according to the patent application "is an agent known to accelerate the delivery of the drug through the skin into the bloodstream." Id. at *1-2. The patent application claimed all penetration enhancers including isopropyl myristate, the penetration enhancer actually used in AndroGel. Id. at *2. The patent examiner at the U.S. Patent and Trademark Office ("PTO") rejected the claim which included all penetration enhancers. Id. Thereafter, Unimed and Besins submitted an amendment narrowing their claim encompassing all penetration enhancers to a claim naming only twenty-four specific penetration enhancers, including isopropyl myristate. Id. at *2-3. After a series of additional amendments, Unimed and Besins further narrowed their claim to one penetration enhancer, isopropyl myristate, only. Id. at *3. On this basis, the '894 patent was issued on January 7, 2003. Id. at *4. It is scheduled to expire on January 6, 2020.

As is often the case with successful pharmaceutical products, generic manufacturers sought entry into the market to compete with AndroGel. In December 2008, Perrigo submitted to the FDA two ANDAs for a generic testosterone 1% gel in both pump

and packet form. The ANDAs referenced AndroGel and the '894 patent. However, the Perrigo product contained isostearic acid as its penetration enhancer rather than AndroGel's isopropyl myristate claimed in the '894 patent.

Pursuant to the procedures established by the Hatch-Waxman Act, Perrigo in June 2009 served paragraph IV notices on both Unimed and Besins as co-owners of the '894 patent. In those notices, Perrigo disclosed the filing of its ANDAs for a generic 1% testosterone gel. Perrigo further asserted that its ANDAs would not infringe the '894 patent for AndroGel because the Perrigo products did not contain "about 0.1% to about 5% isopropyl myristate," the sole penetration enhancer formulation claimed in the patent. Perrigo also stated in its notices that the prosecution history of the '894 patent would estop Unimed and Besins from filing a patent infringement claim. Finally, Perrigo offered to provide to outside counsel representing Unimed and Besins confidential access to the full ANDAs.

Thereafter Unimed and Besins, along with Unimed's parent Solvay, jointly retained the law firm of Finnegan, Henderson, Farabow, Garrett and Dunner, LLP ("Finnegan, Henderson") to assess the Perrigo paragraph IV notices and the Perrigo ANDAs. Finnegan, Henderson obtained confidential access to the full ANDAs and confirmed that Perrigo's ANDAs contained

isostearic acid, not isopropyl myristate. Besins also separately retained the law firm of Foley and Lardner LLP ("Foley and Lardner"). Outside counsel at Foley and Lardner did not receive confidential access to the ANDAs.

On July 17, 2009, Solvay and Unimed issued a press release announcing that "[a]fter careful evaluation" the companies had decided not to file a patent infringement suit against Perrigo. The press release explained that the Perrigo product "contains a different formulation than the formulation protected by the AndroGel patent." It further stated that "[t]his distinction played a role in the company's decision not to file patent infringement litigation at this time" but "the company does not waive its right to initiate patent infringement litigation at a later stage based on new or additional facts and circumstances." The ultimate decision not to file suit was made by Solvay in-house attorneys Shannon Klinger, Peter Edwards, and Dominique Dussard. Besins also determined that it was "standing down" from bringing an infringement suit but did not join in the Solvay press release or issue its own public announcement.

Sometime in 2009, the FDA became aware of cases of accidental secondary exposure of children to TTRTs due to skin-to-skin transference from patients using these products. Based on this information, the FDA required safety-related labeling changes and a Risk Evaluation and Mitigation Strategy

("REMS") for transdermal testosterone gel products currently on the market. Thereafter Auxilium Pharmaceuticals, Inc., the manufacturer of Testim, submitted a citizen petition to the FDA regarding a generic version of Testim. To facilitate the drug approval process, the FDA permits private entities to provide comments and opinions by filing citizen petitions. 21 C.F.R. § 10.30. A petition can request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." Id.

In response to the Auxilium citizen petition, the FDA directed on August 26, 2009 that any application for a generic testosterone gel product containing a penetration enhancer different from the referenced brand-name drug would be required to be submitted as a section 505(b)(2) NDA rather than an ANDA. The application must also include certain additional safety studies regarding the risk of secondary exposure.

On April 9, 2010, AbbVie, now the owner of AndroGel, filed its own citizen petition with the FDA. In that petition, AbbVie noted the FDA's ruling in response to the Auxilium citizen petition regarding all generic testosterone products containing penetration enhancers different than those contained in the reference-listed brand-name drug. AbbVie thus sought assurance from the FDA that Perrigo would be required to resubmit its 2009 ANDAs referencing AndroGel as section

505(b)(2) NDAs. AbbVie also requested that Perrigo be directed to provide to the AndroGel patent holders a new paragraph IV notice. Finally, it asked that Perrigo be required to conduct transfer and hand-washing studies as set forth in the FDA's response to the Auxilium petition.

On October 4, 2010, the FDA granted in part and denied in part AbbVie's citizen petition. The FDA directed that any application by a generic manufacturer for a product referencing AndroGel that contained a different penetration enhancer must be submitted as a section 505(b)(2) NDA. It also agreed that the applicants would be required to submit new paragraph IV notices.

On January 13, 2011, Teva filed a section 505(b)(2) NDA for its generic version of AndroGel 1% which described a different penetration enhancer, isopropyl palmitate, than AbbVie used in its brand-name AndroGel. The application sought approval to manufacture and to distribute the product in two different sachet sizes as well as in a pump form. This application superseded an ANDA for generic testosterone that Teva had filed on December 29, 2008, prior to the FDA's ruling on the Auxilium citizen petition.

On March 16, 2011, Teva sent to Solvay, AbbVie, Unimed, and Besins a paragraph IV notice regarding its section 505(b)(2) NDA. Teva asserted that its product did not infringe the '894 patent because "the Teva formulation does not contain

isopropyl myristate," the penetration enhancer claimed in the '894 patent. Teva laid out the prosecution history of the '894 patent and its position that, because the claims of the '894 patent were narrowed to disclose only isopropyl myristate, "the prosecution history estops the patentees from asserting infringement under the doctrine of equivalents." Teva also offered confidential access to certain information regarding its section 505(b)(2) NDA to allow the patent holders to assess whether an infringement action would have merit.

AbbVie retained outside counsel at the law firm of Munger, Tolles and Olson LLP ("Munger Tolles") to evaluate the Teva paragraph IV notice. Counsel at Munger Tolles was provided with access to the Teva section 505(b)(2) NDA and provided in-house counsel at AbbVie with its opinion. Besins again retained Foley and Lardner to evaluate the notice. Foley and Lardner was supplied with confidential access to the NDA and submitted its analysis to Besins.

On April 29, 2011, within 45 days after receiving the paragraph IV notice, AbbVie, Unimed, and Besins commenced an action in the U.S. District Court for the District of Delaware alleging the Teva's product infringed the '894 patent.[5]

5. As one witness explained at trial, most patent infringement suits are filed in either the District of Delaware or the District of New Jersey because "they tend to be slow-moving dockets."

See Abbott Prods., Inc. v. Teva Pharm. USA, Inc., No. 11-384 (D. Del. Apr. 29, 2011). The suit against Teva triggered the Hatch-Waxman automatic stay of FDA approval of the Teva product. Consequently, the FDA could not approve Teva's generic testosterone drug for 30 months after March 16, 2011 or until September 17, 2013 unless the district court resolved the lawsuit sooner.

The intellectual property ("IP") litigation group at AbbVie had direct accountability for patent litigation. Four in-house patent attorneys in that group had final responsibility for evaluating the Teva paragraph IV notice and made the decision to file the patent infringement suit against Teva: (1) Johanna Corbin; (2) Adam Chiss; (3) Anat Hakim; and (4) Jose Rivera. All of these attorneys had extensive experience in patent law and with AbbVie. Corbin is currently vice president of the IP group and the lead IP attorney at AbbVie who has worked in that group since 2005. Chiss was divisional vice president of IP litigation and before that had served as senior counsel in IP litigation. Anat Hakim was divisional vice president and associate general counsel of IP litigation at AbbVie and previously had been a partner at Foley and Lardner. Finally, Rivera was a divisional vice president of the IP group and had previously worked in private practice. The general counsel of AbbVie, Laura Schumacher, also

signed off on the final decision. Schumacher has been with AbbVie since 2005. No business persons at AbbVie were involved in the decision to sue. At trial, AbbVie presented evidence that the decision whether to file a complaint is always made solely by the legal department and does not require approval from management.

As for Besins, the decision to sue was made by Thomas MacAllister, its in-house counsel. MacAllister is an experienced intellectual property attorney who previously worked as a patent examiner at the U.S. Patent and Trademark Office. Besins conferred with outside counsel as well as AbbVie about the Teva product and potential litigation. Like AbbVie, Besins or its agents had confidential access to the portions of Teva's NDA that disclosed the formulation of its product prior to filing the complaint against Teva. In addition, in-house counsel for Besins conferred with in-house counsel for AbbVie before making the decision to initiate the lawsuit.

Around this time AbbVie also was preparing for FDA approval and launch of its low-volume formulation of AndroGel, known as AndroGel 1.62%. The FDA issued final approval of brand-name AndroGel 1.62% on April 29, 2011, and AbbVie began selling it in May 2011. The 1.62% formulation is indicated for the same condition and has the same active ingredient but less total gel. Sales of AndroGel 1.62% grew more slowly after

launch in 2011 than defendants initially anticipated but by June 2012 constituted the majority of total AndroGel sales. AndroGel 1.62% accounted for total AndroGel sales as follows: 57% during the last 7 months of 2012, 67% in 2013, 76% in 2014, and 83% in 2015.

In June 2011, Teva submitted a case status report proposing a schedule for early summary judgment proceedings in the patent infringement suit in the District of Delaware. AbbVie, Unimed, and Besins filed a supplemental case status report opposing any summary judgment proceedings. On August 1, 2011, before discovery had commenced, Teva filed a motion for summary judgment. Teva asserted that based on prosecution history estoppel there could be no viable claim of infringement of the '894 patent. On October 25, 2011, the court set trial on the issue of prosecution history estoppel for May 21, 2012.

On August 18, 2011, AbbVie filed a citizen petition with the FDA requesting that it refrain from granting a therapeutic equivalence rating to section 505(b)(2) products referencing AndroGel, including Teva's testosterone product, or in the alternative, requesting that it assign the product a BX rating. If a BX rating was assigned, there could be no automatic substitution at the pharmacy under state law.

Meanwhile, on July 4, 2011 Perrigo re-filed with the FDA its application for approval of a generic testosterone 1%

gel as a section 505(b)(2) NDA. On September 20, 2011, Perrigo sent AbbVie, Unimed, and Besins a new paragraph IV notice. As in its 2009 notice, Perrigo certified that the '894 patent was not infringed because its generic testosterone product did not contain "about 0.1% to 0.5% isopropyl myristate," the penetration enhancer claimed in the patent.

Perrigo's letter also explained that the prosecution history of the '894 patent precluded any valid infringement claim. Perrigo stated that "a lawsuit asserting the '894 patent against Perrigo would be objectively baseless and a sham, brought in bad faith for the improper purpose of, inter alia, delaying Perrigo's NDA approval." It further asserted that "a bad faith motive for bringing such a suit would be particularly apparent in light of representations and admissions made, inter alia, in [Solvay's] Friday, July 17, 2009 press release." Perrigo offered confidential access to certain information regarding the NDA. Again, AbbVie and Unimed retained Munger Tolles as outside counsel to analyze Perrigo's NDA. Foley and Lardner evaluated Perrigo's NDA on behalf of Besins and also issued its opinion to Besins.

On October 31, 2011, AbbVie, Unimed, and Besins filed suit in the District of New Jersey alleging that Perrigo's 1% testosterone gel infringed the '894 patent. See Abbott Prods., Inc. v. Perrigo Co., 11-6357 (D.N.J. Oct. 31, 2011). As in the

Teva litigation, the filing of the complaint against Perrigo triggered an automatic 30-month stay under the Hatch-Waxman Act. Thus, absent a court ruling or settlement resolving the litigation, the stay would preclude final FDA approval of the Perrigo generic testosterone product until March 20, 2014.

The same four AbbVie in-house attorneys as had made the decision to sue Teva again made the decision to file the suit against Perrigo with approval from the same general counsel. They conferred with outside counsel, who had confidential access to the Perrigo section 505(b)(2) NDA. No AbbVie business person was involved in the decision to file the Perrigo action. After consultation with AbbVie and outside counsel, Besins' same in-house attorney made the decision that it would join in bringing the Perrigo litigation.

AbbVie reached out to Teva to discuss an amicable resolution of the dispute before the complaint was filed in April 2011. Perry Siatis, an in-house attorney for AbbVie, was the main negotiator on behalf of AbbVie.[6] At that time, Siatis was Divisional Vice President of the IP strategy group and head intellectual property attorney at AbbVie. Although that initial contact did not lead to a settlement, AbbVie again raised the subject with Teva during an in-person meeting on October 28,

6. Siatis had no involvement in the decision to sue either Teva or Perrigo for patent infringement.

2011, three days after the court in the Teva litigation had set a trial date. Although Teva at the outset pushed for an entry date as early as September 17, 2013, the final date of the 30-month Hatch-Waxman stay, AbbVie countered with an entry date of January 1, 2015. AbbVie thereafter agreed to an entry date of December 27, 2014, which would allow Teva to make some sales in 2014. On December 20, 2011 the parties reached a final settlement in the Teva litigation, in which Teva received a license to launch its product beginning December 27, 2014.[7]

While the Teva negotiations were ongoing, settlement negotiations were taking place in the Perrigo litigation. Sometime on or before November 3, 2011, Siatis approached Perrigo to initiate settlement negotiations. On December 8, 2011 the parties executed a binding term sheet, which included the dismissal of all claims and counterclaims with prejudice. In addition, AbbVie agreed to pay Perrigo $2 million dollars as reasonable litigation expenses.

During the negotiations Perrigo pushed for an earlier entry date but was unsuccessful and ultimately accepted an offer from defendants of January 1, 2015. However, the settlement

7. During this time AbbVie was negotiating with Teva regarding disputes related to two other drugs, Simcor and TriCor. Agreements related to Simcor and TriCor were executed on the same day as the AndroGel settlement. However, there is no evidence that these negotiations were linked to the AndroGel settlement.

contained an acceleration clause whereby Perrigo would be permitted to launch if another generic came to market. Andrew Solomon, general counsel for Perrigo, explained that the company had been monitoring the Teva litigation and thought there was "a very good probability Teva could prevail" at the trial scheduled for May 2012 and thereafter launch its product, so "that would provide a much earlier Perrigo license date." As a result of the Teva settlement, Perrigo's licensed entry date was moved up to December 27, 2014 under the acceleration clause.

On February 14, 2012, the FDA approved Teva's section 505(b)(2) NDA for the packet presentation of its TTRT product. During review of the application, the FDA had identified a potential safety concern with the packaging used in the pump presentation of the drug.[8] In response to this concern, Teva withdrew the pump presentation from its application. As a result, the FDA approved Teva's product in sachet form only.

After receiving FDA approval, Teva waited for the FDA Office of Generic Drugs to assign a TE rating for its product. On December 21, 2012, AbbVie filed a citizen petition supplement requesting that the FDA refrain from granting a TE rating to Teva's product or, in the alternative, grant it a BX rating.

8. Specifically, during a meeting on June 27, 2011, the FDA recommended that Teva withdraw its pump configuration with the option to resubmit it as a post-approval amendment once the issue was resolved.

Later, on January 31, 2013, the FDA approved Perrigo's section 505(b)(2) NDA for its generic version of AndroGel 1%. Thereafter the FDA considered a TE rating for Perrigo's generic product. During this period, AbbVie filed an additional citizen petition on December 11, 2013. The December 11, 2013 citizen petition supplemented the August 18, 2011 citizen petition and requested that the FDA issue a BX rating for Perrigo's product.

In the months before its December 27, 2014 licensed entry date approached, Perrigo took a number of steps to follow up with the FDA regarding its TE rating. Perrigo sent three letters to the FDA. It received no response other than being informed that the FDA needed more time to evaluate the therapeutic equivalence of the product.

Perrigo filed a lawsuit against the FDA in the United States District Court for the District of Columbia on March 21, 2014. See Perrigo Israel Pharm. Ltd. v. U.S. Food & Drug Admin., No. 14-475 (D.D.C. Mar. 21, 2014). Perrigo asserted that the FDA had engaged in unreasonable delay. It requested that the court enter a mandatory injunction compelling the FDA to publish a TE rating for Perrigo's NDA product as soon as possible. On April 10, 2014, the FDA filed its first response to the lawsuit. The FDA contended that "Perrigo has itself obviated the need for a prompt decision by reaching an agreement with the innovator not to market until December 2014." The FDA

further represented that it expected to issue a TE rating for Perrigo's product "by July 31, 2014—some five months before Perrigo's planned product launch."

Prior to the deadline, on July 23, 2014, the FDA determined that Perrigo's section 505(b)(2) NDA product was therapeutically equivalent to AndroGel and issued it an AB rating.[9] That same day, however, the FDA assigned a BX rating to Teva's product. Specifically, the FDA concluded that the data submitted by Teva was "insufficient to determine TE [therapeutic equivalence] to AndroGel 1%." As a result, under all state laws the Perrigo generic testosterone product would be auto-substitutable at the pharmacy for brand-name AndroGel 1% prescriptions, but the Teva product would not.

Perrigo launched its AB-rated generic version of AndroGel 1% on December 27, 2014, its licensed entry date under the settlement agreement with defendants. Perrigo would not have entered the market without first receiving a decision from the FDA on its TE rating. Perrigo achieved its goal to obtain an AB rating for its product and would have challenged the FDA had it received only a BX rating.

Teva, in contrast, never set in motion the sale of its generic testosterone replacement product. Timothy Crew, Teva's

9. Perrigo voluntarily dismissed the lawsuit on July 24, 2014, one day after the FDA issued its TE rating to Perrigo.

Commercial Operations Officer from the time that Teva filed its NDA until late 2012, was a strong proponent of bringing the Teva product to market even absent an AB rating. Crew identified a "'brand' push through managed care" marketing strategy in which Teva would go directly to managed care organizations and pharmacy benefit managers in an attempt to negotiate preferential formulary placement for a non-AB rated product and thereby influence physicians' prescribing decisions.[10] Crew considered the Teva generic testosterone product his "pet project."

Teva underwent management changes in November 2012. Crew left the company, and Alan Oberman became the new Chief Executive Officer of Teva. Shortly thereafter, Maureen Cavanaugh, Vice President of Customer Operations and Marketing for Teva, recommended to Oberman that Teva not launch the BX rated product. Cavanaugh explained that Teva's generic group had no sales force and had never launched a non-AB rated retail pharmacy product. She further opined that a BX-rated product with no perceived advantage over brand-name AndroGel would

10. A formulary is a "listing of medications for which an insurer or managed care organization provides coverage." See Saltzman v. Indep. Blue Cross, 384 F. App'x 107, 109 n.3 (3d Cir. 2010) (citations omitted). Formularies generally divide medications into tiers with different copays for each tier. See id. at 109. Typically, the first tier includes generic medications with the lowest copay, while higher tiers include brand-name drugs with higher copays. See id.

capture only 10-11% of the brand-name product's sales and perhaps less than 5%.

Teva faced other obstacles to launching its BX-rated product. Teva had contracted with Cipla, an India-based company, to manufacture its generic testosterone replacement drug. Before it could begin the manufacturing process, Cipla required a $10 million capital expenditure from Teva, which could be paid up front or over time through a 35% royalty on sales. Cipla projected that it would require 12-24 months or more to achieve operational readiness. Pursuant to another contract, Teva was also required to pay a royalty of 5-7.5% on sales to a third company, BioSante.

As discussed above, Teva had received FDA approval for the sachet presentation of its product only. At the time that Teva withdrew the pump presentation from consideration by the FDA, pump sales made up 40-50% of AndroGel sales. Thus the failure to obtain approval for a pump product had a negative impact on the commercial viability of Teva's product.

Ultimately, on May 1, 2015, Teva transferred ownership of the 505(b)(2) NDA product and all intellectual property necessary to market the product to ANI Pharmaceuticals, Inc. ("ANI"), its development partner.

III

To prevail on its claim of illegal monopolization, the FTC must establish that defendants filed sham litigation against Teva and Perrigo as outlined by the Supreme Court in PRE. Whether litigation is a sham involves a two part test. We have already resolved the first part of the test, that is, that the lawsuits were objectively baseless in the sense that "no reasonable litigant could realistically expect success on the merits." AbbVie Inc., 2017 WL 4098688, at *4 (quoting PRE, 508 U.S. at 60). The second part of the test requires the court to decide whether defendants subjectively intended to interfere directly with a competitor's business interests by using the government process as an anticompetitive weapon. PRE, 508 U.S. at 60-61. Only if the lawsuits were both objectively and subjectively baseless will the FTC have demonstrated that defendants engaged in sham litigation.

As stated above, we have already determined that the lawsuits against Teva and Perrigo in 2011 were objectively baseless as a matter of law in light of the undisputed facts concerning the prosecution history of the '894 patent. See AbbVie Inc., 2017 WL 4098688, at *1-4, *11. We found that Unimed and Besins secured the '894 patent only by amending their patent application from an initially broad claim covering all penetration enhancers to a narrow claim covering only one

penetration enhancer—isopropyl myristate at a particular concentration. See id. at *6-8, *10. Instead of isopropyl myristate, Teva used isopropyl palmitate and Perrigo used isostearic acid as a penetration enhancer in their generic versions of AndroGel. We concluded that "any reasonable person who reads the prosecution history of the '894 patent can reach no other conclusion than that the applicants have purposefully and not tangentially excluded isopropyl palmitate and isostearic acid as penetration enhancers equivalent to isopropyl myristate." Id. at *11.

We emphasized that "the purpose of prosecution history estoppel is to protect the patentees' competitors from patent infringement litigation based on the doctrine of equivalents if the prosecution history demonstrates that an equivalent not specifically disclosed in the patent has been purposefully and not tangentially excluded from its scope." Id. at *11. Given the patent prosecution history for the '894 patent, AbbVie and Besins did not tangentially exclude all other penetration enhancers and could not reasonably have expected success on the merits in their suits against Teva and Perrigo alleging patent infringement under the doctrine of equivalents.[11] Id.

11. Defendants have moved for reconsideration of that decision. On June 27, 2018, we denied the motion in a separate order (Doc. # 438).

Defendants cannot have it both ways. They cannot, as they did here, purposely surrender claims to all penetration enhancers except one to obtain a patent and then claim infringement when a party uses a penetration enhancer that they deliberately surrendered. See id. at *10-11.

We now focus our inquiry on the subjective component of the FTC's sham litigation claim, which was one of the issues litigated in the nonjury trial held in this action. At the outset, we readily acknowledge that a plaintiff claiming that a lawsuit was a sham faces an uphill battle. The First Amendment to the United States Constitution prohibits Congress from making any law respecting "the right of the people . . . to petition the Government for a redress of grievances." U.S. Const. amend. I. It is well-established that the First Amendment right to petition the government includes the right to have access to the courts. PRE, 508 U.S. at 56-57; see also U.S. Const. amend. I. Under the Noerr-Pennington doctrine articulated by the Supreme Court, "[t]hose who petition [the] government for redress are generally immune from antitrust liability."[12] PRE, 508 U.S. at

12. The Noerr–Pennington doctrine originated from two separate antitrust cases, United Mine Workers of America v. Pennington, 381 U.S. 657 (1965) and Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961). Pennington involved efforts by several companies and a union to lobby the Secretary of Labor regarding minimum wage regulations. 381 U.S. at 660. In Noerr, a group of railroads engaged in a publicity campaign designed to foster the adoption of certain laws and

56. Noerr-Pennington immunity, however, is not absolute. "[A]ctivity 'ostensibly directed toward influencing governmental action' does not qualify for [First Amendment] immunity if it 'is a mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor.'" Id. at 51 (quoting E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961) (alterations in original)).

Later, in City of Columbia v. Omni Outdoor Advertising, Inc., the Supreme Court explained:

> The 'sham' exception to Noerr encompasses situations in which persons use the governmental process—as opposed to the outcome of the process—as an anticompetitive weapon. A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of a license but simply in order to impose expense and delay.

499 U.S. 365, 380 (1991) (emphasis omitted).

We must initially decide not only the type of proof but also the burden of proof which are required to establish subjective intent. The parties disagree regarding both. According to defendants, the FTC must show that they brought the patent infringement actions with actual knowledge that actions were baseless. The FTC, in contrast, asserts that actual

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regulations harmful to the trucking industry. 365 U.S. at 129-30. The doctrine has since been extended to persons who petition the courts, in addition to legislatures and administrative agencies. See Ca. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 509-10 (1972).

knowledge or bad faith is not required under PRE. Instead, the FTC argues that the subjective baselessness inquiry concerns only "whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor." See PRE, 508 U.S. at 60-61 (internal citation and quotation marks omitted). Accordingly, the FTC urges the court to focus on the "economic viability" of the lawsuit and whether defendants "sue[d] primarily for the benefit of collateral injuries inflicted through the use of legal process." Id. at 65.

Unfortunately, the Supreme Court in PRE did not elaborate on this issue. In that case, the Court of Appeals had affirmed an order granting summary judgment for the plaintiff on the defendant's counterclaim alleging a sham lawsuit. Id. at 62-65. The Supreme Court agreed with the Court of Appeals that the lawsuit was not objectively baseless and thus did not reach the subjective intent question. Id. at 65-66.

In support of its position, the FTC cites Kilopass Techology, Inc. v. Sidense Corp., 738 F.3d 1302 (Fed. Cir. 2013). That case, however, involved a motion for attorneys' fees under 35 U.S.C. § 285, which provides that a court "in exceptional cases may award reasonable attorneys' fees to the prevailing party." 738 F.3d at 1304, 1312. The Federal Circuit held that "actual knowledge of baselessness is not required" and

that "a defendant need only prove reckless conduct to satisfy the subjective component of the § 285 analysis." Id. at 1310. It further explained that courts may "dra[w] an inference of bad faith from circumstantial evidence thereof when a patentee pursues claims that are devoid of merit" and that "[o]bjective baselessness alone can create a sufficient inference of bad faith to establish exceptionality under § 285, unless the circumstances as a whole show a lack of recklessness on the patentee's part." Id. at 1311, 1314.

Since then, the Supreme Court has expressly distinguished the standard for a claim of sham litigation from that applicable to motions for attorneys' fees under § 285. See Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749, 1757-58 (2014). The Court reasoned that the Noerr-Pennington doctrine was created as "a narrow exception for 'sham litigation'—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances." Id. at 1757. It further observed that "[t]he threat of antitrust liability . . . far more significantly chills the exercise of the right to petition than does the mere shifting of attorney's fees." Id. Thus the standard for fee-shifting, which is governed by the statutory language of 35 U.S.C. § 285, is irrelevant to the subjective intent standard for sham litigation under PRE. Id.

Many of the authorities cited by the FTC are not helpful to our analysis regarding subjective intent. For example, in In re Flonase Antitrust Litigation, the defendant conceded that there was sufficient evidence for plaintiffs to survive summary judgment on subjective intent and as a result the court did not address the issue. 795 F. Supp. 2d 300, 311 (E.D. Pa. 2011). Other authorities cited by the FTC dealt with motions to dismiss and do not contain a fulsome analysis of the evidence required to support the subjective intent prong of PRE. See Moldex Metric, Inc. v. 3M Co., No. 14-1821, 2015 WL 520722, at *7, *9 (D. Minn. Feb. 9, 2015); TransWeb, LLC v. 3M Innovative Props. Co., No. 10-4413, 2011 WL 2181189, at *15 (D.N.J. June 1, 2011); Rochester Drug Coop., Inc. v. Braintree Labs., 712 F. Supp. 2d 308, 316, 319-21 (D. Del. 2010); In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 643-44 (E.D. Mich. 2000).

After review of the decisions cited by both parties, we conclude that the subjective intent required to overcome Noerr-Pennington immunity is not merely the intent to thwart competition. It is well-established that "the essence of a patent grant is the right to exclude others from profiting by the patented invention" and thereby to interfere with a competitor's business. See Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980). As our Court of Appeals has

recognized, the Hatch-Waxman Act "incentivizes brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so" and therefore "[w]e are not inclined to penalize a brand-name manufacturer whose litigiousness was a product of Hatch-Waxman." In re Wellbutrin, 868 F.3d at 157-58 (internal quotation marks and citation omitted). Knowledge that the filing of a lawsuit would trigger the automatic stay is not by itself evidence of a bad-faith motive. Id.; see also In re Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1365 (S.D. Fla. 2004).

As the Supreme Court noted in Omni Outdoor Advertising, a classic example of "sham" activity is the filing of frivolous objections to a license application with no expectation of prevailing but simply in order to impose expense and delay. See 499 U.S. at 380. Clearly, a frivolous lawsuit under those same circumstances is also a sham. The sham exception under Noerr-Pennington, of course, is narrow so as not to infringe on a party's constitutional right to petition the government for redress of grievances. Consequently, we conclude that the FTC must prove that defendants had actual knowledge that the patent infringement suits here were baseless in order both to meet its burden under Omni Outdoor Advertising and PRE and to avoid interference with defendants' First Amendment rights.

The parties, as noted above, further disagree as to the burden of proof required to establish subjective intent. The FTC contends that it must simply satisfy a preponderance of the evidence standard, the general standard for civil antitrust claims. See, e.g., LePage's Inc. v. 3M, 324 F.3d 141, 166-69 (3d Cir. 2003). Defendants counter that a finding of subjective intent demands clear and convincing evidence.

The Supreme Court has not addressed this question. Nor has our Court of Appeals. The Courts of Appeals for the Ninth and Seventh Circuits in decisions that predate PRE have both required clear and convincing evidence that defendants prosecuted actions in bad faith to satisfy the subjective prong of a sham litigation claim. See Handgards, Inc. v. Ethicon, Inc., 743 F.2d 1282, 1288-93 (9th Cir. 1984); MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1155 (7th Cir. 1983).

In support of their position that clear and convincing evidence is required, defendants point to Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp., 382 U.S. 172 (1965). There, the Supreme Court held that an allegation that the defendant "knowingly and willfully" obtained a patent through fraudulent representations to the Patent Office would not be entitled to Noerr–Pennington immunity for a subsequent lawsuit alleging infringement of that patent. 382 U.S. at 177-78. The Federal Circuit has since specified that clear and

convincing evidence is needed to establish a Walker Process monopolization claim. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998). It observed that "[t]he road to the Patent Office is so tortuous and patent litigation is usually so complex," that there must be "no less than clear, convincing proof of intentional fraud involving affirmative dishonesty." Id. (internal citation omitted).

The authorities cited by the FTC to support its position that a preponderance of the evidence is sufficient are not on point. Those cases concern the standard for an award of attorneys' fees in a patent case under 35 U.S.C. § 285, not the subjective intent standard for sham litigation antitrust claims. See, e.g., Kilopass Tech., Inc., 738 F.3d at 1315-16. As stated above, the Supreme Court has expressly distinguished sham litigation in the Noerr-Pennington context from motions brought under § 285. See Octane Fitness, LLC, 134 S. Ct. at 1757-58.

We conclude that the FTC must prove by clear and convincing evidence the subjective intent element of a sham litigation. We do so in light of the Federal Circuit's decision in C.R. Bard as well as the importance of the First Amendment right to petition the government for a redress of grievances as explained in Noerr, Pennington, and California Motor Transport Co.

Having determined that the FTC has the burden to establish by clear and convincing evidence that defendants had actual knowledge that their infringement suits against Teva and Perrigo were baseless, we now consider the evidence presented at trial and the reasonable inferences to be drawn therefrom.

The FTC puts great emphasis on the 2009 press release by Solvay on behalf of its subsidiary Unimed, co-owner of the '894 patent, before Solvay and Unimed were acquired by AbbVie in February 2010. The press release announced the companies' decision not to sue Perrigo for infringement of the '894 patent after Perrigo filed with the FDA its ANDA for a generic version of AndroGel. Solvay gave as its reason that the Perrigo product "contains a different formulation than the formulation protected by the AndroGel patent." The FTC also presented evidence regarding a July 2009 email written by MacAllister, in-house counsel for Besins, stating that Besins, the co-owner of the '894 patent, was "standing down" from pursuing Perrigo for infringement.

None of the in-house AbbVie attorneys identified as the decision-makers regarding the 2011 suits against Teva and Perrigo was previously employed by Solvay or Unimed. As for Besins, it did not explain whether its decision not to pursue a patent infringement suit was based on the merits or was simply recognizing the reality that it alone could not initiate such a

suit without Unimed, the co-owner of the '894 patent. See, e.g., Int'l Nutrition Co. v. Horphag Research Ltd., 257 F.3d 1324, 1331 (Fed. Cir. 2001). While Solvay and its in-house attorneys certainly got it right in 2009, this evidence is not probative as to the subjective intent of defendants' decision-makers here some two years later in 2011.

Both parties also rely on various business planning documents to support their positions on subjective intent. The FTC, for example, points to an August 8, 2011 meeting attended by Jeffrey Stewart, then Vice President of U.S. Proprietary Pharmaceuticals at AbbVie, and several other AbbVie executives and in-house attorneys to discuss AndroGel. This meeting took place shortly after Teva filed its motion for summary judgment in the patent infringement case in which AbbVie had sued it. During that meeting Stewart, looking into the future, drew a chart depicting a dramatic erosion of AndroGel sales following entry of an AB-rated generic after a "lost case" eight months hence in April 2012, the month in which this court had scheduled a hearing to take place on Teva's summary judgment motion.

Thereafter, AbbVie created "AndroGel Scenarios" with various potential dates for generic entry, including: (1) November 2011, the date by which the FDA had agreed to

review Teva's section 505(b)(2) NDA[13]; (2) April 2012, the date on which the summary judgment motion could be decided in the Teva matter; and (3) April 2013, an estimate of the date on which a trial on the merits may have concluded in the Teva matter. In an email on September 30, 2011, James Hynd, one of the AbbVie executives responsible for the AndroGel franchise, characterized the April 2012 entry date as "[t]he most likely scenario."

Defendants, meanwhile, point to the official 2012 annual plan for AbbVie's U.S. Proprietary Pharmaceuticals Division. AbbVie began work on that plan in summer of 2011 and finalized it in late fall of 2011. In that plan, AbbVie forecasted increased sales for AndroGel. It also projected an increase in total "Selling, General, and Administrative" ("SG&A") spending for AndroGel from 2011 to 2012. While the plan "assumed LOE [loss of exclusivity]" for several other products, it made no mention of any loss of exclusivity for AndroGel. Defendants also highlight the AbbVie long range plan ("LRP") that was created in 2011. The LRP is a five to ten year business plan that is updated every year through a planning

13. This is commonly known as the Prescription Drug User Fee Act ("PDUFA") date. Under that Act, the FDA collects a fee from companies applying for drug approval and, in exchange, the FDA provides a "goal date" by which it will review the application. See 21 U.S.C. § 379h.

process that generally begins in January and ends in May. The LRP created in 2011 uses as the loss of exclusivity date for AndroGel August 31, 2015, the licensed entry date granted to two other generic competitors, Par Pharmaceutical and Watson Pharmaceuticals, Inc.

We do not find these and other similar business documents to be persuasive or even relevant to the issue of subjective intent. Significantly, none of these corporate documents, as far as we know, was created by or influenced anyone who played a role in the decisions to sue Teva and Perrigo for patent infringement. Nor is there any evidence in the record as to what, if anything, the decision-makers in the legal department told the business people or vice versa about the merits or prospects of the litigation. These corporate documents are simply not probative of the state of mind of the in-house attorneys who made the decisions to sue.

As evidence of their subjective good faith, defendants also rely on the fact that they obtained favorable settlements in their lawsuits against Teva and Perrigo. Specifically, defendants point out that they initially proposed to both Teva and Perrigo a market entry date of January 1, 2015, a date which extended far beyond the maximum 30-month Hatch-Waxman stays applicable to the two lawsuits. Although Teva and Perrigo countered on several occasions with earlier entry dates,

defendants held firm to their initial offers in both negotiations. In the end, Teva and Perrigo secured an entry date of December 27, 2014 for their products, just days earlier than defendants' first proposals.[14] Defendants maintain that they would not have insisted on such a late entry date if they knew the infringement suits were frivolous or if they otherwise were motivated only to use the litigation process itself and the automatic Hatch-Waxman stay as an anti-competitive weapon. We find this argument unpersuasive.

Parties often settle litigation for a variety of reasons independent of the merits of the claims. It is true that the settlements prevented Teva and Perrigo from entering the market until after the automatic Hatch-Waxman stays would have expired. On the other hand, the settlements permitted Teva and Perrigo to enter the market years before the '894 patent was set to expire and before any other generic competitor could come to market. They also permitted Teva and Perrigo to limit their litigation costs, and Perrigo obtained $2 million from AbbVie for reasonable litigation expenses. Even frivolous lawsuits can be very costly to defend and to take to trial, especially when plaintiffs, such as the defendants here, have extensive resources.

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14. As stated above, Perrigo ultimately agreed to an entry date of January 1, 2015 but this date was moved to December 27, 2014 pursuant to an acceleration clause in the contract.

Charles Cotesworth Pinckney's steadfast response, "not a six-pence, sir," in rejecting a request of French officials for a payment of money in the XYZ Affair, and Representative Robert Goodloe Harper's now famous toast in a similar vein, "Millions for Defense but not a Cent for Tribute," at a dinner in 1798 in Philadelphia, while admirable in many spheres of life, generally have no applicability in the real world when lawsuits are being settled. We find that the terms of the Teva and Perrigo settlements here do not support defendants' subjective good faith.

The FTC points to the various citizen petitions filed by AbbVie regarding the applications submitted by Teva and Perrigo for FDA approval and for TE ratings for its products. For all of these petitions, the FDA granted in part the relief requested by AbbVie. Because they were found to be at least partially meritorious, we do not consider the citizen petitions as evidence of any improper subjective intent by defendants.

The FTC further points to evidence that AbbVie attempted to accelerate the transition of patients from AndroGel 1% to AndroGel 1.62% in summer 2011. Again, there is no evidence that those who decided to bring the infringement actions against Teva and Perrigo played any role in this process.

It is, of course, the FTC which bears the burden of proof by clear and convincing evidence that defendants had the subjective intent to file sham infringement actions against Teva and Perrigo. In determining subjective intent, the court must zoom in on the individuals at AbbVie and Besins who made the decisions to file the infringement actions against Teva and Perrigo and discern what these individuals knew. The state of mind of individual decision-makers is of course imputed to the corporations for which they act. See, e.g., In re Color Tile Inc., 475 F.3d 508, 513 (3d Cir. 2007).

The individuals, as noted above, who made the decision on behalf of AbbVie on whether to file the objectively baseless lawsuits against Teva and Perrigo were four experienced patent attorneys with sign-off from the general counsel of AbbVie. The record reflects that no business executives were in any way involved—not even with a perfunctory sign-off. As for Besins, the decision to sue was likewise made by in-house counsel for the company. Again no business people participated in the decisions to sue or were otherwise involved.

As the finder of fact, the court may consider both direct and circumstantial evidence when evaluating defendants' subjective intent. See Howard Hess Dental Labs. Inc. v. Dentsply Intern., Inc., 602 F.3d 237, 257-58 (3d Cir. 2010) (citing Advo, Inc. v. Phila. Newspapers, Inc., 51 F.3d 1191,

1199 (3d Cir. 1995)). We may determine what weight and credence to give this evidence and may also draw reasonable inferences therefrom. See id. In making findings of fact, the court, like jurors, should not leave common sense at the courthouse steps.

Triers of fact are routinely called upon to determine a party's state of mind. U.S. Postal Serv. Bd. of Governors v. Aikens, 460 U.S. 711, 716-17 (1983). As our Supreme Court has recognized:

> The law often obliges finders of fact to inquire into a person's state of mind. . . . The state of a man's mind is as much a fact as the state of his digestion. It is true that it is very difficult to prove what the state of a man's mind at a particular time is, but if it can be ascertained it is as much as fact as anything else.

Id. (internal citations and quotations omitted). We routinely instruct juries to decide a person's intent in both criminal and civil proceedings:

> Often the state of mind . . . with which a person acts at any given time cannot be proved directly, because one cannot read another person's mind and tell what he or she is thinking. However, [defendants'] state of mind can be proved indirectly from the surrounding circumstances. Thus, to determine [defendants'] state of mind . . . at a particular time, you may consider evidence about what [defendants] said, what [defendants] did and failed to do, how [defendants] acted, and all the other facts and circumstances shown by the evidence that may prove what was in [defendants'] mind at that time. . . .

> You may also consider the natural and probable results or consequences of any acts [defendants] knowingly did, and whether it is reasonable to conclude that [defendants] intended those results or consequences. You may find, but you are not required to find, that [defendants] knew and intended the natural and probable consequences or results of acts [defendants] knowingly did. This means that if you find that an ordinary person in [defendants'] situation would have naturally realized that certain consequences would result from [defendants'] actions, then you may find, but you are not required to find, that [defendants] did know and did intend that those consequences would result from [defendants'] actions.

Third Circuit Model Criminal Jury Instructions § 5.01. This explanation is also reflected in our Circuit's model jury instructions for civil cases where intent is relevant, such as those under civil rights statutes. Those model instructions state that a plaintiff "is not required to produce direct evidence of intent" and that intent "may be inferred from the existence of other facts." See, e.g., Third Circuit Model Civil Jury Instructions § 5.1.2. Because of the difficulty of proving a person's state of mind, intent is usually a matter of inference from evidence in the record both in civil and criminal cases. See Herman & MacLean v. Huddleston, 459 U.S. 375, 391 n.30 (1983); Resolution Tr. Corp. v. Fid. & Deposit Co. of Md., 205 F.3d 615, 642–43 (3d Cir. 2000); McLean v. Alexander, 599 F.2d 1190, 1198 (3d Cir. 1979).

None of the attorneys who was a decision-maker at AbbVie testified at the trial. While in-house counsel for Besins did testify, he did not say a word about his reasoning for bringing suit against Teva and Perrigo. Defendants invoked the attorney-client privilege as well as the attorney work product doctrine and did not assert reliance on advice of outside counsel as an affirmative defense.[15] Defendants have cited authority that we may not draw adverse inferences on subjective intent from a party's justifiable reliance on these privileges. We agree. We do not and will not draw any negative inference as to subjective intent based on defendants' decision to invoke the attorney-client privilege and the attorney work product doctrine and thereby to shroud certain information from view.[16] See Freedom Card, Inc. v. JPMorgan Chase & Co., 432 F.3d 463, 479-80 n.25 (3d Cir. 2005).

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15. The FTC has not challenged the general proposition that attorney-client privilege or the attorney work product doctrine applies but did engage in motion practice regarding whether certain documents were in fact shielded from discovery by these privileges. It also asserted in various pretrial motions and trial briefs that defendants waived these privileges to the extent defendants asserted that the in-house counsel who made the decision to sue acted in good faith.

16. This is not an unusual situation. It is no different from that faced by courts every day in criminal trials, in which juries are instructed to make findings about intent but not to draw a negative inference based on a defendant's failure to testify. See United States v. Waller, 654 F.3d 430, 435-38 (3d Cir. 2011). We also note that juries in criminal cases may rely on circumstantial evidence to find intent beyond a

With no direct evidence of the subjective intent of the decision-makers, we must decide whether their subjective intent to file a sham lawsuit has been proven by clear and convincing evidence from the surrounding circumstances and the natural and probable consequences of their knowing acts. It is unrefuted that the attorneys who decided to sue Teva and Perrigo for patent infringement were aware of the paragraph IV notices from Teva and Perrigo. In the paragraph IV notices, Teva and Perrigo declared that their products did not contain as a penetration enhancer isopropyl myristate in the particular concentration claimed in the '894 patent. Outside counsel for defendants had confidential access to the section 505(b)(2) NDAs of Teva and Perrigo, which included the penetration enhancers used by Teva and Perrigo. Both paragraph IV notices called to the attention of the decision-makers that any infringement actions by defendants would be barred by prosecution history estoppel. Perrigo went so far as to assert that any infringement suit against it would be a sham.

The decision-makers at AbbVie and Besins in 2011 knew that Teva and Perrigo used penetration enhancers for their generic products which were distinct from the one penetration enhancer claimed in the '894 patent. We reasonably infer that

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reasonable doubt, a standard higher than the clear and convincing standard applicable here. See id. at 436.

the decision-makers also were aware of the prosecution history of the '894 patent and specifically that the patent application originally claimed all penetration enhancers including those in the Teva and Perrigo products and that those penetration enhancers used by Teva and Perrigo were ultimately excluded from the protection of the '894 patent. The prosecution history detailed that the original claims covered all penetration enhancers but were ultimately reduced to one, isopropyl myristate. This history is outlined in our prior summary judgment decision. See AbbVie Inc., 2017 WL 4098688, at *4-11. As we found there, "any reasonable person who reads the prosecution history of the '894 patent" would know that all penetration enhancers other than isopropyl myristate in particular concentrations were surrendered. Id. at *11.

The reason and motivation for the lawsuits against Teva and Perrigo are also proper considerations which inform our decision on subjective intent. See Omni Outdoor Advertising, Inc., 499 U.S. at 380. Regardless of what the business people knew or had in mind or what any of AbbVie's specific corporate documents or business people revealed, we reasonably infer that the patent attorneys, some of whom were long-time employees, were generally aware of the extensive financial success of AndroGel. It was no secret that AndroGel was a blockbuster product for defendants. It was bringing in hundreds of millions

of dollars annually as of 2011 with a very high profit margin. Sales of AndroGel were $604 million, $726 million, and $874 million in 2009, 2010, and 2011 respectively. The patent attorneys also clearly recognized that the entry of generic versions of AndroGel with their much lower prices would quickly and significantly erode this ideal financial picture. Their reason and motivation for the filing of these objectively baseless actions against potential competitors was to staunch, at least for a time, this looming reversal of fortune.

In sum, all of the decision-makers, we reiterate, were very experienced patent attorneys, who also knew the extensive financial benefits to defendants if generic versions of AndroGel were kept or delayed from entry into the market. It is a compelling inference that they knew the law concerning the prosecution history estoppel and related principles and understood that prosecution history estoppel barred the infringement suits against Teva and Perrigo. They decided to file these lawsuits anyway. Since these experienced patent attorneys filed objectively baseless infringement lawsuits, it is reasonable to conclude that they intended the natural and probable consequences of acts they knowingly did. This leads ineluctably to an inference that the subjective intent of the decision-makers was to file sham lawsuits. We find by clear and convincing evidence that these attorneys had actual knowledge

that the infringement lawsuits they initiated in 2011 against Teva in the United States District Court for the District of Delaware and against Perrigo in the United States District Court for the District of New Jersey were baseless and that they acted in bad faith. The only reason for the filing of these lawsuits was to impose expense and delay on Teva and Perrigo so as to block their entry into the TTRT market with lower price generics and to delay defendants' impending loss of hundreds of millions of dollars in AndroGel sales and profits. They had no expectation of prevailing in the lawsuits. See Omni Outdoor Advertising, Inc., 499 U.S. at 380. All the findings concerning subject intent are by clear and convincing evidence. The actions and intent of these AbbVie and Besins attorneys, of course, are binding on the defendants.

Again, we recognize the importance of the constitutional right to petition the Government for redress of grievances through the filing of lawsuits. For those reasons, this court understands its responsibility to act with caution before finding that any lawsuit was a sham. Regrettably, this is that exceptional case compelling such a finding.

IV

The FTC alleges that defendants have violated section 5 of the FTC Act, which prohibits "[u]nfair methods of competition in or affecting commerce." 15 U.S.C. § 45(a). The

prohibitions under the FTC Act include, but are not limited to, conduct that violates the Sherman Act, 15 U.S.C. §§ 1 et seq. See, e.g., FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 454-55 (1986). Specifically, the FTC claims that defendants had monopoly power in the TTRT market throughout the United States and unlawfully sought to maintain that power through the filing of the sham lawsuits against Teva and Perrigo so as to prevent or delay the entry into the market of much less expensive generic versions of AndroGel to the detriment of the consuming public.

Thus, to prove its claim the FTC must establish not only that defendants engaged in sham litigation but also that the sham litigation was used to maintain monopoly power in the relevant market. Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007). Monopoly power is "the ability to control prices and exclude competition in a given market." Id. "[A] patent does not necessarily confer market power upon the patentee" and therefore the FTC must prove that defendants in fact possessed monopoly power. See Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28, 45 (2006). Monopoly power is assessed as of the time of the anticompetitive conduct. See Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp., 959 F.2d 468, 472-73, 481 (3d Cir. 1992).

The Supreme Court has ruled that questions of monopoly power must be resolved according the particular facts of each case and that "formalistic distinctions rather than actual market realities are generally disfavored in antitrust law." Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 466-67 (1992). Monopoly power may be proven through direct evidence of supra competitive prices and restricted output. Mylan Pharm. Inc., 838 F.3d at 434. In the alternative, monopoly power may be proven through indirect evidence. Id. at 435. Here, the FTC has presented no direct evidence of monopoly power but instead relies on indirect evidence to establish this part of its claim.[17]

To support a finding of monopoly power through indirect evidence, the FTC must show that: (1) defendants had market power in the relevant market; and (2) barriers existed to entry into that market. Id. Market power is in turn defined as "the power to raise prices above competitive levels without losing so many sales that the price increase is unprofitable." Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 445 n.2 (3d Cir. 1997) (internal citation omitted). Market

17. Direct evidence of monopoly power is "rare" and would require, among other things, evidence that defendants maintained abnormally high price-cost margins on AndroGel and that they restricted output. See Mylan Pharm. Inc., 838 F.3d at 434-35 & n.53. The FTC has not presented such evidence.

power can be inferred from a market share significantly greater than 55%. Dentsply Intern., Inc., 399 F.3d at 187 (citing Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 201 (3d Cir. 1992)). As our Court of Appeals has explained, the size of market share is a primary determinant of whether monopoly power exists. Pa. Dental Ass'n v. Med. Serv. Ass'n of Pa., 745 F.2d 248, 260 (3d Cir. 1984).

We must begin by defining the relevant market. See Dentsply Intern., 399 F.3d at 187. The definition of the relevant market "is a question of fact as to which the plaintiff bears the burden of proof." Mylan Pharm. Inc., 838 F.3d at 435 (quoting Broadcom Corp., 501 F.3d at 307). The FTC must prove both the relevant product or products that comprise the market as well as the geographical area for the market. See Queen City Pizza, Inc., 124 F.3d at 442. There is no dispute here that the relevant geographic market encompasses the United States.

To determine whether products are in the same market, we ask "if they are readily substitutable for one another," an inquiry that requires us to assess "the reasonable interchangeability of use between a product and its substitute." Mylan Pharm. Inc., 838 F.3d at 435 (internal citation omitted). The term "'[i]nterchangeability' implies that one product is roughly equivalent to another for the use to which it is put." Id. at 436 (quoting Allen–Myland, Inc. v. Int'l Bus. Machs.

Corp., 33 F.3d 194, 206 (3d Cir. 1994)). It also means that "while there might be some degree of preference for . . . one [product] over the other, either would work effectively." Id. (quoting Allen-Myland, Inc., 33 F.3d at 206 (alterations in original)). We also look to cross-elasticity of demand, which is defined as "[a] relationship between two products, usually substitutes for each other, in which a price change for one product affects the price of the other." Id. (internal citations omitted). "Cross-elasticity of demand is a measure of the substitutability of products from the point of view of buyers. More technically, it measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." Id. at 437 (quoting Queen City Pizza, Inc., 124 F.3d at 438 n.6).

As the Supreme Court has recognized, "in some instances one brand of a product can constitute [the relevant] market." Eastman Kodak Co., 504 U.S. at 482. However, courts generally approve of single-product markets only "in rare circumstances." Town Sound & Custom Tops, Inc., 959 F.2d at 480; see also Mylan Pharm., Inc. v. Warner Chilcott Pub. Co., No. 12-3824, 2015 WL 1736957, at *8 (E.D. Pa. Apr. 16, 2015).

The FTC first proposes what is in essence a single-product market: brand-name AndroGel 1% and brand-name AndroGel 1.62% and their generic equivalents. Within this

market, defendants held 100% of sales until entry of Perrigo's generic AndroGel 1% product. After that point, 85% of the AndroGel 1% market converted to generic versions of AndroGel 1% within 24 months, and 90% within 31 months.

In seeking to prove its proposed relevant market, the FTC relies on the expert testimony of Dr. Carl Shapiro, a professor at the Haas School of Business at the University of California at Berkley who previously served as a member of the President's Council of Economic Advisors. Dr. Shapiro performed the Hypothetical Monopolist Test ("HMT"). That test begins with a narrow set of products, called the candidate market, and asks whether a hypothetical monopolist selling those products could impose a small but significant non-transitory increase in price ("SSNIP"), which would be a 5% increase or more, without losing too many sales to make the price increase unprofitable. If the answer is yes, then the market is correctly defined because products outside the candidate market are not effective price constraints. If not, then the candidate market is too narrow and the relevant market includes other products.

Dr. Shapiro began with a candidate market of brand-name AndroGel and generic versions of AndroGel.[18] He

18. Dr. Shapiro explained that he included brand-name AndroGel 1.62% in his analysis because the delay in generic entry caused by the sham lawsuits provided defendants with additional time to convert AndroGel 1% sales to AndroGel 1.62%. Dr. Shapiro opined

explained that in this situation, the question under the HMT model is whether defendants, as the manufacturers and distributors of brand-name AndroGel, could prevent the price of AndroGel from falling more than 5% by excluding generic competition.

Using data provided by defendants, Dr. Shapiro first calculated the hypothetical monopoly price, which is the price defendants charged for AndroGel prior to generic entry. He then calculated the change in price for AndroGel after generic entry, using a weighted average price of brand-name and generic AndroGel.[19] Dr. Shapiro performed the test as of the time of the filing of the sham lawsuits in April 2011 and October 2011. He relied on projections of the effect of generic entry created by AbbVie, Teva, and Perrigo. Dr. Shapiro found that entry of an AB-rated generic would cause market prices for AndroGel to decline by at least 41% and that entry of a BX-rated generic would cause a decline of 11%. Based on these calculations, Dr. Shapiro concluded that a hypothetical monopolist of

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that excluding AndroGel 1.62% from the test market could lead to "artificial and misleading" results. This is consistent with AbbVie's own business projections, which predicted that entry of a generic 1% product would impact AndroGel 1.62% sales.

19. Dr. Shapiro defines average weighted price as "the market price charged by the pharmaceutical companies" and opines that it "is the best way to measure the disparate impact on different customers [i.e., payors, pharmacy benefit managers, and pharmacies] because it measures 'the total payments that are involved.'"

brand-name and generic AndroGel could profitably impose a price increase of more than 5% by excluding competition. Thus, he opines that AndroGel and its generic counterparts constitute the appropriate relevant market for our analysis.

To support Dr. Shapiro's reliance on the HMT, the FTC points to our Court of Appeal's decision in FTC v. Penn State Hershey Medical Center, 838 F.3d 327 (3d Cir. 2016). There, the district court applied the HMT to determine the relevant geographic market in evaluating whether a hospital merger violated the antitrust laws. Id. at 344-45. On appeal, the Court concluded that the district court failed properly to formulate and apply the test. Id. There is no indication that the HMT test is required or even applicable in a monopolization case such as this.

We find that the analysis used by our Court of Appeals in Mylan is the appropriate one here. In that case, the Court observed that "the pharmaceutical market functions in a unique way." 838 F.3d at 428. Specifically, it stated:

> [I]n a well-functioning market, a consumer selects and pays for a product after evaluating the price and quality of the product. In the prescription drug market, by contrast, the doctor selects the drug, which creates a certain separation between the buyer and the manufacturer. Moreover, in most cases, a third-party, such as a health insurance company, pays for the drug. As a result, consumer buying behavior may have less of an impact on manufacturer

> pricing than it otherwise would in a traditional open market.

Id. (internal citations and quotation marks omitted).

Due to the vastly different costs associated with launching generic products as compared to brand-name products, generics can be priced considerably lower than brand-name products.[20] AB-rated generics are often priced at a substantial discount far exceeding 5%. This is the result of an intentional regulatory framework promulgated under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and the Hatch-Waxman Act which provides incentives for innovators that develop brand-name drugs while also encouraging the introduction of low-cost generic drugs to the market. See Actavis, Inc., 570 U.S. at 142. Under this regulatory scheme, application of the HMT would result in a market limited to a brand-name drug and its AB-rated generic in almost every instance.[21] See In re Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675, 682 (D.N.J. 2005). This approach thus "would render most brand

20. Generics generally may forgo certain research and development, marketing, and other costs that a brand-name product must incur to launch. See In re Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675, 682 (D.N.J. 2005).

21. Furthermore, as Dr. Shapiro himself has recognized, the HMT may also lead to relatively narrow markets that would exclude some competing products when gross margins are high, which is the case in the pharmaceutical industry.

name pharmaceutical companies as per se monopolists prior to generic entry." See id. at 683.

The facts of Mylan further support our decision. There, the Court of Appeals rejected the plaintiff's contention that the market consisted of only Doryx, a specific brand-name tetracycline approved for the treatment of acne and its generic equivalent. Mylan Pharm. Inc., 838 F.3d at 436. It instead agreed with the district court that "the market was much broader and consisted of all oral tetracyclines prescribed to treat acne." Id. In reaching that conclusion, the Court looked to the degree of reasonable interchangeability and cross-elasticity of demand between oral tetracyclines. Id. at 435–36. It did not apply the HMT. See id. We therefore reject the FTC's proposed single-product market as defined under the HMT.

In the alternative, the FTC proposes a product market consisting of all topical testosterone replacement therapies (as stated above, "TTRTs"). While defendants argue for a broader market including injectables, they do not disagree that TTRTs are part of that market. The TTRTs include the following products:

Patches

- Testoderm (launched in 1994)
- Androderm (launched in 1995)

Gels and Solutions

- AndroGel 1% (launched in 2000)
- Testim (launched in 2002)
- AndroGel 1.62% (launched in 2011)
- Axiron (launched in 2011)
- Fortesta (launched in 2011)
- Vogelxo (launched in 2014, along with an authorized generic of the same product)

Buccal Tablets

- Striant (launched in 2003)[22]

The evidence overwhelmingly demonstrates that all TTRTs, including AndroGel, are reasonably interchangeable. All TTRTs contain the same active ingredient, testosterone. All are approved by the FDA for the treatment of hypogonadism. Furthermore, all TTRTs are consistent with guidelines for the treatment of hypogonadism promulgated by the Endocrine Society, the oldest and largest professional body dedicated to the advancement of clinical care and research in the field of endocrinology.

Defendants presented evidence that some patients have switched between AndroGel and other TTRTs. Defendants' economic expert Dr. Pierre Cremieux presented data from OptumHealth Care

22. Natesto, a testosterone nasal spray, was approved by the FDA in 2014 but was not marketed until 2015, after the time period at issue here.

Solutions, Inc. showing insurance claims for 18 million patients nationwide, which included 46,000 patients who filed a prescription for AndroGel in the five years preceding generic entry. That dataset demonstrated that 25.8% of all AndroGel patients also used another TTRT product. The OptumHealth data is commonly used in the pharmaceutical industry and has been the basis for hundreds of peer-reviewed publications.

It is true that the various TTRTs may have relative advantages and disadvantages and that an individual patient may prefer one product over another. For instance, some patients may prefer AndroGel over Testim due to Testim's "musky" scent. Certain patients may dislike Fortesta, which is applied to the front and inner thighs, as compared to AndroGel, which is applied to the upper arms, shoulders, and abdomen. However, "[i]nterchangeability is defined by rough equivalence, not perfect correspondence." Mylan Pharm., Inc., 2015 WL 1736957, at *10 (citing Queen City Pizza, Inc., 124 F.3d at 436). Even if more patients prefer AndroGel to other TTRTs, the "test for a relevant market is not commodities reasonably interchangeable by a particular plaintiff, but 'commodities reasonably interchangeable by consumers for the same purposes.'" Queen City Pizza, Inc., 124 F.3d at 438 (quoting United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395 (1956)). There is no dispute that, as stated above, all TTRTs contain the same

active ingredient and all are approved by the FDA as safe and effective for the treatment of hypogonadism. Accordingly, the fact that certain patients may prefer AndroGel over other TTRTs does not defeat a finding of interchangeability.

Mylan also requires an analysis of cross-elasticity of demand in determining what products are in the relevant market. 838 F.3d at 437. The record demonstrates and no party disputes that there is cross-elasticity of demand between all TTRTs. During the relevant time period, AndroGel competed on price within the TTRT market by offering rebates to payors to obtain better formulary placement and thereby encourage doctors to prescribe AndroGel. Between 2011 and 2014, AbbVie paid $438 million in rebates to payors, an amount which represented 18.9% of gross sales for AndroGel. Despite these rebates, AndroGel lost several accounts to other TTRTs. Effective July 1, 2011, United Healthcare removed AndroGel from its formulary in favor of Testim, which resulted in a loss of approximately $80 million in sales for AndroGel. When Axiron and Fortesta, two low volume testosterone gels, entered the market in early 2011, rebates on TTRTs increased and AndroGel lost additional business. As of January 1, 2013, CVS Caremark removed AndroGel from its formulary in favor of Fortesta, which resulted in approximately $300 million in lost revenue. And in February 2013, TriCare removed AndroGel from preferred formulary

status and replaced it with Fortesta. AbbVie also competed with other TTRTs by developing a copay assistance program. Under that program, AbbVie would bear a portion of a patient's copay, thereby lowering the actual out-of-pocket cost to the patient and encouraging the patient to fill his or her prescription for AndroGel. The other manufacturers of TTRTs also utilized such programs to increase sales. Nonetheless, as will be shown, AndroGel continued to have hundreds of millions of dollars in sales and huge profit margins and retained a high of 71.5% and never lower than in excess of 60% of the TTRT market from 2011 through 2014.

The evidence presented at trial demonstrated that the pharmaceutical companies within the TTRT market spent significant amounts of money on promotional activity to compete for sales. AbbVie employed a sales force of over 1,000 employees to promote its AndroGel franchise and spent significant money on maintaining that sales force. Sales representatives for AndroGel were compensated based in part on their sales compared to other TTRTs. AbbVie also invested in direct-to-consumer media advertising, including in television, print, and internet.

AbbVie itself viewed other TTRTs as competitors to AndroGel. During trial, several AbbVie employees testified that they considered Testim, Axiron, Fortesta, and other TTRTs to be

AndroGel's competitors. In addition, many documents introduced into evidence demonstrate that AbbVie tracked the TTRT market and considered other TTRTs as competitors. In particular, AbbVie reported to its Board of Directors as well as to investors regarding AndroGel's sales within the TTRT market. All of this evidence supports our finding that there is cross-elasticity of demand between AndroGel and other TTRTs.

Defendants counter that the relevant market should be defined to include not only TTRTs but also all testosterone replacement therapies (as stated above, "TRTs"), that is TTRTs plus injectables.[23] We reject this position. It is true that injectables contain testosterone, the same active ingredient as AndroGel. It is also true that injectables, like AndroGel, are approved by the FDA as safe and effective for the treatment of hypogonadism. In addition, defendants introduced evidence of some patient switching between AndroGel and injectables.

Some patients prefer AndroGel to injectables due to a fear of needles and the associated potential for pain and discomfort. To administer the injection, a 1.5 inch-long needle must be inserted deep into a muscle, typically the buttocks or thigh, until the needle is no longer visible. Yet some prefer injectables to AndroGel because of the peak in testosterone

23. Defendants exclude oral formulations of testosterone, which are distinguishable in efficacy and potential side effects and are generally not recommended within the medical community.

levels that injectables initially provide. On the other hand, some patients dislike the peaks and troughs associated with injectables and thus prefer the steady dosing provided by AndroGel. However, as noted earlier, individual patient preferences will not defeat a finding of interchangeability as long as there is "rough equivalence" between the products. Mylan Pharm., Inc., 2015 WL 1736957, at *10; see also Queen City Pizza, Inc., 124 F.3d at 438. Thus, there is reasonable interchangeability of use between AndroGel and injectables.

But even assuming reasonable interchangeability, there is little cross-elasticity of demand between AndroGel and injectables to include injectables in the relevant market. As noted above, "[c]ross-elasticity of demand is a measure of the substitutability of products from the point of view of buyers. More technically, it measures the responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." Mylan Pharm. Inc., 838 F.3d at 437 (quoting Queen City Pizza, Inc., 124 F.3d at 438 n.6).

Injectables entered the market decades before AndroGel launched in 2000 and the vast majority are generics. As a result, injectables enjoyed the most favorable formulary status with the lowest copay, typically $5-$10 per injection. During the relevant period, the wholesale acquisition cost of injectables was two to three times lower than that of AndroGel.

Since launch, AbbVie has consistently raised AndroGel's wholesale acquisition cost, despite the fact that injectables were available at a fraction of the cost. James Hynd, one of the principal AbbVie executives responsible for the AndroGel franchise, confirmed that AbbVie did not price AndroGel against injectables. For example, AbbVie did not offer rebates to payors in an attempt to match the price of injectables.

Furthermore, AbbVie documents show that while the company tracked injectable sales, it did not consider injectables as direct competition to AndroGel. Hynd believed that injectable patients were "not our [AndroGel] patient type."[24] Similarly, Frank Jaeger, Director of Marketing for AndroGel from 2010 through 2014, testified that AbbVie did not consider injectables as competition and that the company believed based on market research that it could not transition injectable patients to AndroGel. Instead, as stated above, Jaeger and others identified TTRTs such as Axiron, Fortesta and Testim as AndroGel's true competitors. We credit this testimony of Hynd and Jaeger.

Defendants produced an internal AbbVie document stating that a rise in the copay for AndroGel was correlated

24. While Hynd testified that he changed his view and began to recognize injectables as competition, he did not do so until 2014, well after the sham lawsuits were filed and when entry of generic versions of AndroGel was imminent. We do not find credible his change of view.

with an increase in injectables' sales. However, there is no evidence of the underlying analysis supporting the statement and thus no way to evaluate whether there was in fact a causal relationship between the two events. Moreover, this statement focuses on copays, which are patients' out-of-pocket costs, and does not account for the other levels of pricing applicable in the pharmaceutical industry, such as the amount paid by insurance companies and other payors. In contrast to this statement, the record demonstrates that AbbVie attributed the increase in injectables' sales to a variety of factors, including patient preference, the existence of "Low-T" Centers, and the disproportionate negative publicity testosterone gels received after reports associating TTRTs with heightened cardiovascular risk.

For similar reasons, the patient switching study introduced by Dr. Cremieux is also not evidence of cross-elasticity of demand between AndroGel and injectables. That study does not contain information regarding the reasoning behind the patients' choices. Those patients who moved between injectables and AndroGel may have done so for a variety of reasons, including side effects, personal preferences, and reports of cardiovascular risks from TTRTs, as well as price. Because cross-elasticity of demand focuses on the relationship between pricing for products, evidence of switching for other or

unknown reasons is irrelevant to our inquiry on this issue. See Mylan Pharm. Inc., 838 F.3d at 437.

Accordingly, we find that all TTRTs including AndroGel had both interchangeability of use and cross-elasticity of demand during the relevant time period. In contrast, there was not the cross-elasticity of demand between TTRTs and injectables so as to include injectables within the relevant market.[25] We therefore define the relevant market as the market for all TTRTs, that is all transdermal testosterone replacement therapies within the United States.

We now turn to the question of whether defendants possessed monopoly power in the defined market. To support a finding of monopoly power, the FTC must prove that defendants had a dominant share in the relevant market and that there were significant barriers to entry into that market. Broadcom Corp., 501 F.3d at 307. Generally, as noted, a market share significantly larger than 55% is required to establish prima facie market power. See Dentsply Int'l, Inc., 399 F.3d at 187. Barriers to entry include "regulatory requirements, high capital costs, or technological obstacles, that prevent new competition

25. The TRT market would also include subcutaneous pellets such as Testopel, which constitute a de minimis share of the TRT market. There was no evidence presented at trial regarding cross-elasticity of demand between AndroGel and this product. Pellets, like injectables, are not part of the relevant market here.

from entering a market in response to a monopolist's supracompetitive prices." Broadcom Corp., 501 F.3d at 307.

In the TTRT market, AndroGel was by far the most-prescribed product and was widely-recognized as the "market leader" from before 2011 through 2014.[26] In 2011, AndroGel's annual U.S. net sales exceeded $870 million. By 2012, annual U.S. net sales for the AndroGel franchise grew to $1.152 billion. In 2013, AndroGel's U.S. net sales were approximately $1.035 billion. And in 2014, AndroGel U.S. net sales totaled $934 million. These sales figures are calculated after payment of millions of dollars in rebates and the loss of some accounts.

AndroGel's share of the TTRT market was 71.5% at the time that the first sham lawsuit against Teva was filed in April 2011 and 63.6% at the time that the sham lawsuit against Perrigo was filed at the end of October 2011. Thereafter AndroGel's share remained above 60% until the end of 2014, when Perrigo's generic 1% testosterone product entered the market. The closest competitor, Testim, had a share of only approximately 20% of the TTRT market at the time of the filing of the first sham lawsuit, but thereafter its share dropped to approximately 12%. Axiron was launched on March 28, 2011 and had captured approximately 14% of the TTRT market by April 2014. No other TTRT product

26. The medical experts for both sides testified that they have prescribed AndroGel for hypogonadism more than any other product.

ever held 10% or more of the market during the period from April 2, 2011 through the end of 2014.

AndroGel's market share was always more than four times larger than the market share of any of its brand-name competitors, except for a short period when its market percentage was slightly smaller, but still over three times the market share of Testim. AbbVie was able to maintain its share of the TTRT market with a profit margin of over 65% during the relevant period, even with huge rebates. It was also able to increase the wholesale acquisition cost for AndroGel throughout this time period. We find based on this data that AndroGel had a dominant share of the TTRT market from April 2011 through December 2014.

The monopoly power of AndroGel is supported by the significant barriers to entry into the TTRT market. See Mylan Pharm. Inc., 838 F.3d at 435. First, any prospective entrant with a brand-name drug must invest large amounts of time and capital in research and development. There are then significant technical and regulatory requirements in the prescription pharmaceutical market that do not exist with respect to ordinary consumer products. Brand-name products must obtain FDA approval through the submission of an NDA. This process may be lengthy. Among other things, the prospective entrant must demonstrate the capability to manufacture, process, and package the

pharmaceutical product in a manner that is adequate "to preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d); see also id. §§ 355(b)(1), (c)(4). During the FDA approval process, third parties including competitors may file citizen petitions to request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action" on the NDA, as happened here. See 21 C.F.R. § 10.30. This may further prolong the approval process.

Once approved, the brand-name drug company generally does not attempt to market directly to patients, the ultimate users. Instead, it must convince physicians to prescribe the drug to patients. This requires a significant and knowledgeable sales force that generally meets with physicians individually. The sale and marketing of prescription drugs is highly regulated. See generally 21 U.S.C. § 331. For example, the sales force is not permitted to claim that its company's product is better or more effective than a competitor's product, nor is it permitted to promote the drug for uses other than those contained in the drug's labeling. Id.; see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 239-40 (3d Cir. 2012). The company must also ensure that pharmacies will stock the drug and that third-party payors will reimburse for it. This requires a team of skilled employees who

can negotiate contracts with insurance companies and other payors. If the company seeks patent protection, which is not uncommon, it must endure the rigorous patent approval process before the Patent and Trademark Office.

While the Hatch-Waxman Act provides streamlined procedures for the approval of generic products through the filing of an ANDA or section 505(b)(2) NDA, the FDA may ask for additional information and testing as happened here with Perrigo and Teva. The drug once approved must undergo a further process before a different group at the FDA to obtain a therapeutic equivalence ("TE") rating so that the generic drug developer may take advantage of state auto-substitution laws. Again, Teva and Perrigo both confronted this hurdle.

There can be additional obstacles for generic drug companies where, as here, a brand-name drug manufacturer holds a patent for the reference-listed drug. Generic entrants must also consider the possibility of patent infringement litigation by the owner of the referenced brand-name drug and the accompanying delay caused by the automatic thirty-month stay under the Hatch-Waxman Act before entry into the market, as occurred here.

In short, a prospective entrant to the pharmaceutical market whether with a brand-name drug or a generic drug has significant capital, technical, regulatory, and legal barriers

to overcome before being able to enter the TTRT market. Again, this is a far cry from entry into a market to sell an ordinary consumer product. As demonstrated by the record, Teva and Perrigo encountered these barriers, and Teva ultimately decided not to launch its generic testosterone 1% product when it did not receive an AB rating from the FDA.

In order to counter the existence of barriers to entry, defendants reference the fact that three brand-name TTRT products entered the market between 2011 and 2014: (1) Fortesta, manufactured by Endo Pharmaceuticals (February 28, 2011); (2) Axiron, manufactured by Eli Lilly and Co. (March 28, 2011); and (3) Vogelxo, manufactured by Upsher-Smith Laboratories, Inc. (July 2014).[27] These products, however, each maintained a relatively small share of the market compared to AndroGel as discussed in more detail above. Specifically, during the relevant time period Axiron achieved a high of only approximately 14% of the TTRT market, while Fortesta and Volgelxo each held under 10% of the market. Consequently, they did not pose significant competition to defendants' monopolistic conduct.

The barriers enumerated above are sufficiently high to be a factor in our finding of monopoly power. See Broadcom

27. An authorized generic of Vogelxo was also launched at the same time as the brand-name product.

Corp., 501 F.3d at 307. The purpose of the FDCA, of course, is to protect the public from products that are not safe and effective. See, e.g., Wyeth v. Levine, 555 U.S. 555, 566-67, 574 (2009). The barrier to entry into a prescription drug market is rightly a stringent one to ensure that this salutary goal is achieved.[28]

In sum, we find that the FTC has proven that defendants had a dominant share of the TTRT market in the relevant period and that significant barriers existed for entry into that market. The FTC has established the actual market reality that defendants possessed monopoly power and illegally and willfully maintained that monopoly power through the filing of sham litigation. This sham litigation delayed the entry of much less expensive competitive generic products into the TTRT market to the detriment of consumers and protected the

28. Defendants cited Barr Laboratories, Inc. v. Abbott Laboratories, 978 F.2d 98 (3d Cir. 1992). This case is inapposite. In that private antitrust action, plaintiff claimed attempted monopolization involving oral erythromycin products, which are prescription antibiotics. 978 F.2d at 102. Unlike the present action, Barr did not involve a patent. Id. In Barr, there were 32 manufacturers and defendant Abbott only held a high of 51.19% of the market in one year. Id. at 103. During the relevant time period the number of products competing for sales increased from 111 to 176. Id. Under the circumstances, the Court held that barriers to entry remained low and ultimately concluded that no attempted monopolization existed. Id. at 113-14. In contrast, the evidence before the court in this pending action demonstrates that the barriers were significant to entry into the TTRT market.

defendants against loss of hundreds of millions of dollars in sales and profits.

V

We now move to the issue of the appropriate relief. The FTC seeks equitable relief in the form of disgorgement by defendants of profits which the FTC seeks to return to consumers through the establishment of a fund for this purpose. It also seeks an injunction.

Defendants first contend that section 13(b) of the FTC Act does not permit the FTC to seek equitable monetary relief such as disgorgement. This section provides that the FTC "may bring suit in a district court of the United States to enjoin any such act or practice . . . [and] in proper cases the [FTC] may seek, and after proper proof, the court may issue, a permanent injunction." 15 U.S.C. § 53(b). Defendants assert that because section 13(b) simply references relief in the form of an "injunction," the court may not order disgorgement.

In support of their position, defendants cite Kokesh v. SEC, 137 S. Ct. 1635 (2017). Kokesh addressed the narrow question of whether the five-year statute of limitations in 28 U.S.C. § 2462 applied "to claims for disgorgement imposed as a sanction for violating a federal securities law." 137 S. Ct. at 1639. According to defendants, Kokesh stands for the proposition that disgorgement is punitive in nature and thus not

included among the equitable remedies authorized under the FTC Act. Kokesh, however, did not involve section 13(b) but instead dealt with federal securities law. Moreover, the Supreme Court specifically declined to address whether courts possessed authority to order disgorgement in SEC enforcement proceedings. See id. at 1642, n.3. We will not stretch Kokesh beyond its holding and will not read it to prevent the court from granting the well-established equitable relief of disgorgement.

The Supreme Court, in Mitchell v. Robert De Mario Jewelry, Inc., held that the provision of the Fair Labor Standards Act, which specifically authorized courts to restrain violations, includes the power to order reimbursement for loss of wages for unlawful discharge or discrimination. 361 U.S. 288, 296 (1960). The Supreme Court aptly stated:

> When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes. As this Court long ago recognized, "there is inherent in the Courts of Equity a jurisdiction to . . . give effect to the policy of the legislature."

Id. at 291-92 (quoting Clark v. Smith, 38 U.S. 195, 203 (1839)). This language in our view is equally applicable here to the FTC Act. Id.; see also United States v. Lane Labs-USA, Inc., 427 F.3d 219, 223 (3d Cir. 2005).

The weight of authority, in accordance with Mitchell, supports the conclusion that the grant of authority in section 13(b) to provide injunctive relief includes the full range of equitable remedies, including the power to order a defendant to disgorge illegally obtained funds. See, e.g., FTC v. Cephalon, Inc., 100 F. Supp. 3d 433, 437-39 (E.D. Pa. 2015) (Goldberg, J.). Our Court of Appeals has expressed agreement with this position. FTC v. Magazine Solns., LLC, 432 F. App'x 155, 158 n.2 (3d Cir. 2011). This is in line with other appellate precedent in this Circuit, which states that disgorgement "is an equitable remedy meant to prevent the wrongdoer from enriching himself by his wrongs." Edmonson v. Lincoln Nat. Life Ins. Co., 725 F.3d 406, 415 & n.3 (3d Cir. 2013) (quoting SEC v. Huffman, 996 F.2d 800, 802 (5th Cir. 1993)).

If the defendants' position about section 13(b) is correct, the monopolist will be able to retain its ill-gotten gains and simply face an injunction against future wrongdoing but even then only if the wrongdoing is continuing or is likely to continue. This interpretation would eviscerate the FTC Act. As our Court of Appeals has stated, "if the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters, then we are obligated to construe [the] statute[] sensibly and [to] avoid constructions which

yield absurd or unjust results." Douglass v. Convergent Outsourcing, 765 F.3d 299, 302 (3d Cir. 2014) (internal quotation marks and citations omitted). We reject defendants' argument concerning our authority to order disgorgement under section 13(b) of the FTC Act.

Because disgorgement aims to prevent unjust enrichment, a "court may exercise its equitable power only over the property causally related to the wrongdoing." Commodity Futures Trading Comm'n v. Am. Metals Exch. Corp., 991 F.2d 71, 78–79 (3d Cir. 1993) (quoting SEC v. First City Fin. Corp., 890 F.2d 1215, 1231 (D.C. Cir. 1989)). Courts determine the appropriate amount of equitable monetary relief using a two-step burden shifting framework. First, the government must "establish[] a reasonable approximation of the profits tainted by the violation." SEC v. Teo, 746 F.3d 90, 107 (3d Cir. 2014). This requires that the FTC meet a "but-for" standard of causation. Id. at 105. The burden of going forward then shifts to the defendant to provide "evidence that the [government's] approximation of profits was unreasonable." Id. at 107-08. At this point, the defendant may "point[] to intervening events" that break the chain of causation. Id. at 105-06 (quoting First City Fin. Corp., 890 F.2d at 1232). Under this standard, "doubts concerning the determination of disgorgements are to be resolved against the defrauding party." SEC v. Hughes Capital

Corp., 917 F. Supp. 1080, 1085 (D.N.J. 1996); see also First City Fin. Corp., 890 F.2d at 1231-32.

To determine the appropriate amount of equitable monetary relief to be awarded here, we must make findings about what would have happened absent the sham lawsuits filed by defendants. See First City Fin. Corp., 890 F.2d at 1231-32. The FTC's expert, Dr. Shapiro, constructed a counterfactual world relying on contemporaneous evidence as well as his expert economic analysis. He determined that but for the lawsuits: (1) Teva would have entered the market with a BX-rated product in June 2012; (2) Perrigo would have entered with an AB-rated product in June 2013; and (3) that entry of a generic version of AndroGel 1% would have affected sales of AndroGel 1.62%. He calculated defendants' "incremental revenue," which is the difference between defendants' actual revenue and their counterfactual revenue from June 2012 through the present. Dr. Shapiro then deducted defendants' incremental costs associated with the excess revenue to determine defendants' financial gain attributable to the sham litigation. He determined that this financial gain was $1.35 billion as of the end of March 2018. He opined that this financial gain will continue to accrue until entry of a generic version of AndroGel 1.62%. The FTC also seeks prejudgment interest on this financial gain, compounded quarterly at interest rates

promulgated by the Internal Revenue Service ("IRS"). See 26 C.F.R. § 301.6621-1.

Defendants dispute the FTC's assumptions regarding the entry of Teva and Perrigo as well as the FTC's assumption that entry of a generic 1% would have impacted sales of AndroGel 1.62%. Defendants argue that even absent the sham litigation, Teva would not have entered the market. They concede that Perrigo may have entered the market earlier than it did absent any sham lawsuit but assert that the earliest Perrigo would have entered would have been August 2014. Defendants admit, as they must, that delay in entry of generic 1% would have harmed consumers.

We must decide when, if ever, Teva would have entered the market in the "but-for" world. In the real world, Teva submitted to the FDA on January 13, 2011 a section 505(b)(2) NDA for its generic version of AndroGel 1% in pump and packet forms. Shortly thereafter, defendants filed their sham lawsuit against Teva. In December 2011, Teva entered into a settlement agreement with defendants and thereby agreed to a licensed entry date of December 27, 2014. On February 14, 2012, Teva received FDA approval of its section 505(b)(2) NDA for the packet presentation of its product only. In July 2014, Teva received from the FDA a BX rating on its product due to discrepancies

with the analytical work in Teva's bioequivalence study. Thereafter, Teva decided not to launch its product.

The FTC asserts that, but for the sham lawsuit filed by defendants, Teva would have entered the market with a BX-rated testosterone 1% product in June 2012. The FTC concedes that the filing of the sham lawsuit by defendants did not impact the timing of Teva's FDA approval. Thereafter, the FTC posits that Teva would have continued to move forward with preparations for its launch while waiting for its TE rating. The FTC estimates it would have taken 12-13 months from the time it submitted its section 505(b)(2) NDA to the FDA for Teva to achieve operational readiness.

Defendants dispute whether Teva would have entered the market at all with a BX rating. Teva's generic drug division has never launched a BX-rated retail pharmaceutical product. It has not done so because Teva's generic business model relies on auto-substitution at pharmacies. Without auto-substitution, Teva would have to hire a sales force to promote its BX-rated product. As demonstrated by internal analyses created by Teva, a BX-rated generic without a perceived advantage in the market, such as Teva's product, generally captures only 5% or less of the brand-name product's sales. For this reason, BX-rated generics are rare.

While Tim Crew, Teva's former Commercial Operations Officer, was in particular a strong proponent of a BX-rated launch, Crew left Teva in 2012. Alan Oberman, the Teva executive who replaced Crew, was not a proponent of a BX-rated launch. Maureen Cavanaugh, Vice President of Customer Operations and Marketing for Teva, testified that she, along with the rest of her team, made the recommendation to Teva management to abandon plans for the launch of the testosterone product. She further stated that she did so not because of defendants' infringement litigation but because of Teva's inability to commercialize the product effectively. We find her testimony to be credible.

In addition to its failure to obtain an AB rating, Teva faced other obstacles to the profitable launch of its product. In July 2011, at the suggestion of the FDA, Teva withdrew the pump presentation of its product from consideration due to packaging issues. As a result, the Teva product was approved in packet form only. The pump was preferred by patients over packets because of ease of use. Teva estimated that this setback cut its potential sales opportunity by over 50%. If it intended to continue to pursue a pump presentation for its product, Teva would need to reformulate and then resubmit its section 505(b)(2) NDA to the FDA for consideration.

This would have involved significant additional time and expense, and still may have not been successful.

Teva also faced serious manufacturing issues for its testosterone 1% product. It planned to use Cipla, a contract manufacturer based in India, to manufacture its testosterone 1% gel. Cipla demanded that Teva provide approximately $10 million for construction of manufacturing facilities. Teva had the option of making payment in the form of an up-front capital expenditure or over time as a 35% royalty on sales. Teva never reached an agreement with Cipla regarding this investment. The evidence shows that Teva ultimately refused to make this investment unless the FDA issued an AB rating to its product. Cipla could not move forward with preparations for manufacturing until an agreement was reached.

After considering the evidence presented, the FTC has not established that, but for defendants' sham litigation, Teva would have launched its product in June 2012 or at any time thereafter. We find that Teva's failure to launch was due to other intervening events described above and that the sham litigation against it was not a cause. Accordingly, we will not consider any "but-for" entry date of Teva into the TTRT market when calculating defendants' illegal financial gains.

There remains the question of when Perrigo would have entered the market absent defendants' sham litigation against

it. In the real world, Perrigo had a December 27, 2014 licensed entry date for its generic version of AndroGel 1% under its settlement with defendants. The FDA approved Perrigo's section 505(b)(2) NDA on January 31, 2013 and thereafter Perrigo waited for a TE rating for its drug. Nearly eighteen months elapsed before the FDA granted its generic TTRT an AB rating. During this time, Perrigo submitted three letters to the FDA, dated April 18, 2013, September 13, 2013, and February 18, 2014, requesting that the FDA issue an AB rating. The last letter threatened litigation if the FDA failed to act by March 19, 2014 and enclosed a draft complaint. On March 21, 2014, Perrigo filed a lawsuit against the FDA in the United States District Court for the District of Columbia alleging violation of the FDCA and the Administrative Procedures Act based on the FDA's allegedly unreasonable delay in assigning a TE rating to its product. See Perrigo Israel Pharm. Ltd. v. U.S. Food & Drug Admin., No. 14-475 (D.D.C. Mar. 21, 2014).

On April 10, 2014, the FDA filed a response to Perrigo's motion for a speedy hearing. The FDA asserted that "Perrigo itself has obviated the need for a prompt decision by reaching an agreement with the innovator not to market until December 2014." The FDA further stated that it would issue a TE rating for Perrigo's product by July 31, 2014, some five months before Perrigo's planned launch. In the end, the FDA issued an

AB rating to Perrigo on July 23, 2014, and thereafter Perrigo voluntarily dismissed its lawsuit. Perrigo launched its product on December 27, 2014.

We acknowledge that there is no statutory, regulatory, or other deadline within which the FDA is mandated to issue a TE rating. The time that the FDA needs to consider a TE rating depends on the specific facts of each situation, including the reason why the application for approval of a generic drug was submitted as a section 505(b)(2) NDA rather than an ANDA.

It is apparent from the lawsuit Perrigo brought against the FDA that the FDA knew of Perrigo's December 27, 2014 licensed entry date under the settlement agreement. As a result, it had no compelling need, as it implied in its court papers, to grant the TE rating long before Perrigo's entry date. We find that the FDA, absent the sham litigation and the resultant settlement agreement, would not have delayed the issuance of an AB rating for Perrigo's generic drug for nearly eighteen months after approval of its section 505(b)(2) NDA. The FDA is presumed to act in the public interest, which includes the mission of benefitting consumers by approving the entry of safe and effective lower-cost generic drugs into the market. Every month that the FDA would have delayed in issuing a TE rating to a generic drug that was otherwise ready and able

to launch would have caused significant financial harm to consumers.

Dr. Kenneth Phelps, the FTC's regulatory expert, testified that in his experience it takes no more than one month for the FDA to assign a TE rating for a section 505(b)(2) drug. The FTC's economic expert, Dr. Shapiro, estimated that, but for the sham litigation, Perrigo would have received its TE rating approximately four months from the date of FDA approval of its section 505(b)(2) NDA. He relied on the approximated four months' time lapse in the real world between Perrigo's filing of the lawsuit against the FDA and the FDA's issuance of the TE rating.

Defendants further point to citizen's petitions filed by AbbVie regarding TE ratings to assert that the FDA would not have issued a TE rating to Perrigo sooner. On August 18, 2011, AbbVie filed a citizen's petition requesting that the FDA conduct notice-and-comment rulemaking to establish procedures for its assignment of TE ratings for drugs approved under section 505(b)(2). That petition did not relate specifically to Perrigo but rather to general procedures for TE ratings. Contrary to defendants' position, there is no indication that the FDA refrained from issuing TE ratings for generic drugs while this petition was pending. Later in a supplement filed on December 11, 2013, AbbVie requested that the FDA assign a

BX rating to Perrigo's product. The FDA ultimately responded to this citizen petition in July 2014 at the same time it issued Perrigo's TE rating. However, a June 2013 launch would have been six months before AbbVie filed its supplemental citizen petition, and therefore we find that this supplemental citizen petition would not have delayed Perrigo's launch in the "but-for" world. Thus, the defendants' citizen petition would not have affected Perrigo's "but-for" entry date.

We find that absent the sham lawsuit, Perrigo would have received its AB rating in June 2013 and would have launched its AB-rated generic product at that time. We reject defendants' contention that Perrigo would not have launched its product until August 2014.

The parties next dispute the effect of the sham litigation on sales of AndroGel 1.62%. In his damages model, Dr. Shapiro opines that entry of a generic version of AndroGel 1% would have caused the market share of AndroGel 1.62% to plateau. According to Dr. Shapiro, the delay of generic 1% entrants caused by the sham litigation allowed defendants to transition more patients from brand-name AndroGel 1% to brand-name AndroGel 1.62% and thus avoid auto-substitution for generic versions of AndroGel 1%. We agree. Consequently, Dr. Shapiro properly includes a portion of defendants' profits from AndroGel 1.62% in his calculation of excess profits.

In the real world, AndroGel 1.62% accounted for total AndroGel sales as follows: 57% during the last 7 months of 2012, 67% in 2013, 76% in 2014, 83% in 2015 and 2016, and 82% in 2017. In the "but-for" world, the FTC asserts that AndroGel 1.62%'s share of total AndroGel sales would have frozen at the time that the first generic version of AndroGel 1% entered the market. We have already determined that but for the sham litigation, Perrigo would have entered the market in June 2013. It follows and we find that the share for AndroGel 1.62% would have frozen at approximately 67%.[29]

In response, defendants contend that AndroGel 1.62% is "superior" to AndroGel 1% and thus prescribers will chose AndroGel 1.62% regardless of the availability of a generic version of AndroGel 1%.[30] In support of their position, they point out that AndroGel 1.62% is not subject to auto-substitution for a generic version of AndroGel 1%. They further maintain that sales of AndroGel 1.62% have come not only from patients who previously used AndroGel 1% but also from

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29. As discussed above, the FTC initially took the position that Teva would have entered the market in 2012 with a BX-rated generic version of AndroGel 1%. This would freeze AndroGel 1.62%'s share of the AndroGel market at 51%, which is what the FTC asserts the share would have been during the last seven months of 2012.

30. AndroGel 1.62% has the same active ingredients and effects as AndroGel 1%, but simply requires half the volume of gel. It thus has a quicker drying time and therefore less risk of transference.

patients who used other TRTs or who are new to treatment for hypogonadism. Defendants cite OptumHealth data showing that from the launch of AndroGel 1.62% through March 2016, only 28.1% of AndroGel 1.62% patients had filled an AndroGel 1% prescription within the 12 months preceding their first AndroGel 1.62% prescription. The other sales came from patients who were previously using other TRTs or were new to testosterone replacement therapy. Defendants therefore reason that sales of AndroGel 1.62% would not have been impacted by earlier entry of a generic version of AndroGel 1%. We disagree.

We find in favor of the FTC on this issue. The record shows that sales of AndroGel 1.62% grew more slowly after launch than defendants initially anticipated. Around the time of the filing of the sham lawsuits, defendants were concerned about the impact that entry of a generic version of AndroGel 1% would have on sales for AndroGel 1.62%. Contemporaneous forecasts created by AbbVie during the relevant time period predicted that entry of a generic version of AndroGel 1% would not only erode sales for brand-name AndroGel 1% but would also cause sales of brand-name AndroGel 1.62% to plateau or even decline. For example, in the fall of 2011, AbbVie forecast that sales of AndroGel 1.62% would decrease approximately 30-35% after entry of an AB-rated generic version of AndroGel 1%. In 2014, AbbVie similarly predicted that AndroGel 1.62% could lose 20-27% of its sales

after entry of a generic version of AndroGel 1%. Again, in the real world, AndroGel 1.62%'s share of AndroGel sales did in fact plateau after Perrigo entered the market in December 2014, although by that time AndroGel 1.62%'s share of the total AndroGel market had reached 83%.

The filing of the sham lawsuits allowed defendants additional time to increase sales for AndroGel 1.62% without any competition from a lower priced generic version of AndroGel 1%. Although AndroGel 1% and AndroGel 1.62% are distinct products, both include the same active ingredient and are indicated for the same purpose, that is, to treat hypogonadism. The only significant difference in the record between the two drugs is that AndroGel 1.62% requires a smaller volume of gel. As stated above, AndroGel 1% and AndroGel 1.62% compete within the TTRT market, both with each other as well as with all other TTRTs. Under these circumstances, we find that the filing of the sham lawsuits and the resulting delay in generic entry increased defendants' profits on not only AndroGel 1% but also on AndroGel 1.62%.

The parties further dispute the end date for calculation of defendants' profits subject to disgorgement. As stated above, only profits with a causal connection to the wrongdoing are subject to disgorgement. See Commodity Futures Trading Comm'n, 991 F.2d at 78-79. This court has discretion to

order disgorgement of profits for the time period in which the effects on the market of defendants' wrongful conduct were continuing, even after the entry of Perrigo at the end of 2014. See id. On the other hand, we must not award disgorgement of profits where the causal connection to defendants' wrongdoing has become too attenuated or remote. See Teo, 746 F.3d at 106; SEC v. MacDonald, 699 F.2d 47, 53-55 (1st Cir. 1983).

The FTC takes the position that defendants' financial gain due to the sham lawsuits is ongoing at the rate of $6 million per month until the time in the future when a generic version of AndroGel 1.62% enters the market. We reject this position and instead will award disgorgement of profits through August 2017 only. By that time, Perrigo's generic version of AndroGel 1% had been on the market for 2.5 years and had achieved its maximum penetration rate of approximately 91% of brand-name AndroGel 1% sales. The effect of defendants' wrongful conduct on the TTRT market had largely subsided. We find that any award of disgorgement after that date would be speculative.

Defendants are liable for disgorgement in the amount of $448 million in profits. This amount reflects defendants' financial gain due to the sham lawsuits from June 2013 when Perrigo would have entered the TTRT market through August 2017. In addition, the FTC is entitled to prejudgment interest

calculated at the interest rates set forth by the IRS for underpayments. 26 C.F.R. § 301.6621-1; see also Teo, 746 F.3d at 109-10. In reaching this award, we are guided by the Supreme Court's direction that antitrust cases must be resolved according to the "particular facts disclosed by the record" rather than "formalistic distinctions." Eastman Kodak Co., 504 U.S. at 467-68 (internal citations omitted). We also keep in mind the purpose of our equitable power to grant disgorgement, which is not to provide an award of damages at law but instead to deter violations of antitrust law and to prevent the unjust enrichment of defendants. See Teo, 746 F.3d at 105-06.

We must also decide how liability for the disgorgement award should be apportioned between defendants AbbVie and Besins. Besins contends that it is immune from equitable monetary relief for its violations of antitrust law because it never received any profits from AndroGel. Instead, royalties on U.S. sales of AndroGel were paid to its European corporate affiliate now known as Laboratoires Besins Iscovesco SAS ("LBI SAS") or to another Besins entity, Besins Healthcare Luxemborg SARL ("BHL SARL"). Here, the FTC has named Besins Healthcare, Inc. (as stated above, "Besins") as a defendant.

Besins is one of the entities that instituted the sham lawsuits against Teva and Perrigo. As co-owner of the '894 patent, the sham lawsuits could not have been filed without

Besins. See Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1468 (Fed. Cir. 1998). We have already determined that Besins, along with AbbVie, filed these objectively baseless lawsuits with actual knowledge that the suits lacked merit with no expectation of prevailing and with the intent to impose expense and delay on Teva and Perrigo and to impede at least for a time the expected loss by defendants of hundreds of millions of dollars in sales. As we discussed above, counsel for Besins was an experienced patent lawyer who had access to the paragraph IV notices, the patent prosecution history, and the analysis of outside counsel who had full access to the Teva and Perrigo section 505(b)(2) NDAs. He nonetheless made the decision with the requisite subjective intent to join in these objectively baseless lawsuits. Under these circumstances it is appropriate to impose disgorgement on Besins for its role in filing the sham lawsuits.

It is well established that "disgorgement is an equitable obligation to return a sum equal to the amount wrongfully obtained, rather than a requirement to replevy a specific asset". SEC v. McGee, 895 F. Supp. 2d 669, 689 (E.D. Pa. 2012) (quoting SEC v. Banner Fund Int'l, 211 F.3d 602, 617 (D.C. Cir. 2000)). A wrongdoer such as Besins "may be ordered to disgorge not only the unlawful gains that accrue to the wrongdoer directly, but also the benefit that accrues to

third parties whose gains can be attributed to the wrongdoer's conduct." See SEC v. Contorinis, 743 F.3d 296, 302 (2d Cir. 2014). This result obtains because the purpose of equitable disgorgement is both to deprive a wrongdoer of its unjust enrichment as well as to deter others from violating the law. Teo, 746 F.3d at 105 (citing SEC v. Hughes Capital Corp., 124 F.3d 449, 455 (3d Cir. 1997)).

To accept Besins' position would be tantamount to allowing Besins to enrich unjustly its corporate affiliate through the filing of sham lawsuits. See Contorinis, 743 F.3d at 301-04, 307. It would also "perpetuate rather than correct an inequity." Banner Fund Int'l, 211 F.3d at 617. The Besins entity named as a defendant here is the party that co-owned the '894 patent and the party that filed the sham actions. It is of no import that Besins may have chosen to direct profits from its wrongdoing to affiliated corporate entities LBI SAS and BHL SARL.

Joint and several liability for disgorgement is appropriate "when two or more individuals or entities collaborate or have close relationships in engaging in the illegal conduct." Hughes Capital Corp., 124 F.3d at 455. Nonetheless, a court may apportion liability among tortfeasors when it is reasonable and practical to do so, such as when the recipients of ill-gotten profits and the amount each received

can be determined from the record. Id. at 455. Besins' European affiliates were paid royalties in the amount of 8% of the U.S. net sales of AndroGel through the end of March 2015. As of April 1, 2015, that royalty rate was reduced to 5%. We therefore will apportion liability in those percentages to Besins for the disgorgement award of $448 million plus prejudgment interest according to those percentages.

VI

In addition to disgorgement, the FTC seeks an injunction that in its view would prevent or deter defendants from engaging in similar misconduct in the future. Specifically, the FTC urges an injunction: (1) to prohibit the filing of any claims of patent infringement based on the '894 patent by a product that does not include about 0.1% to about 5% isopropyl myristate; (2) to prohibit defendants from filing any other sham litigation; (3) to prohibit defendants from engaging in any action that misuses government processes for anticompetitive purposes; and (4) to require defendants to certify that any patent infringement litigation or other use of governmental processes has an objectively reasonable basis.

The FTC further contends that an injunction is necessary to restore competitive market conditions. It seeks to compel defendants to license AndroGel 1.62% to one or more generic competitors. It also would command defendants to

manufacture and deliver to these generic competitors a supply of generic AndroGel 1.62% until those competitors are independently able to manufacture the drug themselves.

Section 13(b) of the FTC Act allows the FTC to obtain injunctive relief when a defendant "is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission." 15 U.S.C. § 53(b). As our Supreme Court has recognized, "[t]he purpose of an injunction is to prevent future violations." United States v. W. T. Grant Co., 345 U.S. 629, 633 (1953) (citing Swift & Co. v. United States, 276 U.S. 311, 326 (1928)). Accordingly, the FTC must demonstrate that there is a "cognizable danger of recurrent violation." Id.; see also Madsen v. Women's Health Ctr., Inc., 512 U.S. 753, 765 n.3 (1994). As the moving party, the FTC bears the burden to prove that injunctive relief is warranted. See W. T. Grant Co., 345 U.S. at 633.

The FTC has proven that defendants filed two sham infringement lawsuits, one against Teva in April 2011 and another against Perrigo in October 2011. Defendants were able to exclude competition illegally in the TTRT market from June 2013 until the end of December 2014 as a result of sham litigation and the settlement of sham litigation. Nonetheless, the FTC has presented no evidence that defendants are currently violating antitrust laws or about to violate antitrust laws.

Generic versions of AndroGel have now been on the market for over three years. AndroGel 1%'s share of the market has shrunk since entry of Perrigo, and the '894 patent expires on January 6, 2020. The FTC has not alleged that defendants have filed any other sham lawsuits.[31] The fact that defendants filed two such lawsuits, without more, does not establish that defendants have a pattern or practice doing so. On this record there is no basis to conclude that defendants' misconduct is likely to reoccur.

We are also concerned that the injunction sought by the FTC is overbroad and punitive in nature. Because it would implicate defendants' First Amendment right to petition the government, the injunction must "burden no more speech than necessary to serve a significant government interest." Madsen, 512 U.S. at 765. The injunction sought by the FTC involves the defendants' ability to file patent infringement suits or otherwise to use the governmental process with respect to any patent. Given the fact that the '894 patent was the only patent at issue here and there is no evidence that defendants filed sham litigation or otherwise abused the government process with

31. The FTC has advised the court that since the filing of the lawsuits against Teva and Perrigo in 2011, defendants have filed numerous other patent infringement suits against competitors, including seven lawsuits related to the '894 patent. The FTC has presented no evidence that these lawsuits were shams, and therefore they do not provide support for the injunctive relief sought here.

regard to other patents, the injunctive relief sought by the FTC does not meet the test set forth in Madsen.

We also see no basis to enter an injunction mandating defendants to license to generic competitors its intellectual property rights to AndroGel 1.62%. There is no evidence that sale of AndroGel 1.62% is currently violating, or will violate, section 5 of the FTC Act.

Accordingly, no injunction will be entered.

VII

Based on defendants' violation of section 5 of the FTC Act, the court awards equitable monetary relief in favor of the FTC and against the defendants in the amount of $448 million, which represents disgorgement of defendants' ill-gotten profits from June 2013, when Perrigo would have entered the TTRT market, through August 2017. The FTC is also entitled to prejudgment interest on this award, calculated at the interest rates set forth by the IRS for underpayments as discussed above. See 26 C.F.R. § 301.6621-1. Liability will be apportioned between AbbVie and Besins according to the royalty rates agreed upon by the parties, which were 8% through March 31, 2015 and thereafter 5%.

The parties shall confer and if possible submit to the court for consideration a joint proposed form of judgment and if the parties cannot agree each party shall submit a proposed form

of judgment. The court will enter a judgment after conferring with the parties.

BY THE COURT:

/s/ Harvey Bartle III
J.