UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

In re LANTUS DIRECT PURCHASER ANTITRUST LITIGATION	CIVIL ACTION NO. 16-12652-JGD

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION TO DISMISS

January 10, 2018

DEIN, U.S.M.J.

I. INTRODUCTION

Plaintiffs, FWK Holdings, LLC and Cesar Castillo, Inc., are purchasers of the insulin glargine products Lantus and Lantus SoloSTAR, which are used in the treatment of Type I and Type II diabetes. They have brought a purported class action on behalf of themselves and all others similarly situated against Sanofi-Aventis U.S. LLC ("Sanofi"), the manufacturer of both products, alleging that Sanofi improperly delayed the entry into the market of a competitive product manufactured by Eli Lilly and Company ("Lilly"). In their Amended Class Action Complaint, plaintiffs assert two claims under Section 2 of the Sherman Act (15 U.S.C. § 2) — one for monopolization and one for attempted monopolization. It is the plaintiffs' contention that Sanofi prolonged its monopoly for insulin glargine by (1) improperly listing six patents in the U.S. Federal Drug Administration's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") and (2) pursuing sham litigation against Lilly in which Sanofi asserted claims of patent infringement, allegedly without any basis. The litigation was settled by Sanofi and Lilly shortly before trial.

This matter is before the court on "Defendant Sanofi-Aventis U.S. LLC's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)" (Docket No. 21). Sanofi argues that the court should dismiss both counts of the Amended Complaint (Docket No. 10) ("Am. Compl.") pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. This court finds that the plaintiffs have failed to allege sufficient facts to support a finding of antitrust liability against Sanofi for listing patents in the Orange Book unreasonably, or for engaging in sham litigation with Lilly. Therefore, and for the reasons detailed herein, Sanofi's Motion is ALLOWED and the Amended Complaint is dismissed without prejudice.

II. STATEMENT OF FACTS

Overview

Sanofi is a life sciences company that sells, among other medicines, Lantus — an insulin glargine solution used for Type I and Type II diabetes. Am. Compl. ¶ 3; Def. Mem. (Docket No. 22) at 1. Lantus is sold in vial form or in an injector pen formulation known as Lantus SoloSTAR. Am. Compl. ¶ 3. Sanofi gained approval from the FDA to sell Lantus in vial form in 2000 and to sell Lantus SoloSTAR in 2007. Id. ¶¶ 3, 127. According to the plaintiffs, the original patent for insulin glargine, U.S. Patent No. 5,656,722 ("the '722 patent"), as extended by a period of pediatric exclusivity,[1] expired on February 12, 2015. Id. ¶¶ 103, 105. The plaintiffs contend that "[t]his lawsuit does not challenge Sanofi's right to charge supra-competitive prices for Lantus products up until February of 2015. But it does challenge Sanofi's unlawful conduct in

[1] Pediatric exclusivity grants "an additional six months of market exclusivity to innovator companies that, at written request of the FDA, submit pediatric studies on particular drugs." Nadja R. Allen, *When Does the Clock Begin Ticking?*, 30 AIPLA Q.J. 1, 10-11 (2002).

prolonging its exclusive position beyond February of 2015, i.e., beyond the expiration of the '722 patent." Id. ¶ 121.

Relevant to this litigation, Sanofi is also the holder of other "formulation" patents covering preparations of insulin,[2] and "pen" patents covering injector pens or components thereof.[3] Id. ¶¶ 131-32, 161-66, 221. Sanofi listed these patents in the FDA's Orange Book which, as described below, is intended to put other drug manufacturers on notice of relevant patents, and can trigger a patent-holder's right to bar the entry of a competitor's product into the market while patent infringement claims are resolved. See, e.g., id. ¶ 296. While the plaintiffs contend that Sanofi's listing of six of these patents in the Orange Book was wrongful, and were part of a scheme "to maintain and extend its monopoly power with respect to insulin glargine products – sold under the brand names Lantus and Lantus SoloSTAR," id. ¶ 297, Sanofi has focused its motion to dismiss on one of the "pen" patents, the '864 patent. If Sanofi prevails with respect to its treatment of the '864 patent, the entire complaint must be dismissed as the plaintiffs would not be able to establish any damages in connection with any of the other patents. For all the reasons detailed herein, this court concludes that the plaintiffs have failed to sufficiently allege a claim that the '864 patent was improperly listed in the Orange Book.

[2] These are U.S. Patent No. 7,476,652 ("the '652 patent"), and U.S. Patent No. 7,713,930 ("the '930 patent").

[3] These are U.S. Patent No. 7,918,833 ("the '833 patent"), U.S. Patent No. 8,512,297 ("the '297 patent"), U.S Patent No. 8,556,864 ("the '864 patent"), U.S. Patent No. 8,603,044 ("the '044 patent"), and U.S. Patent No. 8,679,069 ("the '069 patent").

In 2013, Lilly sought FDA approval for its own insulin-glargine product called Basaglar. Id. ¶¶ 4, 187-88. Lilly wanted to sell Basaglar on the U.S. market once the '722 patent had expired in February 2015. Id. ¶ 4. As is required by the FDA, Lilly notified Sanofi regarding the relationship between Basaglar and all of Sanofi's patents listed in the Orange Book for Lantus and Lantus SoloSTAR. Id. ¶ 191. With the exception of the '722 patent that Lilly was waiting to expire, Lilly notified Sanofi of its position that Sanofi's patents "were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the Lilly . . . product." Id.

Sanofi sued Lilly for patent infringement on two of the vial formulation patents and two of the injector pen patents, including the '864 patent. Id. ¶ 205. Suit was brought within the statutorily mandated period of 45 days from receipt of Lilly's notice, thereby triggering an automatic stay of FDA approval of Basaglar for 30 months or until suit was resolved, whichever was sooner. Id. ¶ 206. The plaintiffs contend that this was "sham" litigation, and was brought without any basis and for the sole purpose of extending Sanofi's exclusive period. See, e.g., id. ¶¶ 224-34. As detailed below, this court concludes that the plaintiffs have failed to allege sufficient facts to support that conclusion.

Sanofi and Lilly engaged in extensive pre-trial litigation. See id. ¶ 238. On September 28, 2015, the morning of trial, Lilly and Sanofi settled the litigation. Id. ¶ 241. The settlement included an agreement that Sanofi would grant Lilly a royalty-bearing license so that Lilly could manufacture and sell Basaglar in a KwikPen device globally, and an agreement that Lilly would delay launching Basaglar in the United States until December 15, 2016, even if it obtained final FDA approval before then. Id. ¶¶ 241-43. Plaintiffs have defined the class period in this

litigation as February 13, 2015, when the '722 patent expired, through December 31, 2016, directly after when Lilly was able to sell Basaglar. Id. ¶ 284. Plaintiffs assert that they would have purchased Basaglar instead of Sanofi's products had it been available earlier, but, instead, were forced to buy Lantus and Lantus SoloSTAR products at arbitrarily-inflated prices. Id. ¶¶ 11-12, 250-59.

Regulatory Background[4]

New Drug Applications and Patent Listing Requirements

Drug manufacturers, including Sanofi and Lilly, must gain FDA approval before selling a drug in the United States. The requirements for doing so are listed in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("FDCA"). Am. Compl. ¶ 27. Of relevance to the instant litigation, in connection with their applications for their insulin glargine products, Sanofi and Lilly were required to follow the processes for the approval of new drugs governed by § 505 of the FDCA ("§ 505"), which is codified at 21 U.S.C. § 355. Id. ¶ 28.

Applicants wishing to manufacture and sell a new drug must file a New Drug Application (an "NDA") under § 505(b)(1). Id. ¶ 29. The law mandates that an NDA applicant must submit scientific data demonstrating that a drug is safe and effective, as well as "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." § 505(b)(1); Am. Compl. ¶ 29. Within 30

[4] This court recognizes that the following description of the drug approval process is overly simplistic. It is intended just to highlight the aspects of the statutory scheme relevant to the instant motion to dismiss.

days of FDA approval of an NDA, or amendments or supplements thereto, or if the applicant obtains a new patent relating to the approved product, the applicant must provide the FDA with information regarding each patent that claims the "drug substance," "drug product," or "approved method of use" that falls within the statutorily defined listing requirements. See 21 C.F.R. § 314.53(b)(1); 21 U.S.C. §§ 355(b)(1) & (c)(2); see also Am. Compl. ¶¶ 43-45. The FDA publishes this information in the Orange Book, "so that competitors understand the scope of the brand's ostensible patent protection." See 21 U.S.C. § 355(c)(2); see also Am. Compl. ¶ 23.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), which amended the FDCA and whose provisions are known as the Hatch-Waxman Amendments. Am. Compl. ¶ 32. The Hatch-Waxman Amendments allowed for lower cost alternative brand products to come to market. Id. Under § 505(b)(2), as amended by the Hatch-Waxman Amendments, a brand company can file an NDA relying on data developed not by the applicant, but by a company with an already approved and sufficiently similar product. Id. ¶¶ 37, 38. In doing so, the applicant must certify the relationship between its product and the existing patents listed in the Orange Book on which the applicant is relying. § 505(b)(2); Am. Compl. ¶ 58. Specifically, § 505(b)(2) requires that when investigations relied on in the NDA "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted . . . [,]" an applicant can certify to either of four options: "(i) that such patent information has not been filed, (ii) that such patent has expired, (iii) of the date on which such patent will expire, or (iv) that such patent is invalid or will not be

infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355 (b)(2)(A)(i-iv); see Am. Com. ¶ 58.

When a company files an NDA with a certification under §505(b)(2)'s option IV (a "Paragraph IV Certification") claiming that the product will not infringe a patent or that the relevant patent is invalid, the patent statute treats the certification itself as a technical act of infringement. See 35 U.S.C. § 271(e)(2)(A). This allows the original company that listed the patent a chance to sue. If the patent holder sues the NDA applicant within 45 days of receiving the Paragraph IV Certification, the approval of the NDA is automatically stayed for 30 months, or until the litigation is resolved, whichever is sooner. See 21 U.S.C. §355(c)(3)(C).

Orange Book Listings Requirement

As noted above, 21 C.F.R. § 314.53 (b)(1) dictates which patents applicants must list in the Orange Book when filing an NDA. The regulation provides that applicants should list "patent[s] that claim[] the drug or a method of using the drug . . . [which] consist of drug substance (active ingredient) patents, **drug product (formulation and composition) patents**, and method-of-use patents." Section 314.53 also identifies those patents applicants should exclude, explaining that "[p]rocess patents [and] **patents claiming packaging** . . . are not covered by this section, and information on these patents must not be submitted to FDA." (Emphasis added).

In 2003, the FDA revised the regulations implementing certain statutory provisions included in the Hatch-Waxman Amendments. During the notice and comment period of the rulemaking process for those regulations, the FDA received various comments (hereinafter "Comments") regarding the proposed rule 21 C.F.R. § 314.53, which it summarized as follows:

> (Comment 3) Most comments agreed that patents claiming packaging should not be submitted for listing. However, some comments stated that patents claiming devices or containers that are "integral" to the drug product or require prior FDA approval should be submitted and listed. These comments distinguished between packaging and devices such as metered dose inhalers and transdermal patches, which are drug delivery systems used and approved in combination with a drug.

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a New Drug is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36676-01, 2003 WL 21391636, at 36,680 (June 18, 2003).

The FDA provided a response to the Comments with the final rule, noting that the agency had "clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing."[5] Id. The FDA's response was as follows (hereinafter "FDA Response"):

> (Response) We agree that patents claiming a package or container must not be submitted. Such packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission. However, we have clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing.
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> Section 314.3 defines a "drug product" as "*** a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." **The appendix in the Orange Book lists current dosage forms for approved drug products**. **The list includes** metered aerosols, capsules, metered sprays, gels, and **pre-filled drug delivery systems**. **The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product**. Patents must not be

[5] As detailed below, by purporting to "clarify" the issue, but not directly addressing the status of all "patents claiming devices or containers that are 'integral' to the drug product or require prior FDA approval[,]" the FDA caused confusion in the drug industry as to what types of product patents should be listed.

> submitted for bottles or containers and other packaging, as these are not "dosage forms."

Id. (emphasis added). At issue in connection with this motion to dismiss is whether Sanofi appropriately listed the '864 patent in the Orange Book. In particular, the plaintiffs contend that the '864 patent is just packaging and does not "claim[ ] the finished dosage form of the approved drug product." Sanofi contends that the '864 patent was appropriately listed as a pre-filled drug delivery system.

Sanofi's Products and Patents

Lantus

Sanofi is the holder of the original patent for insulin glargine, the '722 patent. Am. Compl. ¶ 103. Insulin glargine is a long-acting analog insulin for management of diabetes. Id. ¶ 3. The '722 patent expired in August 2014 with a period of pediatric exclusivity extending to February 2015. Id. ¶105. Sanofi listed the '722 Patent in the Orange Book. Id. ¶ 107.

On or around April 20, 2000, the FDA approved NDA No. 21-081 for Lantus, a sterile solution of insulin glargine for use as an injection and sold throughout the United States. Id. ¶¶ 3, 106, 108. As originally approved, Lantus "had two package forms: (1) vials (5 and 10 mL) for use with single-dose syringes, and (2) cartridges (3 mL) for use in an injector pen Sanofi called 'OptiPen™ One.'" Id. ¶ 110. Over the years, Sanofi obtained two additional "formulation" patents relating to the ingredients in the Lantus vial formulation. Id. ¶¶ 123, 126, 131-32. These were also listed in the Orange Book. Id. ¶ 154. Plaintiffs contend that these patents were improperly listed. Id. ¶¶ 155-58. However, since they are not the basis for Sanofi's motion to dismiss, they will not be discussed further herein.

Lantus SoloSTAR and the '864 Patent

In 2007, the FDA approved Sanofi to sell Lantus in another disposable injector pen called SoloSTAR. Id. ¶127. The letter from the FDA approving the NDA noted that "[t]his supplemental new drug application provides for the addition of the Lantus SoloStar disposable insulin injection device." Id. Ex. D.[6] As detailed above, Sanofi holds several patents relating to its injector pen products, including the '864 patent. See note 3, supra. The '864 patent, which is the only patent discussed in detail in the motion to dismiss, expires in 2024. Am. Compl. ¶ 163. That patent "relates to drive mechanisms suitable for use in drug delivery devices, in particular pen-type injectors, having dosage setting means, enabling the administration of medicinal products from a multi-dose cartridge. In particular, the present invention relates to such drug delivery devices where a user may set the dose." Id. Ex. I ('864 patent) at Technical Field section, col. 1, ll. 18-23.[7]

It is undisputed that Lantus SoloSTAR is sold loaded with a dosage of insulin glargine. See, e.g., Am. Compl. ¶¶ 128-29. The FDA approval obviously contemplated a pre-filled device, as evidenced by the warnings it required on the Lantus SoloSTAR carton relating to the condition of the enclosed solution. Id. Ex. D. However, the '864 patent itself does not mention Lantus or insulin glargine. It also does not expressly require that the dispenser be pre-filled.

[6] While the plaintiffs alleged that the FDA approved Lantus SoloSTAR as a "package change," Am. Compl. ¶127, the approval letter from the FDA (attached to the complaint) makes it clear that it was approved as a "disposable insulin injection device." Id. Ex. D. Plaintiffs have not continued to argue that the FDA just approved a package change.

[7] While both parties have asked the court to review the '864 patent, the Amended Complaint contains no allegations as to the correct interpretation of the patent. Nothing herein is intended to constitute a construction of any of the terms of the patent. Rather, the description of the patent terms contained herein is based only on the plain language of the patent.

Nevertheless, the invention claimed is "[a] drive mechanism for use in a drug delivery device" which device includes a "dose dial sleeve" and a "dose limiting mechanism." See, e.g., id. Ex. I at Claims 1, 2 & 5. The "Background" section of the patent makes it clear that the drug delivery device is used for "regular injection[s] by persons without formal medical training[,]" such as in connection with the management of diabetes. Am. Compl. Ex. I. At issue in this litigation is whether the patents for the Lantus SoloSTAR (including its components) are appropriately listed in the Orange Book as a "drug product." While both parties rely on the Comments and FDA Response generated during rulemaking (as quoted above), the plaintiffs argue that the listing was improper because the patent did not "claim[ ] the finished dosage form of the approved drug product" and was just for packaging. Sanofi, on the other hand, argues that the listing was proper because the Lantus SoloSTAR is a "pre-filled drug delivery device" and the patent otherwise relates to an approved drug product. As detailed below, this court finds that while the issue of whether the Lantus SoloSTAR patent is appropriately listed in the Orange Book is an open question, Sanofi's interpretation is reasonable and, therefore, defeats the plaintiffs' antitrust claims.

Lilly's Competing Product

Lilly developed Basaglar, an insulin-glargine product similar to Sanofi's, which Lilly planned to use with its injector pen product KwikPen. Am. Compl. at ¶¶ 185-88. Like the Lantus SoloSTAR, the KwikPen had been approved by the FDA. Id. ¶ 186. In 2013, Lilly filed an NDA under § 505(b)(2). Id. ¶ 187. Lilly sought approval to sell Basaglar in the U.S. upon the expiration of Sanofi's '722 patent's pediatric exclusivity period. Id. ¶¶ 187, 192. Lilly's application relied on Sanofi's previous NDA for Lantus as well as the studies associated

therewith, as is allowed by the Hatch-Waxman Amendments. Id. ¶ 188. "These studies established a 'bridge' between Basaglar and Lantus to demonstrate that Basaglar was sufficiently similar to Lantus such that reliance on Lantus studies was scientifically justified." Id.

As part of its NDA, Lilly filed Paragraph IV Certifications regarding Sanofi's formulation patents and injector pen patents. In doing so, Lilly certified that those Sanofi patents "were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale" of Basaglar. Id. ¶ 191. "Lilly filed a paragraph III certification as to the '722 patent, agreeing to wait to market [Basaglar] until that patent expired." Id.

After receipt of the paragraph III and IV certifications, Lilly and Sanofi signed a confidential access agreement and Sanofi received 66 pages of Lilly's NDA. Id. ¶¶ 201-02. The confidential documents identified for Sanofi the active and inactive ingredients of Basaglar and Lilly's associated injector pen. Id. ¶¶ 202, 204. According to the plaintiffs, but denied by Sanofi, "[t]he documents showed that the Lilly NDA product would not infringe any of the claims [in] the two injector pen patents (the '864 and '044 patents) or any claims in the two vial formulation patents (the '652 and '930 patents)." Id. ¶ 204.

The Lawsuit

In January 2014, Sanofi sued Lilly for infringement based on these formulation and injector pen patents. Id. ¶ 205.[8] The lawsuit was brought within 45 days of Sanofi's receipt of Lilly's Paragraph IV Certification. Id. ¶ 206. As a result of filing the lawsuit, as provided for by

[8] In March 2014, the PTO issued U.S. Patent No. 8,679, 069 ("the '069 patent"), another injector pen patent. Am. Compl. ¶ 221. Sanofi amended the complaint to include infringement claims regarding the '069 patent. Id. ¶ 223.

21 U.S.C. §355(c)(3)(C), FDA approval for Basaglar was automatically stayed for 30 months, or the conclusion of the litigation, whichever was sooner. Id.

Through its lawsuit, "Sanofi sought to have Lilly enjoined 'from engaging in any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the insulin glargine [rDNA origin] injection in a prefilled insulin delivery device, 100 units/mL as claimed by the Patents-in-Suit for the full terms thereof (and any additional period of exclusivity to which Plaintiffs and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities.'" Am. Compl. ¶ 215. Lilly denied the claims of infringement, asserted affirmative defenses of patent misuse and prosecution laches, counterclaimed seeking declarations of non-infringement, invalidity, and non-enforceability of the patents for patent misuse and prosecution laches, and sought an order removing the '864 and '044 Patents from the Orange Book. Id. ¶ 217.

With respect to the '864 patent in particular, the plaintiffs allege that Sanofi brought suit "even though, after reviewing the materials Lilly provided, its lawyers had no basis to conclude that Lilly's KwikPen was covered by any claim of the '864 patent." Id. ¶ 212. However, other than stating that the KwikPen was "different" than and was not the same "type" as the Lantus SoloSTAR, the plaintiffs have not alleged any facts to establish that the KwikPen does not infringe on Sanofi's patents. See, e.g., id. ¶¶ 231-33.

The Sanofi/Lilly dispute was actively litigated. As described by the plaintiffs, the parties "engaged in substantial discovery, including interrogatories and document requests; sub-poenaed non-parties; fought multiple discovery disputes; tendered experts and submitted . . . Daubert motions opposing those experts; and undertook the nuanced and complex process of

claim construction" albeit, according to the plaintiffs, relating to some irrelevant claims. Id. ¶ 238. On September 28, 2015, the morning that trial was set to begin, Lilly and Sanofi settled their suit. Id. ¶ 241. Under the settlement, Sanofi granted Lilly a royalty-bearing license that allowed Lilly to sell Basaglar in the KwikPen device upon the payment of royalties. Id. The settlement also "memorialized Lilly's agreement to stall its Basaglar launch until December 15, 2016 . . . [and] provided the FDA with authority to grant final approval to Lilly's Basaglar NDA." Id. ¶ 242.

Approval of Basaglar

The FDA had granted tentative approval for Basaglar in August 2014. Id. ¶ 236. Plaintiffs contend that were it not for "Sanofi's wrongful Orange Book listings, or Sanofi's filing of the frivolous patent litigation, the FDA would have granted Lilly final approval for Basaglar as soon as the '722 patent's pediatric exclusivity expired in February 2015." Id. ¶ 237. Instead, the FDA granted final approval for Basaglar on December 16, 2015. Id. ¶ 244. In accordance with its settlement with Sanofi, Lilly could not launch Basaglar for another year, until December 15, 2016. Id. ¶ 247.

Alleged Harm

Plaintiffs seek to bring suit on behalf of a proposed class of purchasers who claim to have paid higher prices for insulin glargine products between February 2015 and December 2016 as a result of Sanofi's anticompetitive behavior. See id. ¶¶ 11-12, 284. Plaintiffs claim that the loss to American purchasers during the delay caused by the lawsuit "would have far exceeded a billion dollars." Id. ¶ 9. They allege that were it not for "Sanofi's anticompetitive conduct, the plaintiffs and other members of the class would have: (1) purchased lower-priced

insulin glargine products instead of the higher-priced Lantus and Lantus SoloSTAR products for some or all of their insulin glargine needs; (2) paid a lower price for their insulin glargine products, sooner; and/or (3) paid lower prices for some or all of their remaining purchases." Id. ¶ 254.

Additional facts are included below as necessary.

III. LEGAL STANDARD

A. Standard of Review – Motion to Dismiss for Failure to State a Claim

Motions to dismiss under Rule 12(b)(6) test the sufficiency of the pleadings. When confronted with such a motion, the court accepts as true all well-pleaded facts and draws all reasonable inferences in favor of the plaintiff. See Cooperman v. Individual Inc., 171 F.3d 43, 46 (1st Cir. 1999). The court may also consider "implications from documents attached to or fairly incorporated into the complaint . . . facts susceptible to judicial notice . . . [and] concessions in plaintiff's response to the motion to dismiss." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55-56 (1st Cir. 2012) (internal quotations and citations omitted).

As the First Circuit has explained, in considering the merits of a motion to dismiss, the court proceeds in two steps. First, we "isolate and ignore statements in the complaint that simply offer legal labels and conclusions or merely rehash cause-of-action elements." Id. at 55. Second, we "take the complaint's well-pled (*i.e.*, non-conclusory, non-speculative) facts as true, drawing all reasonable inferences in the pleader's favor, and see if they plausibly narrate a claim for relief." Id. Dismissal is only appropriate if the complaint, so viewed, fails to allege "a plausible entitlement to relief." Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559, 127 S. Ct. 1955, 1967, 167 L. Ed. 2d

929 (2007)). "Plausible . . . means something more than merely possible[.]" Schatz, 669 F.3d at 55. "The bottom line is that the combined allegations, taken as true, must state a plausible, not merely conceivable, case for relief." Carrero-Ojeda v. Autoridad de Energia Electrica, 755 F.3d 711, 718 (1st Cir. 2014) (internal citations and quotations omitted). "Engaging in this plausibility inquiry is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" Germanowski v. Harris, 854 F.3d 68, 72 (1st Cir. 2017) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950, 173 L. Ed. 2d 868 (2009)).

B. Standard for Monopolization and Attempted Monopolization Under the Sherman Act

Plaintiffs bring two counts under the Sherman Act, 15 U.S.C. § 2, one for monopolization and the other for attempted monopolization. Am. Compl. ¶¶ 294-309. In order to be successful on a claim under § 2 of the Sherman Act, a plaintiff must "demonstrate (1) that the defendant possesses monopoly power in the relevant market, and (2) that the defendant has acquired or maintained that power by improper means." Town of Concord, Mass. v. Boston Edison Co., 915 F.2d 17, 21 (1st Cir. 1990) (internal quotations and citations omitted). "[A] practice, a method, a means, is 'improper' if it is 'exclusionary.' To decide whether [a company's] conduct was exclusionary, we should ask whether its dealings with [a competitor] went beyond the needs of ordinary business dealings, beyond the ambit of ordinary business skill, and 'unnecessarily excluded competition' from the [] market." Barry Wright Corp. v. ITT Grinnell Corp., 724 F.2d 227, 230 (1st Cir. 1983) (internal citations omitted). Thus, successful claims of monopolization must establish "that the defendant 'has engaged in impermissible 'exclusionary' practices with the design or effect of protecting or enhancing its monopoly position.'" Boston Scientif Corp. v. Schneider (Europe) AG, 983 F. Supp. 245, 268 (D. Mass.

1997) (quoting Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 195-96 (1st Cir. 1996)). "In other words, the acquisition and maintenance of the power must be willful, rather than a result of legitimate means such as patents, superior products, business acumen, or historic accident." Id. Finally, "[a]ttempted monopolization under § 2 of the Sherman Act requires proof of (1) anti-competitive or exclusionary conduct; (2) specific intent to monopolize; and (3) a dangerous probability that the attempt will succeed. Id. and cases cited.

IV. ANALYSIS

As detailed herein, on the non-conclusory facts alleged, plaintiffs have not presented a plausible case for relief under the Sherman Act with regard to either the claim of improper Orange Book listings or of sham litigation. The court will address each in turn. Sanofi has also moved to dismiss the Amended Complaint on the grounds that the plaintiffs have failed to allege the relevant market and, hence, have failed to establish that Sanofi possessed monopoly power. Sanofi informed the court during oral argument that it would not pursue this ground if it prevails on its other arguments. Since this court concludes that the plaintiffs have failed to plead an improper means of acquiring monopoly power, this court will not address the arguments regarding whether plaintiffs have adequately pled that Sanofi possessed monopoly power in the relevant market.

A. The Orange Book Listing of the '864 Patent

As detailed above, one of the purposes of the Orange Book "is to provide would-be generic manufacturers with notice of any patent rights that are implicated by a brand-name drug." United Food & Comm. Workers Unions & Employers Midwest Health Befits Fund v. Novartis Pharm. Corp., Civil Action No. 15-cv-12732, 2017 WL 2837002, at *5 (D. Mass. June 30,

2017) (hereinafter "United Food"). Applicants are "required by law" to identify "any patent that 'claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'" In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) (quoting 21 U.S.C. § 355(b)(1)). For its part, the FDA is required by law to publish the information provided by the applicant in the Orange Book. Id. (citing 21 U.S.C. 355(b)(1) & (c)(2)). Thus, "[t]he FDA does not independently determine whether a particular drug product actually reads on a particular patent claim, and it does not examine the asserted patents to ensure their validity." United Food, 2017 WL 2837002, at *6.

It is undisputed that "listing presumptively valid patents in the Orange Book and enforcing them against infringers are not bases for an antitrust claim; Orange Book listing is a statutory obligation and enforcement is a statutory right." In re Lipitor Antitrust Litig., MDL No. 2332, 2013 WL 4780496, at *21 (D.N.J. Sept. 5, 2013); see also In re Solodyn (Minocylcine Hydrochloride) Antitrust Litig., No. 14-md-02503-DJC, 2015 WL 5458570, at *12 (D. Mass. Sept. 16, 2015) (since patent was never held to be invalid or unenforceable and defendant was required by statute to submit its patents for listing in the Orange Book, the listing in and of itself could not form the basis for a Section 2 claim). Nevertheless, improperly listing a patent in the Orange Book may subject the patent holder to antitrust liability. See Buspirone, 185 F.

Supp. 2d at 372-73 (conduct in providing information for listing in Orange Book is "not immune from liability under the Sherman Act.").[9]

A defendant may be found to have acquired or maintained monopoly power by improper means if the defendant engaged in unambiguously wrongful conduct that resulted in the improper listing of patents in the Orange Book. See, e.g., In re Remeron Antitrust Litig., 335 F. Supp. 2d 522, 529-30 (D.N.J. 2004) (motion to dismiss antitrust claim denied where defendant filed its Orange Book listing more than a year after the 30 day period required by FDA regulations and plaintiffs alleged a scheme to delay generic competition); Buspirone, 185 F. Supp. 2d at 374, 376 (antitrust claim based on improper listing allowed to proceed where the defendant had affirmatively misrepresented to the FDA that a patent covered uses which the defendant itself had abandoned in the approval process). On the other hand, if an applicant "had a reasonable basis for the submission," then the listing does not constitute improper means for antitrust purposes. See Organon, Inc. v. Mylan Pharm., Inc., 293 F. Supp. 2d 453, 460 (D.N.J. 2003) (given ambiguities in statutory and regulatory language, applicant had a "reasonable basis" to list patent in Orange Book; motion to dismiss antitrust claim based on improper listing allowed); see also Buspirone, 185 F. Supp. 2d at 374, 376 (standard to be applied is whether the listing was "objectively baseless").

[9] Under the Noerr-Pennington doctrine, as articulated in E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961), and United Mine Workers of Am. v. Pennington, 381 U.S. 657, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965), "petitioning activity ... is generally immune from suit under the Sherman Act." Buspirone, 185 F. Supp. 2d at 368. Courts have held that unlike litigation, which is protected, submitting information for the Orange Book is not petitioning activity. Id. at 372-73. Since this principle is not in dispute here, no extended discussion is warranted.

Based, in part, on their original contention that the FDA approved the Lantus SoloSTAR as a "package change," the plaintiffs alleged in their Amended Complaint that it was obvious that the '864 patent should not have been listed in the Orange Book. Am. Compl. ¶ 127. See note 6, supra. Given the clear instructions by the FDA that patents for packaging should not be listed, this allegation may have been sufficient to survive a motion to dismiss. However, the record is now clear that the Lantus SoloSTAR was approved as a drug delivery system, and not merely as a package. Am. Compl. Ex. D. Therefore, further analysis is needed.

The FDA has expressly interpreted "drug products" which must be listed in the Orange Book to include "pre-filled drug delivery systems." As the plaintiffs recognized in their Amended Complaint, Lantus SoloSTAR was, in fact, sold as a pre-filled drug delivery system. Am. Compl. ¶¶ 127-29. The FDA approval for the Lantus SoloSTAR also contemplated that it would be sold as a pre-filled drug delivery system. Id. Ex. D. Therefore, it was not unreasonable for Sanofi to believe that it should list the Lantus SoloSTAR, and its components, in the Orange Book.

Moreover, an argument can be made that listing the Lantus SoloSTAR and its components is consistent with the purposes of the Orange Book, which is to put others on notice of potentially relevant patents. As plaintiffs have alleged in the Amended Complaint, Lilly's competitive products included both a drug and a drug delivery system. Therefore, the patents relating to the drug delivery system would be relevant to determining whether Lilly's products were subject to patent infringement claims.

It is also significant that the Lantus SoloSTAR is clearly not just a package, or container to hold a drug, but rather is an integral part of the way insulin glargine can be used to treat

diabetes. Therefore, while it may be debatable whether the Lantus SoloSTAR fits neatly into the category of patents that must be disclosed, it does not fit into the category of patents that must not be disclosed.

In arguing against the above conclusion, plaintiffs contend that the '864 patent should not have been listed in the Orange Book because the FDA stated in its Response to Comments quoted above that "the key factor is whether the patent being submitted claims the finished dosage form of the approved drug product" and there is no such "claim" in the '864 patent. See Am. Compl. ¶¶ 171-72. Although the requirement for such an express claim is not detailed in the regulations themselves, this court recognizes that it must give significant deference to an agency interpretation of its own regulations. Fed. Energy Regulatory Comm'n v. Silkman, 177 F. Supp. 3d 683, 711 (D. Mass. 2016) (finding that the court "must accept the reasonable interpretation of an ambiguous provision by the agency delegated authority to make that interpretation.") (relying on U.S. v. Mead Corp., 533 U.S. 218, 226-27, 121 S. Ct. 2164, 2171, 150 L. Ed. 2d 292 (2001))). However, the Response itself is ambiguous, and does not directly address the Comments, which concerned all delivery devices "that are 'integral' to the drug product or require prior FDA approval[.]" See note 5, supra. Moreover, even assuming such a "claim" must be made in the patent, it is not clear whether or not the "claims" of the '864 patent, which are for a drug delivery device which includes a dose dial sleeve and a dose limiting mechanism, among other things, are sufficient to satisfy any such requirement. In sum, regardless which party's interpretation would ultimately be accepted by the FDA, the plaintiffs have not pled sufficient facts to establish that Sanofi's decision to list the '864 patent in the Orange Book was unreasonable or objectively baseless.

This conclusion is bolstered by the fact that Sanofi is not alone in its interpretation of the FDA listing requirements. Sanofi has submitted publicly available evidence that on six different occasions from 2005 to 2012, companies have written to the FDA inquiring about the correct interpretation of the listing requirements.[10] Plaintiffs conceded at oral argument that there are no other relevant inquiries or responses that the court should consider. These inquiries show that the question asked of the FDA during its rulemaking comment period, i.e., should all patents for "containers that are 'integral' to the drug product or require prior FDA approval" be submitted to the Orange Book, remains unanswered. See note 5, supra. The FDA's "clarification" in response to these Comments left a significant ambiguity.

[10] "The court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FRE 201(b). "The court: (1) may take judicial notice on its own; or (2) must take judicial notice if a party requests it and the court is supplied with the necessary information." Fed. R. Evid. 201(c). The court hereby takes judicial notice of the following requests for clarification with regard to the fact that they contain a question for the FDA, not for the truth of their contents. See OrbusNeich Med. Co., Ltd., BVI v. Boston Scientific Corp., 694 F. Supp. 2d 106, 111 (D. Mass. 2010) ("The public filing of [a] document with a regulatory agency [] makes it a proper subject of judicial notice, at least with regard to the fact that it contains certain information, though not as to the truth of its contents."). The court takes notice of: (1) Request for Advisory Opinion on behalf of GSK, Docket No. FDA-2005-A-0476 (Jan. 10, 2005), available at https://www.regulations.gov/document?D=FDA-2005-A-0476-0003; (2) Request for Advisory Opinion by Ropes & Gray, Docket No. FDA-2006-A-0063 (Aug. 10, 2006), available at https://www.regulations.gov/document?D=FDA-2006-A-0063-0005; (3) Request for Advisory Opinion on behalf of AstraZeneca, Docket No. FDA-2007-A-0099 (June 21, 2007), available at https://www.regulations.gov/document?D=FDA-2007-A-0099-0003; (4) Letter on behalf of GSK, Docket No. FDA-2005-A-0476 (Feb. 11, 2009), available at https://www. regulations.gov/document?D=FDA-2005-A-0476-0004; (5) Request for Advisory Opinion on behalf of Forest Laboratories, Docket No. FDA-2011-A-0363 (May 12, 2011), available at https://www.regulations.gov/document?D=FDA-2011-A-0363-0001 as well as responses thereto; (6) Letter from FDA to Forest Laboratories, Docket No. FDA-2011-A-0363-0008 (Nov. 7, 2011), available at https://www.regulations.gov/document?D=FDA-2011-A-0363-0008; (7) Request for Advisory Opinion on behalf of Novo Nordisk, Docket No. FDA-2012-A-1169 (Nov. 26, 2012), available at https://www.regulations.gov/document ?D=FDA-2012-A-1169-0001.

Since at least 2005, drug manufacturers have sought to determine whether patents directed to drug delivery systems that do not recite the approved active ingredients or formulation should be listed in the Orange Book. See note 10, supra. In the absence of any response to several inquiries to the FDA, in 2007, AstraZeneca informed the FDA that it was going to continue to list in the Orange Book patents for approved pre-filled drug delivery systems even if the patent neither disclosed nor claimed the active ingredient or formulation of the approved drug product. Request for Advisory Opinion on behalf of AstraZeneca, Docket No. FDA-2007-A-0099 (June 21, 2007), available at https://www.regulations.gov/document?D=FDA-2007-A-0099-0003. Similarly, in 2009, GlaxoSmithKline ("GSK") wrote to the FDA informing the agency that "in the absence of further guidance from the FDA, [GSK] has modified its Orange Book listing practice to list those patents . . . that claim all or a portion of integrated drug-device products, regardless of whether the approved drug substance is specifically mentioned in the claims of such patents." Letter from GSK to FDA, Docket No. FDA-2005-A-0476 (Feb. 11, 2009), available at https://www.regulations.gov/document?D=FDA-2005-A-0476-0004. In 2011, in response to an inquiry from Forest Laboratories, Inc., the FDA wrote that "due to the need to address other Agency priorities," it "has been unable to reach a decision" on "whether a patent that claims a drug delivery device whose use is integral to the administration of the active ingredient and the approval of the NDA, but that does not claim the active ingredient of the approved drug product, should be submitted for listing in [the Orange Book]." Interim Response to Forest Laboratories, Inc., Docket No. FDA-2011-A-0363 (Nov. 7, 2011), available at https://www.regulations.gov/document?D=FDA-2011-A-0363-0008. No further response was received from the FDA and, in 2012, Novo Nordisk again asked for an advisory opinion, and, like

others before it, notified the FDA that it intended to list patents in the Orange Book for pre-filled drug delivery systems "regardless of whether or not the patents disclose or claim the active ingredient or formulation of the approved drug product."[11] Request for Advisory Opinion, Docket No. FDA-2012-A-1169 (Nov. 26, 2012), available at https://www.regulations.gov/ document?D=FDA-2012-A-1169-0001. Again there was no response from the FDA. Thus, by the time of Lilly's Paragraph IV Certification, the FDA had been informed that a number of drug manufacturers were listing their drug delivery systems in the Orange Book, even if the relevant patents did not claim "the finished dosage form of the approved drug product," but had not indicated that such a listing was improper. The fact that the FDA did not cite to its Response, but, rather, stated that "it had been unable to reach a decision" compels the conclusion that the question whether a patent for a delivery system must claim "the finished dosage form of the approved drug product" was not answered in the Response, and remains an open question.

While this court makes no determination as to the correct interpretation of the FDA Comments, it is clear from these requests that the issue whether the '864 patent should have been listed is an open question in the industry. For the reasons detailed herein, Sanofi's interpretation of the listing requirements was reasonable. The plaintiffs have pled no other facts that lead to the conclusion that Sanofi knew or should have known that its listing of the '864 patent was incorrect. Therefore, the Sherman Act claims, insofar as they rely on the improper Orange Book listing of the '864 patent, are dismissed.

[11] As described in the letter to the FDA, this was a change in its position – before then, Novo Nordisk had not listed such patents in the Orange Book.

B. The Sham Litigation Claim

Plaintiffs also contend that Sanofi sought to wrongfully extend its exclusionary period by "[c]ommencing and maintaining a sham litigation against Lilly to delay introduction of competing insulin glargine products into the U.S. market." Am. Compl. ¶ 296. Once Lilly filed its Paragraph IV Certification in its NDA, Sanofi had the statutory right to sue under 35 U.S.C. § 271(e)(2)(A) in order to enforce its patent. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568-69 (Fed. Cir. 1997). The Paragraph IV Certification is deemed to be "a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." Id. at 1569. However, "[t]he occurrence of the defined 'act of infringement' does not determine the ultimate question whether what will be sold will infringe any relevant patent." Id. Thus, while a patent holder has the right to bring patent infringement litigation upon receipt of a Paragraph IV Certification, it is not obligated to do so.

The filing of a lawsuit is generally protected activity under the First Amendment, as recognized by the Noerr-Pennington doctrine. See note 9, supra. However, immunity is lost if the lawsuit is a "sham." See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 2015 WL 5458570, at *11 ("Under the Noerr-Pennington doctrine, filing a lawsuit is protected under the First Amendment unless the lawsuit is a 'sham.'") (citing Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56, 60-61, 113 S. Ct. 1920, 1926, 1928, 123 L. Ed. 2d 611 (1993))). In the instant case, plaintiffs contend that Sanofi had no reasonable belief that Basaglar or its KwikPen infringed its patents when initiating the lawsuit against Lilly. However,

as detailed herein, the allegations of the Amended Complaint are insufficient to state a claim for sham litigation.

The Supreme Court has identified a two-part definition for sham litigation.

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if the challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor. . . .

Prof'l Real Estate Investors, Inc., 508 U.S. at 60 (internal quotations and emphasis omitted). "Only if the suit is found to be objectively baseless may the court proceed to the second prong of the test." Morton Grove Pharm. v. Par Pharm. Cos., Inc., 2006 WL 850873, at *10 (N.D. Ill. 2006).

Specific to the '864 patent, the plaintiffs make two principal claims in support of their sham litigation argument. First, the plaintiffs claim that Sanofi initiated litigation while knowing that Lilly's KwikPen did not infringe the '864 patent. Second, the plaintiffs contend that Sanofi sued on the '864 patent knowing that the patent should not have been listed in the Orange Book to begin with. As the court has already dismissed the Orange Book listing claim, the plaintiffs' second argument need not be addressed further.

The Facts as Alleged do not Establish that the Lawsuit was "Objectively Baseless"

"A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent . . . is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them,

whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment." United Food, 2017 WL 2837002, at *11 (quoting Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003)). Thus, to prevail on its sham litigation claim, the plaintiffs must establish that Sanofi "had no reasonable basis to believe that its patent claims were valid or that they were infringed by [Lilly.]" 800 Adept, Inc. v. Murex Sec., Ltd., 539 F.3d. 1354, 1370 (Fed. Cir. 2008), and cases cited. Here, however, the facts as alleged do not show that Lilly was "almost certain to be found not to have infringed" the '864 patent. United Food, 2017 WL 2837002, at *11.

According to the Amended Complaint, prior to bringing suit Sanofi had "[t]he pages of Lilly's § 505(b)(2) application [that] (1) showed the list of ingredients of Lilly's NDA product, and (2) identified the type of injector pen by which the Lilly NDA product would be administered." Am. Compl. ¶ 204. Other than repeatedly stating that the documents showed that Lilly's products "would not infringe any of the claims in the two injector pen patents (the '864 and '044 patents) or any claims in the two vial formulation patents (the '652 and '930 patents)[,]" the plaintiffs have offered no facts in support of these conclusions. Id. ¶¶ 204, 211-12, 231-33. Since this court must disregard conclusory allegations of fact and law, Schatz, 669 F.3d at 55, the allegations of the Amended Complaint are insufficient to show that the underlying lawsuit lacked any reasonable merit.

Other facts also support the conclusion that the lawsuit was not objectively baseless.[12] While none of these facts, in and of themselves, establish that the litigation brought by Sanofi was not sham litigation, they all combine to defeat any contention that the litigation was objectively unreasonable when brought. See United Food, 2017 WL 2837002, at *10-13 (finding that plaintiffs fail to sufficiently plead sham litigation after considering multiple factors); AstraZeneca AB v. Mylan Labs., Inc., MDL Docket No. 1291, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) (finding that suit was not a sham based on an analysis of the extent of the underlying litigation and because a Paragraph IV Certification gave "an objectively reasonable basis to sue.").

As an initial matter, in its litigation with Lilly, Sanofi was enforcing patents that had never been invalidated or found unenforceable against an obvious act of infringement. While this is not a prerequisite to a claim of sham litigation, it is not irrelevant: patents are presumed to be valid, and patent holders are entitled to enforce their rights under their patents, so parties claiming sham litigation must overcome these presumptions. See United Food, 2017 WL 2837002, at *10 ("The Court declines to adopt a bright-line rule requiring that a patent be invalidated or tarnished before a plaintiff can allege a sham litigation claim, but notes that it is difficult to conceive of a scenario in which a sham litigation claim would go forward without the patent having been invalidated or otherwise tarnished."). Moreover, with respect to the '864 patent, as detailed above, there was industry support for the proposition that such patents

[12] The court may take judicial notice of the docket of any court case. Maher v. Hyde, 272 F.3d 83, 86 n.3 (1st Cir. 2001). Here the underlying case is found at Sanofi-Aventis U.S. LLC v. Eli Lilly & Co., No. 1:14-cv-00113-RGA-MPT (D. Del.) ("Sanofi I").

should be listed in the Orange Book. Thus, the fact that Sanofi sought to protect the '864 patent in the face of a Paragraph IV Certification is not obviously unreasonable.

Moreover, the record in the underlying litigation establishes that Sanofi's contention that the KwikPen infringed on the '864 patent was not objectively baseless. As detailed above, the plaintiffs' assertion that there was no infringement is not supported by any facts in the Amended Complaint. In contrast, the parties in Sanofi I engaged in a claim construction dispute addressing various elements of the '864 patent. If Lilly's KwikPen was completely different, and bore no relationship to the Lantus SoloSTAR (as plaintiffs allege) there would have been no reason for Lilly to have participated in a claims construction exercise. Instead, both Lilly and Sanofi proposed different interpretations of various elements of the '864 patent, and the court adopted and rejected some of each of the parties' suggestions. See Sanofi I, Docket No. 192. The record does not support the conclusion that Sanofi should have known that there was no way that Lilly's KwikPen could be found to have infringed on Sanofi's product.

The fact that the underlying litigation was heavily contested, while not conclusive, also weighs against a finding that the litigation was a sham. The '864 patent was litigated for over a year and a half before the parties came to a settlement agreement on the eve of trial. The docket indicates an active and hard-fought dispute. The sham litigation exception to the Noerr-Pennington immunity was not intended to provide all third parties with an opportunity to re-litigate cases. Rather, the doctrine is reserved for those cases where plaintiffs can assert facts showing that the patent suit was objectively meritless. See AstraZeneca AB, 2010 WL 2079722, at *4 (finding that the underlying lawsuit was "hard-fought and close" and that such an "outcome hardly bespeaks baseless litigation."); see also Asahi Glass Co., Ltd., 289 F. Supp. 2d

at 995 (". . . to avoid turning every patent case into an antitrust case, some threshold of plausibility must be crossed at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase . . . an infringement suit must be adjudged to be objecttively baseless before it can be considered an unlawful method of competition . . ."). The fact that Sanofi I was litigated so extensively before settlement is evidence that the claims involved were not baseless.

The settlement in Sanofi I, while not dispositive, further shows that the underlying suit did not lack any merit. See Toyo Tire & Rubber Co., Ltd. v. Atturo Tire Corp., No. 14 C 0206, 2017 WL 1178224, at *4 (N.D. Ill. Mar. 30, 2017) (". . . courts have invariably held that lawsuits terminating in favorable settlement are also objectively reasonable and are not shams"). Obviously "[p]arties may settle a litigation for a variety of reasons independent of the merits of the claims." Morton Grove, 2006 WL 850873, at *11 (internal citations omitted). Nevertheless, a "favorable prior settlement may afford support for a belief that subsequent litigation will be successful[.]" Id. Here, plaintiffs argue that the settlement was not, in fact, a "favorable" one since it allowed Lilly to enter the market many years before all of the relevant patents expired. However, Sanofi points to the fact that it is going to be paid royalties from Lilly in connection with the sale of Lilly's products, and that the settlement delayed Lilly's entry into the market until December 2016. Given the existence of the royalty payments, and the delayed entry into the market, it cannot be said that the settlement was so insignificant that the underlying

litigation was obviously a sham. Rather, the fact of the settlement helps defeat a finding that the litigation was objectively baseless.[13]

In light of the plaintiffs' failure to establish that the litigation was objectively baseless, this court need not address the second prong of the sham litigation test. Accordingly, plaintiffs' antitrust claims based on a contention of sham litigation are dismissed.

C. Plaintiffs' Other Claims Fail for Lack of Causation

In light of the court's conclusion that the litigation concerning the '864 patent was not a sham litigation, the remainder of the claims of the Amended Complaint relating to the other Sanofi patents must be dismissed. Since Sanofi was entitled to bring its patent litigation against Lilly due to the '864 patent, Sanofi was entitled to the 30 month delay in Lilly's entry into the market.

"An antitrust plaintiff must prove a causal connection between the antitrust violation and actual damages suffered." In re Wellbutrin XL Antitrust Litig., 2012 WL 1657734, at *33 (E.D.P.A. May 11, 2012). In an antitrust class action, "individual injury (also known as antitrust impact) is an element of the cause of action; to prevail on the merits, every class member must prove at least some antitrust impact resulting from the alleged violation." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3rd Cir. 2008). Plaintiffs have alleged harm due to "artificially-inflated" prices for insulin glargine products between February of 2015, when the

[13] In the Amended Complaint, the plaintiffs assert that in the Consent Judgment settling Sanofi I, "Sanofi finally admitted that Lilly's Basaglar did not infringe the vial formulation patents or DCA injector pen patents." Am. Compl. ¶ 242. This allegation is not supported by the record. Rather, the Consent Judgment provides that "by virtue of the license granted by Sanofi to Eli Lilly as part of the Settlement Agreement" Lilly's product does not infringe on the formulation or pen patents. See Sanofi I, Docket No. 279 at 24.

‘722 Patent expired, and December 2016, when Lilly was permitted to sell Basaglar pursuant to the Sanofi I settlement.

As explained above, plaintiffs have not pled facts showing that the listing of the ‘864 patent in the Orange Book was unreasonable, or that the litigation enforcing the ‘864 patent was a sham. Thus, the ‘864 patent stood as a lawful bar to Lilly’s market entry for as long as it remained in effect, unless otherwise agreed. The ‘864 patent was set to expire in 2024. Regardless of the anticompetitive harm caused by the formulation and other pen patents on which plaintiffs have sued in the instant case, the ‘864 patent stood as a lawful bar to entry during the period of alleged harm. This court therefore dismisses those claims as there is no plausible argument for causation.

V. CONCLUSION

For the reasons detailed herein, the Motion to Dismiss (Docket No. 21) is ALLOWED and the Plaintiffs’ Amended Class Action Complaint is dismissed without prejudice.

SO ORDERED.

/ s / Judith Gail Dein
Judith Gail Dein
United States Magistrate Judge