IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN MANUFACTURING, LIMITED; AND AMGEN USA, INC Plaintiffs, v. SANOFI; SANOFI-AVENTIS U.S. LLC; AVENTISUB LLC f/d/b/a AVENTIS PHARMACEUTICALS INC.; and REGENERON PHARMACEUTICALS, INC., Defendants.	)	Civ. No. 14-1317-SLR (Consolidated)

MEMORANDUM ORDER

At Wilmington this 5th day of January, 2017, having reviewed the papers filed in connection with plaintiffs' motion for permanent injunction, and having heard oral argument on the same;

IT IS ORDERED that the motion (D.I. 336) is granted, for the following reasons:

1. **Procedural background.**[1] On October 17, 2014, plaintiffs Amgen Inc., Amgen Manufacturing Limited, and Amgen USA Inc. (collectively "plaintiffs") brought this action alleging infringement of certain patents against defendants Sanofi, Sanofi-Aventis U.S. LLC, Aventisub LLC, and Regeneron Pharmaceuticals, Inc. (collectively "defendants"). (D.I. 1) On February 22, 2016, defendants stipulated to infringement of certain asserted claims of the patents-in-suit. (D.I. 235) The parties proceeded to trial

[1] A fuller recitation of the procedural and factual background may be found in the court's post-trial opinion. (D.I. 389)

on March 8, 2016, arguing the validity of the asserted claims. On March 16, 2016, the jury returned a verdict finding the asserted claims of the patents-in-suit valid. (D.I. 302, 304) On March 23 and 24, 2016, the court heard evidence on plaintiffs' request for a permanent injunction. The court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338(a).

2. **Factual background.**[2] Physicians recognize dyslipidemia caused by elevated LDL ("low density lipoprotein" or "bad" cholesterol) as a major risk factor for cardiovascular disease. Starting in 2005, plaintiffs developed Repatha™ ("Repatha"), which uses the active ingredient "evolocumab." Evolocumab is a monoclonal antibody that targets PCSK9[3] to prevent it from engaging the low density lipoprotein receptor ("LDLR") protein and ultimately lowers the levels of LDL in the blood. Plaintiffs filed for FDA approval on August 27, 2014, which they received in August 2015. Plaintiffs then launched Repatha. Repatha is offered in a 140 mg dose and 420 mg dose.

3. Defendants developed PRALUENT® alirocumab ("Praluent"), a monoclonal antibody that reduces LDL cholesterol levels in the blood. Defendants filed for regulatory approval in November 2014 using an orphan drug priority review voucher, and received FDA approval in July 2015. Defendants then launched Praluent, which is provided in a 75 mg low dose and a 150 mg high dose. According to defendants, more than 80% of patients on Praluent are able to hit their LDL target on the low dose.

---

[2] The facts and arguments discussed below are taken from the parties' briefing and corresponding hearing transcripts. (D.I. 347, 348, 362, 369, 376)

[3] Proprotein convertase subtilisin kexin type 9 is a specific antibody involved in regulating the levels of the low density lipoprotein receptor protein.

4. **Standard.** In *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (vacating and remanding *MercExchange, L.L.C. v. eBay Inc.*, 401 F.3d 1323, 1339 (Fed. Cir. 2005)) (hereinafter "*eBay*"), the Supreme Court overruled the Federal Circuit's longstanding "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." The Supreme Court held in *eBay* that permanent injunctions in patent cases must be based on a case-by-case assessment of the traditional equitable factors governing injunctions. *Id.* at 391-92. That is, to be awarded a permanent injunction, a plaintiff must demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.* at 391. "[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id.* at 394.

5. In *eBay*, the Court specifically cautioned against the application of categorical rules, classifications, and assumptions in these analyses. *Id.* at 392. Nevertheless, courts (presumably struggling to balance the absence of a presumption of irreparable harm with a patentee's right to exclude) have frequently focused upon the nature of the competition between a plaintiff and a defendant in the relevant market in the context of evaluating irreparable harm and the adequacy of money damages. *See, e.g., TruePosition Inc. v. Andrew Corp.*, 568 F. Supp. 2d 500, 531 (D. Del. 2008). Courts

awarding permanent injunctions typically do so under circumstances in which the plaintiff practices its invention and is a direct market competitor.[4] Plaintiffs also frequently succeed when their patented technology is at the core of their business, and/or where the market for the patented technology is volatile or still developing.[5]

6. There is no dispute that both Repatha and Praluent are approved by the FDA to lower LDL cholesterol in a select group of patients. They are the only therapeutics in the PCSK9 inhibitor market, making the parties head-to-head competitors in a targeted and developing market. The parties at bar are large companies with multiple products, both on the market and in the development pipeline. The parties are also each innovators, having independently developed their PCSK9 inhibitor.

---

[4] *See, e.g., Muniauction, Inc. v. Thomson Corp.*, 502 F. Supp. 2d 477, 482 (W.D. Pa. 2007) ("Plaintiff and defendants are direct competitors in a two-supplier market. If plaintiff cannot prevent its only competitor's continued infringement of its patent, the patent is of little value.") (granting permanent injunction); *Johns Hopkins Univ. v. Datascope Corp.*, 513 F. Supp. 2d 578, 586 (D. Md. 2007) (granting permanent injunction where infringing product was plaintiffs' "only competition" and "thus, its sale reduce[d] the [p]laintiffs' market share"); *Transocean Offshore Deepwater Drilling, Inc. v. GlobalSantaFe Corp.*, 2006 WL 3813778, *4 (S.D. Tex. Dec. 27, 2006) (granting permanent injunction requiring structural modifications to infringing deepwater drilling rigs where "the customer base for deep water drill rigs is small, and [defendant] has not only used [its] rigs equipped with the infringing structure to compete for the same customers and contracts as [plaintiff], but also to win contracts over competing bids from [plaintiff]").

[5] *See, e.g., Martek Biosciences Corp. v. Nutrinova Inc.*, 520 F. Supp. 2d 537, 558-59 (D. Del. 2007) (granting permanent injunction where plaintiff was a direct competitor "likely to lose market share that it may not be able to recapture," as plaintiff's patented technology was its primary revenue source, and defendant was plaintiff's only competitor and was "targeting [plaintiffs] customers in that industry"); *TiVo, Inc. v. EchoStar*, 446 F. Supp. 2d 664 (E.D. Tex. 2006) (granting permanent injunction where: (1) parties were direct competitors; (2) "plaintiff [was] losing market share at a critical time in the market's development;" (3) the parties agreed that customers in the relevant market tend to remain customers of the company they first purchased from; and (4) as a "relatively new company with only one primary product," plaintiff's "primary focus is on growing a customer base specifically around the product" competing with the infringing product).

7. **Irreparable harm.** Plaintiffs present traditional evidence of loss of market share and momentum. Specifically, plaintiffs allege that they have been forced to compete with defendants for contracts with insurers and exclusive formulary positions, particularly since defendants were first to market. Plaintiffs argue that defendants' market position is causing harm to their reputation as the innovator in the PCSK9 cholesterol-lowering medicine, and defendants' marketing of Praluent as "The First U.S. FDA-Approved PCSK9 Inhibitor" compounds such harm. Defendants respond that it is well known that plaintiffs were the first to file a biologics license application with the FDA and receive regulatory approval worldwide for Repatha. According to defendants, Repatha would have faced pricing pressures even without competition from Praluent. This factor weighs in favor of plaintiffs.

8. **Remedies at law.** Plaintiffs assert that patent protection is fundamental to their business model and they will not be able to fully recoup their investment in Repatha without an injunction. Monetary damages will not suffice under the present circumstances, as plaintiffs intended to use their patent to maintain market exclusivity. Moreover, the developing PCSK9 inhibitor market, together with the reputational harm, make monetary damages speculative. In contrast, defendants allege that plaintiffs have not suffered reputational harm and, even if they did, such harm is measurable. Defendants maintain that monetary damages are sufficient, in as much as the parties' experts quantified the extent of past financial injury during the liability phase of the case. This quantification, however, does not include reputational harm and defendants do not offer any method of calculation. This factor weighs in favor of plaintiffs.

9. **Balance of hardships.** Both parties have spent billions of dollars and over a decade of work to bring their respective products to market. If an injunction does not issue, plaintiffs lose the market share occupied by defendants and face continued competition. If an injunction issues, defendants lose business going forward and the ability to make and market Praluent. This factor is neutral.

10. **Public interest.** Plaintiffs rely on the traditional notions of being a patent holder and a verdict winner. Plaintiffs point to the FDA's approval of Repatha to treat all patients covered by the Praluent label to assuage the consequence of an injunction on patients. (JTX 392) Defendants rely heavily on the availability of (and physicians' alleged preference for) the low 75 mg dose of Praluent to argue that an injunction would harm the treatment of patients. Defendants also point to Praluent's label stating that "[t]he recommended starting does for Praluent is 75 mg." (PTX 5012)

11. The court will not substitute its judgment for that of the FDA, nor delve into weighing testimony on the propriety of treating patients with the 75 mg dose of Praluent (instead of the 150 mg dose or the 140 mg dose of Repatha). The public generally is better served by having a choice of available treatments. Therefore, the court finds itself between a rock and a hard place, i.e., being a patent holder and a verdict winner should be a meaningful factor in the balancing test, but taking an independently developed, helpful drug off the market does not benefit the public. "[T]he touchstone of the public interest factor is whether an injunction, both in scope and effect, strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 863 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011). The court concludes that the public

interest of having a choice of drugs should prevail. This factor weighs in favor of defendants.

12. **Conclusion.** For the aforementioned reasons, plaintiffs have demonstrated irreparable harm, as well as the inadequacy of money damages. The public interest factor weighs in favor of defendants. Plaintiffs' motion for a permanent injunction (D.I. 336) is granted. Given the ramifications of an injunction, the court will delay its imposition for thirty (30) days to allow defendants the opportunity to appeal and request expedited review of this ruling by the Federal Circuit, and/or to encourage the parties to reach an appropriate business resolution.

United States District Judge