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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
	:	

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

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Pursuant to the Court's December 20, 2002 Order ("12/20/02 Order," entered on December 27, 2002), Pfizer submits this reply memorandum in further support of the entry of the Proposed Order submitted with Pfizer's January 7, 2003 letter to the Court.

PRELIMINARY STATEMENT

In opposing entry of Pfizer's Proposed Order, Reddy seeks to retain the benefits of the Paragraph IV certification it made to the FDA, including a determination of the scope of Pfizer's rights under the '909 patent at least nine months earlier than it otherwise could have been obtained, while avoiding the consequences of its certification, including a judicial finding that its proposed product infringes Pfizer's '909 patent during its original term.

Reddy contends that, because it represented that it does not seek to market its proposed amlodipine maleate product "before the expiration" of U.S. Patent No. 4,572,909 (the "'909 Patent"), which it claims is February 25, 2003, Pfizer is not entitled to a finding that the product will infringe the '909 patent during the period up to and including that date. (Opp. at 6.) In its December 17, 2002 decision, the Court determined, *inter alia*, the scope of Pfizer's rights under the '909 patent during the period after February 25, 2003. While the Court concluded that those rights are limited, the expiration date of the patent is, in fact, July 31, 2006 (not including pediatric exclusivity). Consequently, Reddy seeks approval of its paper NDA prior to expiration of the '909 patent, as provided for in 35 U.S.C. §271(e)(2)(A).

Reddy also argues that the Court cannot find infringement of the '909 patent through February 25, 2003 because Pfizer has not shown Reddy's intent to market its proposed product before that date. Reddy confuses the requirements for subject matter jurisdiction in Hatch-Waxman patent infringement actions brought pursuant to §271(e)(2)(A), with the showing

needed to establish infringement. Under a proper analysis, Reddy's admissions are sufficient for the Court's finding of infringement.

Pfizer raised the issue of Reddy's infringement prior to February 26, 2003 in its opposition to Reddy's motion to dismiss (*see* Mem. of Pl. Pfizer Inc. in Opp. to Def. Mot. to Dismiss Complaint (Corrected), dated Aug 27, 2002, at 35-38). If the Court intends to dispose of the case in its entirety, Pfizer respectfully submits that is entitled to the findings it has requested.

ARGUMENT

I. PFIZER IS ENTITLED TO A FINDING THAT REDDY INFRINGES THE '909 PATENT THROUGH FEBRUARY 25, 2003.

A. The Expiration Date Of The '909 Patent Is July 1, 2006.

Reddy bases its argument that the Court may not find infringement of the '909 patent through February 25, 2003 on its contention that it has not sought to market its proposed amlodipine maleate product "before the expiration" of the '909 patent, because it has represented that it does not seek to sell the product until after February 25, 2003. Consequently, it contends that the requirements of §271(e)(2)(A), upon which Pfizer predicates its product infringement clause, have not been met.[1] (Opp. at 6-7.) The most obvious flaw in Reddy's argument is that Pfizer has obtained, pursuant to the PTR, an extension of the term of the '909 patent to July 31, 2006. Reddy's argument ignores the fact that, regardless of the scope of rights available to Pfizer under the patent based on this Court's December 17, 2002 decision, the "expiration date" of the '909 patent is July 31, 2006, not February 25, 2003. *See* Electronic Orange Book Listing showing July 31, 2006 as expiration date of '909 patent (without taking into account pediatric

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[1] 35 U.S.C. §271(e)(2)(A) provides that "[i]t shall be an act of infringement to submit an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under [the FFDCA] to engage in the commercial manufacture, use or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

exclusivity) (attached as Ex. 2 to Pfizer Mem.). It cannot be disputed that Reddy sought (and seeks) FDA approval to market its amlodipine maleate product prior to July 31, 2006.

Moreover, Reddy's current position regarding the "expiration date" of the '909 patent cannot be reconciled with its filing a Paragraph IV certification, the action that led to this litigation (*See* Pfizer Mem. Ex. 3). By making a Paragraph IV certification, Reddy triggered this suit, in which the Court has jurisdiction to determine infringement both before and after February 25, 2003. Neither the statute (21 U.S.C. §355(b)(2)(A)(iv)) nor the regulation (21 C.F.R. §314.50(i)(A)(4)) which govern the certification permits Reddy to delay the effectiveness of its Paragraph IV certification, or to provide different certifications for different "expiration dates."

Reddy's Paragraph IV certification started the clock that led to this patent infringement action. At the same time, it placed at issue Reddy's infringement of the '909 patent over the entire period following the certification. If Reddy wished to avoid the question of its infringement prior to February 26, 2003, it could have made a Paragraph III certification pursuant to 21 C.F.R. §314.50(i)(A)(3) and 21 U.S.C, §355(b)(2)(A)(iii), and amended it to a Paragraph IV certification after February 25, 2003. Had it followed that course, this patent litigation would not have begun until the amendment was filed. By making a Paragraph IV certification on May 1, 2002, instead of February 26, 2003, Reddy chose to accelerate by nearly nine months a judicial determination of Pfizer's rights under the '909 patent, as extended pursuant to the PTR. Reddy should not now be permitted to avoid the full consequences of its choice.

B. Reddy's Admissions Are Sufficient To Support The Court's Finding Of Infringement.

Reddy also argues that the Court cannot make a finding that Reddy's proposed product infringes the '909 patent through February 25, 2003 because "Pfizer must show that Reddy also had the purpose in mind of selling its product before patent expiration." (Opp. at 8.) This argument fails because it conflates the requirements for subject matter jurisdiction in paper NDA and ANDA patent infringement actions brought prior to FDA approval and commercial sale of a potentially infringing product, with the showing needed to establish infringement. Section 271(e)(2)(A), on which Reddy relies (*see* Opp. at 6), does not state the requirements for a finding of infringement. It is a jurisdictional provision that permits a patentee to commence patent litigation prior to FDA approval of an ANDA or paper NDA filer's proposed product.

In *Warner-Lambert Co. v. Apotex Corp.*, No. 02-1073, __ F.3d __, 2003 WL 124307 (Fed. Cir. January 16, 2003) (attached hereto as Exhibit 1) (cited in Reddy Opp. at 5), the Federal Circuit Court of Appeals explained that "35 U.S.C. §271(e)(2)(A) simply provides an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." *Warner-Lambert Co.*, __ F.3d at __, 2003 WL 124307 at *14. Here, there can be no dispute that Pfizer, in bringing this action, has met the jurisdictional requirements set forth in §271(e)(2)(A), and Reddy has never challenged the Court's jurisdiction.

Once jurisdiction is established, "the substantive determination whether actual infringement . . . will take place is . . . just the same as it is in other infringement suits, including those in a non-ANDA context," *Warner-Lambert*, __ F.3d at __, 2003 WL 124307 at *14, with one difference. The inquiry in a paper NDA or an ANDA case is "hypothetical," involving "whether, if a particular drug *were* put on the market [before the patent's expiration date], it

would infringe the relevant patent." *Id.* (quoting *Bristol-Myers Squibb Co. v. Royce Labs.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995). Thus, having met the jurisdictional requirements of §271(e)(2)(A), Pfizer need show only that, if Reddy's proposed product were put on the market prior to the expiration of the '909 patent, it would infringe that patent. Contrary to Reddy's contention (*see* Opp. at 8), in carrying out this analysis there is no requirement that Pfizer show "that Reddy also had the purpose in mind of selling its product before patent expiration." Infringement is a strict liability offense, and requires no showing of intent or motivation. *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 645 (1999) ("Actions predicated on direct patent infringement . . . do not require any showing of intent to infringe"); *Jurgens v. CBK Ltd.*, 80 F.3d 1566, 1570 n.2 (Fed. Cir. 1996).

Reddy's admission to the Court in its opening brief in support of its motion to dismiss, that "[t]he parties . . . agree that the drug product defendants seek to make -- amlodipine maleate -- is covered by [the '909 patent]," establishes that, if Reddy's product were commercially sold prior to February 25, 2003, it would infringe the '909 patent. (*See* Pfizer Mem. at 6; *see also Royce Labs*, 69 F.3d at 1135 ("Since Royce did not challenge the validity of the '776 patent and did not contend that its generic version of captopril was not *covered* by the claims of the patent, it is clear that if it marketed its product [before the expiration of the patent] it would be an infringer." (emphasis added)).) Under *Warner-Lambert* and *Royce*, nothing more is required to show that Reddy's proposed product infringes the '909 patent until February 25, 2003. This Court so concluded when it determined that the '909 patent provided "protection" against amlodipine maleate, and that that protection ended on February 25, 2003. (*See* Pfizer Mem. at 6.)

Reddy's reliance on 21 U.S.C. §271(e)(1) (*see* Opp. at 6-7) is completely misplaced. Whether or not Reddy has, or is, engaged in activities directed to FDA approval of its amlodipine maleate product is beside the point. As the Federal Circuit explained in *Royce*, even though activities specified in §271(e)(1) may not be infringing, "once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit." 69 F.3d at 1132. In other words, by filing its Paragraph IV certification, Reddy made §271(e)(1) irrelevant.

II. PFIZER IS ENTITLED TO A FINDING THAT THE '909 PATENT IS VALID.

Reddy's argument that the Court should not find that the '909 patent is valid fails because it ultimately depends on Reddy's contention that the only issue addressed by the Court in its December 17, 2002 oral decision was the construction of 35 U.S.C. §156. (Opp. at 8-9.) Only by attempting to limit the decision in this way can Reddy assert that the Court did not pass on the validity of the '909 patent.

The December 17 decision is not so limited and, indeed cannot be, if it is to resolve all of the issues in this litigation. As discussed above, the Court, based on Reddy's own admissions, determined that Reddy's proposed product infringes the '909 patent, through February 25, 2003. Reddy fails to address, or even mention Pfizer's showing that, in finding infringement, the Court implicitly, and necessarily, found that that the '909 patent was valid. *See* Pfizer Mem. at 10, citing *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 an invalid patent").[2] For these reasons, Pfizer is entitled to a finding that the '909 patent is valid.

III. PFIZER IS ENTITLED TO INJUNCTIVE RELIEF

Finally, Reddy argues that Pfizer is not entitled to an injunction because, Reddy contends, Pfizer has not shown irreparable harm. Reddy's arguments fail for two reasons. *First*, regardless of whether injunctive relief under 35 U.S.C. §271(e)(4)(B) is permissive, there is no question that relief under §271(e)(4)(A) is mandatory following a finding of infringement. *See* 35 U.S.C. §271(e)(4)(A) (a court "shall" order that approval of infringing paper NDA or ANDA be deferred until expiration of the patent). Reddy's opposition memorandum is completely silent as to the mandatory relief provided for in §271(e)(4)(A).

Second, when a patent is found to be infringed, irreparable harm is presumed. Reddy fails to address the cases cited by Pfizer which held that an injunction is proper even where, as Reddy has, the defendant represents that it will not market the infringing product. *See* Pfizer Mem. at 8, citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988); *Glaxo Inc. v. Boehringer Ingelheim Corp.*, 954 F. Supp. 469, 476 (D. Conn. 1996).

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[2] The Court should not be moved by Reddy's assertion that it may be barred from asserting invalidity in the future. The Court's 12/20/02 Order will be appealed, and it will either be affirmed or vacated. If it is affirmed, there will be no need to relitigate the validity of the '909 patent. If it is determined on appeal that the Court's Order is incorrect, the Order will be vacated and the Court's findings will not prevent Reddy from addressing the patent's validity on remand. *U.S. Philips Corp. v. Sears Roebuck & Co*, 55 F.3d 592, 598 (Fed. Cir. 1995) ("A vacated judgment has no collateral estoppel or *res judicata* effect"); *Nat'l Iranian Oil Co. v. Mapco Int'l, Inc*, 983 F.2d 485, 489 (3d Cir. 1992) (noting that when a district court's decision is vacated, it "will have no *res judicata* or collateral estoppel effect.").

CONCLUSION

For all of the foregoing reasons and those set forth in Pfizer's January 7, 2003 letter to the Court and the memorandum that accompanies it, the Court should enter the Proposed Order submitted by Pfizer.

Respectfully submitted,

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