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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC.,	
Plaintiff,	Civil Action No. 02-CV-2829
v.	Honorable Katharine S. Hayden
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.,	
Defendants.	ORAL ARGUMENT IS REQUESTED

**MEMORANDUM OF PLAINTIFF PFIZER INC.
IN SUPPORT OF THE COURT'S ENTRY OF ITS PROPOSED ORDER**

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In its December 20, 2002 Order ("12/20/02 Order," entered on December 27, 2002) granting defendants' motion to dismiss, the Court directed that "[f]urther Orders may be submitted consistent herewith within fifteen (15) business days." Pursuant to this authorization, Plaintiff Pfizer Inc. ("Pfizer") submits this memorandum in support of the entry of its Proposed Order, submitted herewith. Pfizer's Proposed Order is consistent with the 12/20/02 Order, but includes additional provisions necessary to fully effectuate the Court's oral decision of December 17, 2002.

PRELIMINARY STATEMENT

This case is a patent infringement action concerning Pfizer's patented invention directed to the drug amlodipine and its pharmaceutically acceptable salt forms. The U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,572,909 (the "'909 patent") to Pfizer on February 25, 1986. The original term of the patent expires on February 25, 2003, and the PTO extended the patent's term through July 31, 2006 pursuant to the Patent Term Restoration Act ("PTR"), 35 U.S.C. §156. Reddy is seeking to market the maleate salt form of amlodipine during the restored term of the '909 patent. In moving to dismiss Pfizer's Complaint for patent infringement, Reddy argued that the scope of the rights associated with the '909 patent, during its restored term, is limited solely to the besylate salt form of amlodipine. Reddy's non-infringement argument is directed only to the restored period of the '909 patent, and does not respond to the Complaint's allegations regarding infringement of the patent during its remaining original term, up to and including February 25, 2003. As to this period, Reddy admits that its proposed product infringes the patent. (*See* Def. Mem. In Supp. of Motion to Dismiss ("Def. Mem."), at 1.)

Pfizer's Proposed Order, based on the decision rendered orally by the Court on December 17, 2002, contains findings addressed to the infringement and validity of Pfizer's '909 patent during the time period prior to February 26, 2003. (*See* Proposed Order ¶¶ 2-3.) It also prohibits defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Reddy") from commercially selling their proposed amlodipine maleate product prior to February 26, 2003, and prohibits the FDA from approving the product prior to that date. (*Id.* ¶¶ 4-5.)[1]

Although Reddy has represented to the Court and to the FDA that it will not market its proposed product during at least the original term of the '909 patent (through February 25, 2003), there is too much at stake here to permit Pfizer to rely on Reddy's promises. Pfizer respectfully submits that it is entitled to the relief requested in the Proposed Order because: (1) Reddy admits that its amlodipine maleate product infringes the '909 patent; (2) Reddy does not dispute that the patent is valid and, as a matter of law, the patent is presumed valid; and (3) as recognized by the Court, Reddy has undertaken not to market its product before February 26, 2003, at the earliest. In these circumstances, 35 U.S.C. §271(e)(4) requires that the Court grant injunctive relief during the period that Reddy admits infringement.

STATEMENT OF FACTS

This is a patent infringement action brought under 35 U.S.C. §271(e)(2)(A). Reddy seeks FDA approval for a drug utilizing Pfizer's patented cardiovascular therapeutic agent, amlodipine,

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[1] Pfizer was awarded by the FDA an additional six months of exclusivity, beyond the expiration of the '909 patent, based on the work Pfizer performed, at FDA's request, studying amlodipine in children ("pediatric exclusivity"). Pfizer has concluded that the issue of pediatric exclusivity is appropriately addressed first to FDA, and the Proposed Order does not provide for injunctive relief based on pediatric exclusivity. Pfizer does not intend, thereby, to waive its statutory right to that exclusivity before the FDA.

in the maleate salt form. Pfizer currently markets amlodipine under the name Norvasc® as a hypertension and angina medicine, in an amlodipine besylate salt formulation. Norvasc® is the leading drug for hypertension and angina and is one of Pfizer's most successful products. Norvasc® accounts for more than $1.5 billion in U.S. sales annually.[2]

In its Complaint, Pfizer alleges that Reddy's product infringes the '909 patent, which covers Pfizer's invention of a class of compounds, known as dihydropyridines, with anti-hypertensive therapeutic activity, including amlodipine and its pharmaceutically acceptable salts. (Cmplt. ¶¶ 13-14.) For almost ten years, the FDA, pursuant to Pfizer's applications, reviewed amlodipine in both its maleate and besylate salt forms. Pfizer's studies required great effort and the expenditure of hundreds of millions of dollars. *See* Peter Tollman et al., *A Revolution in R&D: How Genomics and Genetics Are Transforming the Biopharmaceutical Industry* 12, Ex. 2 (Boston Consulting Group, Inc. 2001) (citing costs of studies generally). Although Pfizer had conducted its clinical trials of amlodipine primarily using the maleate salt form, and submitted extensive data concerning the maleate salt form to the FDA, Pfizer (with FDA approval) ultimately commercially launched, and now sells, amlodipine in the besylate salt form. *See* 57 Fed. Reg. 54600, 54601 (Nov. 19, 1992); 58 Fed. Reg. 7893 (Feb. 10, 1993).

During the lengthy review the FDA conducted, Pfizer was unable to market any amlodipine product and it could not exploit the '909 patent to protect a product that was on the market. As a result, the PTO awarded Pfizer a "Certificate Extending Patent Term" under the PTR. Pfizer also earned an additional period of six months of regulatory exclusivity under

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[2] *See* "Pfizer Inc Segment/Product Revenues Full Year 2001 (Unaudited)," *available at* www.pfizer.com/download/news/2002_0123_Q4earnfin4.pdf, *printed on* December 19, 2002 (Ex. 1).

21 U.S.C. §355a for pediatric trials it performed on amlodipine ("pediatric exclusivity"). (Cmplt. ¶ 16.) Pfizer's '909 patent is currently listed in the Orange Book with an expiration date of July 31, 2006, and a separate pediatric exclusivity date of January 31, 2007.[3]

Reddy filed a "paper" NDA seeking approval to sell amlodipine malcate tablets in December 2001. (*See* Reddy Notice Letter to Pfizer, dated May 1, 2002, regarding Reddy's Paragraph IV Certification (Ex. 3).) The paper NDA relies on Pfizer's amlodipine studies and data regarding the amlodipine maleate and besylate salts. 21 U.S.C. §355(b)(2). On May 1, 2002, Reddy provided Pfizer with notice of its "paragraph IV" patent certification, filed in conjunction with its paper NDA, asserting that manufacture, use or sale of its amlodipine maleate salt would not infringe the '909 patent. (*Id.*) On June 12, 2002, Pfizer brought suit against Reddy for patent infringement based on its paper NDA and paragraph IV certification, pursuant to 35 U.S.C. §271(e)(2)(A).

On June 21, 2002, Reddy moved pursuant to Rule 12(b)(6), Fed. R. Civ. P., to dismiss Pfizer's Complaint with prejudice. Reddy based its motion to dismiss on its contention that its particular salt form of Pfizer's amlodipine drug, amlodipine maleate, does not fall within the scope of the restored '909 patent, an argument that relates only to the '909 patent *after* February 25, 2003, the expiration date of the original term of the '909 patent. Reddy conceded in its moving papers that its proposed amlodipine maleate product falls within the claims of the '909 patent as originally issued by the PTO. (Def. Mem. at 1.)

On December 17, 2002, the Court orally issued a decision granting Reddy's motion to dismiss. The Court subsequently issued the 12/20/02 Order dismissing Pfizer's Complaint. The

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3 *See* Orange Book entry for Pfizer's Norvasc® product, *printed on* October 22, 2002 (Ex. 2).

12/20/02 Order was entered on the docket on December 27, 2002. Both before and after December 20, 2002, the parties attempted to negotiate a form of Order effectuating the Court's decision, but were unable to reach agreement. Pursuant to the Court's authorization in the 12/20/02 Order, specifically permitting the parties to submit "further Orders" consistent with it, Pfizer now asks that the Court also enter the Proposed Order submitted herewith.

ARGUMENT

Pfizer's Proposed Order is consistent with the 12/20/02 Order, in that it provides for dismissal of the Complaint and contains a finding that Reddy's product will not infringe the '909 Patent after February 25, 2003. (*See* Proposed Order ¶¶ 1, 6.)[4] However, Pfizer respectfully submits that, in dismissing Pfizer's Complaint in its entirety, without regard to Reddy's undisputed infringement of the '909 patent through February 25, 2003, the 12/20/02 Order does not fully implement the findings made by the Court in its oral decision on December 17, 2002. In order to resolve all of the issues alleged in the Complaint, including the issue of Reddy's admitted infringement of the '909 Patent prior to February 26, 2003, Pfizer respectfully submits that the Court should also enter the Proposed Order, submitted herewith. The Proposed Order, because it addresses *all* of the claims of the Complaint, will constitute a final decision for appeal purposes.

[4] Of course Pfizer believes, respectfully, that the Court erred in finding no infringement of the '909 patent after February 25, 2003. Moreover, as discussed below, because the Court found that facts pleaded in the Complaint justify granting some relief to Pfizer for the period prior to February 26, 2003, Pfizer believes that the Court properly should have denied Reddy's motion to dismiss. For these reasons, in its Proposed Order Pfizer expressly reserves its right to appeal the Court's judgment. (*See* Proposed Order ¶ 1.)

I. PFIZER IS ENTITLED TO THE FINDINGS AND RELIEF SOUGHT IN ITS PROPOSED ORDER.

A. Pfizer Is Entitled To A Finding That The '909 Patent Is Infringed, And To An Injunction Against Further Infringement Up To And Including February 25, 2003.

Reddy does not contest infringement of the '909 patent through February 25, 2003, the patent's original expiration date prior to its extension under the PTR. Similarly, Reddy has not contested the validity of the '909 patent in this case or in its paragraph IV certification to FDA. (*See* Ex. 3.) In its brief in support of its motion to dismiss, Reddy stated "[t]he parties . . . agree that the drug product defendants seek to make -- *amlodipine maleate -- is covered by [the* '909 *patent]*." (Def. Mem. at 1, emphasis added.) In May of this year, Reddy made the same admission to the FDA, stating that Pfizer's "patent rights covering amlodipine maleate expire on the original expiration date of February 25, 2003."[5]

Based on these unambiguous admissions, the Court, in its oral decision on December 17, 2002, found that Reddy's amlodipine maleate product infringes the '909 patent during its original term. The Court stated its finding that "the expiration date of the amlodipine maleate patent protection enjoyed by Pfizer must be February 25, 2003, the original patent expiration date." (Tr. of Hearing on December 17, 2002 ("12/17/02 Tr.") (Ex. 5), at 23; *see also id.* at 22-23.) Based on the Court's statement, Pfizer is entitled to a finding that the '909 Patent is infringed by Reddy's amlodipine maleate product through February 25, 2003. (*See* Proposed Order ¶¶ 2-3.)

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5 Letter from David G. Adams, Counsel to Dr. Reddy's Laboratories, Inc. to Douglas Throckmorton, Acting Director of the FDA's Center for Drug Evaluation and Research (Div. of Cardio-Renal Drug Products), dated May 1, 2002 ("Adams Letter") (Ex. 4), at 2.

In addition to admitting its infringement of Pfizer's '909 patent, Reddy further represented that it "will not seek to market its product until that portion of the '909 patent which applies to amlodipine maleate expires." (Def. Mem. at 1.) It had earlier made the same representation to the FDA. (Adams Letter (Ex. 4), at 2 ("Reddy does not intend to market its product until [February 25, 2003] and does not seek FDA approval prior to that date.").) The Court recognized these concessions at the December 11, 2002 oral argument on Reddy's motion to dismiss in stating, without contradiction by Reddy, that "Dr. Reddy insists that it does not plan to market its new drug until after February 25, 2003." (Transcript of 12/11/02 Hearing ("12/11/02 Tr.") (Ex. 6), at 6; *see also* 12/17/02 Tr. (Ex. 5), at 3 ("Defendant Dr. Reddy would like to market amlodipine maleate, another salt of the amlodipine molecule, as its own therapeutic heart medicine beginning in February, 2003 after the date that Pfizer's patent was originally set to expire.").)

Nevertheless, Reddy has previously certified to the FDA, without any qualification, that the '909 patent "will not be infringed" by Reddy's manufacture, use or sale of its NDA product.[6] (Ex. 3, at 3.) By filing the paper NDA with such a paragraph IV certification Reddy has committed an act of patent infringement under 35 U.S.C. §271(e)(2)(A).[7] *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (act of infringement under §271(e)(2)(A) consists of

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[6] The statute requires that such a certification of non-infringement be made without qualification. 21 U.S.C. §355(b)(2)(A)(iv). If Reddy had made a "paragraph III certification" under 21 U.S.C. §355(b)(2)(A)(iii) stating when "the patent will expire," §355(c)(3)(B) requires that the FDA approve its NDA, subject to statutory exclusivity, only when the restored '909 patent expires, which Reddy concedes is July 31, 2006.

[7] "(2) It shall be an act of infringement to submit –

(A) an application . . . described in section 505(b)(2) [FDCA] for a drug claimed in a patent or the use of which is claimed in a patent . . ." 35 U.S.C. §271(e)(2)(A).

submitting an ANDA or paper NDA containing the fourth type of certification). As a result of Reddy's undisputed infringement of the '909 patent through February 25, 2003, Pfizer is entitled to injunctive relief under 35 U.S.C. §271(e)(4).

First, that statute provides that, once having found infringement, a court "shall" order that approval of the infringing NDA be deferred until expiration of the uncontested portion of the '909 patent. 35 U.S.C. §271(e)(4)(A). (*See* Proposed Order ¶ 4.)

Second, Pfizer is also entitled to an injunction prohibiting Reddy from manufacturing, using, offering to sell, or selling amlodipine maleate until at least February 26, 2003. (*See* Proposed Order ¶ 5.) The Court has the authority to issue such an injunction pursuant to 35 U.S.C. §271(e)(4)(B), and "[i]t is the general rule that an injunction will issue when infringement has been adjudged, absent a sound reason for denying it." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988) ("an injunction should issue once infringement has been established unless there is a sufficient reason for denying it"). In similar circumstances, courts have issued injunctions notwithstanding the applicant's assurances that it would not market its product. *See id.* at 1282 (mere fact that defendant was no longer making or selling infringing product was "not a sufficient ground for denying an injunction against future infringement"); *Glaxo Inc. v. Boehringer Ingleheim Corp.*, 954 F. Supp. 469, 476 (D. Conn. 1996) (injunction granted notwithstanding defendants representations that it would not market its infringing pharmaceutical product until after expiration of patent in suit).

If Reddy is able to obtain FDA approval, and then changes its mind and begins to sell its product before the original term of the '909 patent expires, the damage to Pfizer's business would be enormous. In any event, "irreparable harm [from infringement] is presumed" where

the patentee's rights are "valid and infringed." *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983). The presumption arises because "[t]he very nature of the patent right is the right to exclude others." *Id.* Absent the ability to exclude others, the value of the patent right is radically diminished, and it no longer provides "as great an incentive to engage in the toils of scientific and technological research." *Id.* at 1578. The loss of the right to exclude others, even for a limited period of time, cannot be fully compensated by money damages. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456-57 (Fed. Cir. 1988); *Atlas Powder Co. v. Ireco Chems.*, 773 F.2d 1230, 1233 (Fed. Cir. 1985). Thus, Pfizer both needs and is entitled to the assurance provided by an injunction prohibiting Reddy's sale of amlodipine maleate.

Moreover, Reddy cannot dispute that Pfizer is entitled to an injunction through February 25, 2003, in light of its previous representations to the Court that its proposed product would infringe the '909 patent and that it will not market the product prior to that date. The statements of a party's attorneys in briefs or in court can estop the party from subsequently taking a different position. *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995); *Hughes Communications Galaxy, Inc. v. United States*, 34 Fed. Cl. 623, 632 n.8 (Ct. Cl. 1995); *accord Fleck v. KDI Sylvan Pools, Inc.*, 981 F.2d 107, 121 (3d Cir. 1992) (plaintiffs who promised bankruptcy court they would not seek recovery against debtor in excess are insurance coverage are estopped from subsequently attempting to do so); *Scarano v. Central R. Co. of N.J.*, 203 F.2d 510, 512-13 (3d Cir. 1953). Here Reddy, through its attorneys, has admitted that its product will infringe the '909 patent up to and including February 25, 2003, and has represented that it will not market its product before that date. Pfizer's Proposed Order simply memorializes these concessions. Reddy should not be permitted now to object to the Proposed Order by taking a position that contradicts its earlier admissions.

In sum, Pfizer is entitled to entry of the Proposed Order, enjoining Reddy's sale of its amlodipine maleate product at least until February 26, 2003, because Reddy is infringing now and infringement is not contested.

B. Pfizer Is Entitled To A Finding That The '909 Patent Is Valid.

In addition to injunctive relief prohibiting Reddy from selling its amlodipine maleate product through February 23, Pfizer is entitled to a finding that the '909 patent is valid. (*See* Proposed Order ¶ 3.) A patent is presumed to be valid, 35 U.S.C. §282, and Reddy has not contested the validity of the '909 patent. As discussed above, Reddy admits, and the Court found, that the '909 patent will be infringed by Reddy's product until February 25, 2003. In recognizing this infringement, Reddy acknowledged, and the Court implicitly determined, that Pfizer's patent is valid. *See Viskase Corp. v. American Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) ("an invalid [patent] claim can not be infringed"); *Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp.*, 984 F. Supp. 239, 253 (D.N.J. 1997) ("[o]ne cannot infringe upon a invalid patent").

Here, a statement by the Court that the '909 patent is valid and infringed during its original term is not merely an academic exercise. In submitting the Proposed Order, Pfizer does not seek injunctive relief from the Court relating to its pediatric exclusivity. While Pfizer is clearly entitled to pediatric exclusivity as a result of its studies of amlodipine in children, it will pursue that relief in the FDA. However, under the literal terms of the statute governing pediatric exclusivity, 21 U.S.C. 355a(b)(2)(B), if a paragraph IV certification is filed with respect to a patent, "and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed," a six month period of pediatric exclusivity is applied to the patent. There are no reported cases or FDA decisions construing this

provision, and the FDA's position is unclear regarding the application of pediatric exclusivity where patent litigation is concluded without express findings of validity and infringement, even though validity and infringement are not disputed. Express findings will ensure that there is no uncertainty or confusion regarding Pfizer's pediatric exclusivity.[8]

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[8] Reddy has not disputed that Pfizer is entitled to six months of pediatric exclusivity. In fact, Reddy has stated publicly that, based on Pfizer's pediatric exclusivity, it does not intend to market its amlodipine maleate product until after August 25, 2003 (the date that pediatric exclusivity would expire absent any PTR extension of the '909 patent). *See* Reddy Press Release "Court determines Pfizer's patent term extension does not extend to Dr. Reddy's Amlodipine Maleate product," dated December 17, 2002 (Ex. 7); Reddy Press Release, "Dr. Reddy's receives Approvable letter for Amlodipine Maleate," dated Oct. 22, 2002 (Ex. 8).

CONCLUSION

For all of the foregoing reasons, the Court should enter the Proposed Order submitted by Pfizer, in order to carry out the full scope of the Court's December 17, 2002 oral decision.

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