IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER LAMBERT COMPANY LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 07-138-JJF
RANBAXY LABORATORIES LIMITED and RANBAXY INC.,	:	
Defendants.	:	

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O P I N I O N

November 29, 2007
Wilmington, Delaware

Joseph J. Farnan Jr.

Farnan, District Judge.

Pending before the Court are two motions filed by Plaintiffs, Pfizer Inc., Pfizer Pharmaceuticals, LLC, Pfizer Limited, C.P. Pharmaceuticals International C.V., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export, Ltd. (collectively, "Pfizer"): (1) a Motion To Dismiss In Part Declaratory Judgment Counterclaims (D.I. 14), and (2) a Motion To Dismiss And For Partial Judgment On The Pleadings Pursuant To Federal Rule Of Civil Procedure 12(c) (D.I. 16). For the reasons discussed, the Court will grant Pfizer's Motions.

BACKGROUND

Pfizer brought this action against Defendants Ranbaxy Laboratories Limited and Ranbaxy Inc. ("Ranbaxy") alleging infringement of two patents owned by Pfizer, United States Patents Nos. 4,681,893 (the "'893 patent") and 6,455,574 (the "'574 patent"). The '893 patent claims a genus of chemical compounds which embraces atorvastatin calcium. Pfizer sells a formulation containing atorvastatin calcium under the registered name Lipitor®.

The '574 patent relates to "pharmaceutical combinations of amlodipine or a pharmaceutically acceptable acid additional salt thereof and atorvastatin or a pharmaceutically acceptable salt thereof, kits containing such combinations and methods of using

such combinations" to treat a variety of cardiac ailments. Pfizer sells a formulation containing amlodipine besylate under the registered name Norvasc®.

Both the '893 patent and the '574 patent are listed in the FDA's Orange Book as covering a product sold by Pfizer under the registered name Caduet®. Caduet® is essentially a product containing both amlodipine besylate and atorvastatin calcium.

In response, Ranbaxy filed an Amended Answer and Counterclaims. By its counterclaims, Ranbaxy seeks a declaratory judgment that (1) the '893 patent and its term extension are invalid, and (2) the '574 patent is invalid and not infringed. Ranbaxy has also interjected United States Patent No. 5,273,995 (the "'995 patent") into this lawsuit by asserting in its Fourth, Fifth, Sixth and Seventh Counterclaims that the '995 patent is invalid and/or unenforceable and not infringed.

Like the '893 patent, the '995 patent also pertains to the atorvastatin calcium pharmaceutical composition sold by Pfizer under the registered name Lipitor®. The Court of Appeals for the Federal Circuit has determined, in prior litigation between the parties (the "Lipitor® Litigation"), that Claim 6 of the '995 patent is invalid for failure to satisfy 35 U.S. § 112. Pfizer has sought to reissue the '995 patent to correct the defect in Claim 6 and to correct defects in other claims. Pfizer has also provided Ranbaxy with a covenant not to sue Ranbaxy on all

remaining claims of the original '995 patent.

STANDARD OF REVIEW

I. Dismissal Under Fed. R. Civ. P. 12(b)(1)

Pursuant to Federal Rule of Civil Procedure 12(b)(1), the Court is authorized to dismiss a complaint, or in this case, a counterclaim, if the Court lacks subject matter jurisdiction over the claims alleged. Motions brought under Rule 12(b)(1) may present either a facial or factual challenge to the Court's subject matter jurisdiction.

When a facial challenge to subject matter jurisdiction is raised, the Court must accept all factual allegations pled in the counterclaim as true and draw all reasonable inferences in favor of the counterclaim plaintiff. The Court's inquiry under Rule 12(b)(1) is limited to the allegations in the counterclaim, the documents referenced in or attached to the counterclaim, and matters in the public record. Gould Electronics Inc. v. U.S., 220 F.3d 169, 176 (3d Cir. 2000). However, the Court may consider "document[s] integral to or explicitly relied upon in the complaint" without converting the motion to dismiss to a motion for summary judgment. The Court may also consider exhibits to a motion to dismiss without converting the motion to a summary judgment motion, if the plaintiff's claims are based on the documents and the documents are undisputedly authentic. Pension Benefit Guaranty Corp. v. White Consolidated Indus.,

Inc., 998 F.2d 1192, 1196 (3d Cir.1993).

In reviewing a factual challenge to the Court's subject matter jurisdiction, the Court is not confined to the allegations of the complaint, or in this case the counterclaim, and the presumption of truthfulness does not attach to the allegations in the counterclaim. Mortensen v. First Fed. Sav. and Loan, 549 F.2d 884, 891 (3d Cir. 1977). Instead, the Court may consider evidence outside the pleadings, including affidavits, depositions and testimony, to resolve any factual issues bearing on jurisdiction. Gotha v. United States, 115 F.3d 176, 179 (3d Cir. 1997).

Pursuant to Rule 12(h)(3), subject matter jurisdiction may be raised at any time during the course of a case and may be raised sua sponte by the Court. Once the Court's subject matter jurisdiction over a counterclaim is challenged, the counterclaim plaintiff bears the burden of proving that jurisdiction exists. Mortensen, 549 F.2d at 891.

II. Judgment On The Pleadings Under Fed. R. Civ. P. 12(c)

A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is governed by the same standards that apply to a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Specifically, the Court must accept the facts alleged in the pleadings as true and draw all reasonable factual inferences in the light most favorable to the nonmovant.

The Supreme Court has retired the standard for dismissal under Rule 12(b)(6) announced in Conley v. Gibson, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1964-1965 (2007) (citing Conley, 355 U.S. at 45-46). Instead, the Supreme Court has instructed that dismissal is not appropriate if the plaintiff alleges sufficiently detailed facts to "raise a right to relief above the speculative level." Id. The moving party bears the burden of demonstrating that dismissal is appropriate under Rule 12(b)(6) and that judgment on the pleadings is appropriate under Rule 12(c).

DISCUSSION

I. Motion To Dismiss In Part Declaratory Judgment Counterclaims

By its Motion To Dismiss In Part Declaratory Judgment Counterclaims, Pfizer requests the Court to dismiss Ranbaxy's Fourth, Fifth, Sixth and Seventh Counterclaims, all of which pertain to the '995 patent. Pfizer contends that there is no justiciable case or controversy between the parties and no declaratory judgment jurisdiction with respect to these counterclaims based on the covenant not to sue.

In response, Ranbaxy contends that Pfizer has not agreed to provide Ranbaxy with a covenant not to sue related to any reissue

of the '995 patent. Thus, Ranbaxy contends that Pfizer may, and in fact intends, to assert any reissue of the '995 patent against Ranbaxy's generic product. Ranbaxy does not oppose the dismissal without prejudice of its Fourth and Fifth Counterclaims regarding noninfringement and invalidity of the '995 patent. In this regard, Ranbaxy acknowledges that the covenant not to sue precludes infringement liability on the existing '995 patent, and infringement and invalidity with respect to any reissued patent rests on the scope of the reissue. However, Ranbaxy maintains that the Court should exercise jurisdiction over its Sixth and Seventh Counterclaims concerning the unenforceability of the '995 patent, because these claims concern Pfizer's conduct before the Patent and Trademark Office ("PTO") in prosecuting the original '995 patent. Therefore, Ranbaxy contends that the reissue proceedings have no affect on its allegations that the '995 patent was procured through inequitable conduct.

The parties agree that Ranbaxy's Fourth and Fifth Counterclaims should be dismissed without prejudice. Accordingly, the Court will focus its decision on whether the Sixth and Seventh Counterclaims alleging unenforceability of the '995 patent should be dismissed.

To establish jurisdiction under the Declaratory Judgment Act for the counterclaims asserted here, Ranbaxy bears the burden of proving that the facts alleged "under all the circumstances show

that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune Inc. v. Genentech, Inc., 127 S. Ct. 764, 771 (2007). As the Supreme Court further explained, jurisdiction over a declaratory judgment action requires "'the dispute [to] be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" Id. (citations omitted).

The standard announced by the Supreme Court in MedImmune replaces the "reasonable apprehension of imminent suit test" that had previously been used to determine whether jurisdiction exists under the Declaratory Judgment Act. See Teva v. Novartis, 482 F.3d 1330, 1339 (Fed. Cir. 2007). As a result, Ranbaxy questions whether MedImmune abrogates the line of Federal Circuit cases holding that a covenant not to sue on an original patent divests the Court of jurisdiction, even when a reissue application covering the same subject matter as the original patent application is pending. See e.g., Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995).

Pfizer contends that Super Sack and its progeny are not altered by MedImmune, because those cases do not depend upon the reasonable apprehension of imminent suit test and instead turn on general Supreme Court precedent, which in effect applied the same test advanced in MedImmune, i.e. a totality of the circumstances test. Indeed, in Benitec Australia, Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1346 (Fed. Cir. 2007), the Federal Circuit noted that Super Sack has not been expressly overruled, and while Super Sack applied the "reasonable apprehension of imminent suit test," it did not depend upon it.

Examining the totality of the circumstances in light of the MedImmune standard for jurisdiction over declaratory judgment claims, the Court concludes that Ranbaxy cannot establish that a current and concrete controversy exists between the parties. The existence of issued and presently enforceable patent claims against a declaratory judgment plaintiff is a necessary prerequisite to the continued litigation of a declaratory judgment action. This basic principle of justiciability stands alone and apart from the "reasonable apprehension of imminent suit" test. See e.g., GAF Building Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 482-483 (Fed. Cir. 1996) ("We therefore hold that a threat is not sufficient unless it is made with respect to a patent that has issued before a complaint is filed.") In this case, Claim 6 of the '995 patent has been

declared invalid, and Pfizer has agreed not to sue Ranbaxy with respect to the other claims of the '995 patent. As a result, there is no valid patent which currently exists that can be enforced against Ranbaxy. See Merck & Co., Inc. v. Apotex, Inc., 488 F. Supp. 2d 418, 423-425 (D. Del. 2007) (Sleet, J.) (applying MedImmune standard and concluding that covenant not to sue divests court of subject matter jurisdiction).

Ranbaxy contends that because the covenant not to sue does not embrace any reissue of the '995 patent, subject matter jurisdiction still exists over its declaratory judgment counterclaims. However, the question of whether a new patent will ever be reissued is speculative, purely hypothetical and unripe for judicial determination. Accordingly, the Court concludes that these circumstances do not support jurisdiction under the MedImmune standard.

For these same reasons, the Court also concludes that Article III standing is lacking in this case. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561 (1992). Ranbaxy has not suffered any injury in fact based upon the original '995 patent in light of the invalidity of Claim 6 and the covenant not to sue regarding the remaining claims. As for any reissue of the '995 patent, any injury Ranbaxy might suffer is, at this juncture, speculative. Pfizer has not yet indicated that it intends to assert a reissued patent against Ranbaxy, and it is unclear

whether the '995 patent will in fact reissue. Treemond Co. v. Shering Corp., 122 F.2d 702, 705 (3d Cir. 1941) ("There can be no doubt than an 'actual controversy' does not exist until the patentee makes some claim that his patent is being infringed."). Indeed, jurisdiction under the Hatch-Waxman Act is also unsupported in this case, because (1) Pfizer cannot enforce a pending reissue application against Ranbaxy; (2) any reissued patent has not been listed in the FDA Orange Book and cannot be until it has issued, 21 U.S.C. § 355(c)(2); and (3) Ranbaxy has not had to certify against a reissued patent. Teva, 482 F.3d at 1344 (describing prerequisites for establishing a justiciable controversy under the Hatch-Waxman Act). Thus, the Court's exercise of jurisdiction in these circumstances would result in nothing more than an advisory opinion regarding the enforceability of a yet to be reissued patent, a result wholly inconsistent with the most basic precepts of jurisdictional jurisprudence.

In sum, the Court concludes that the possibility that a new patent may issue at some future point is insufficient to create the type of real and immediate legal case or controversy as required for declaratory judgment jurisdiction and standing under Article III. Accordingly, the Court will grant Pfizer's Motion To Dismiss Ranbaxy's Fourth, Fifth, Sixth and Seventh Counterclaims.

II. Pfizer's Motion To Dismiss And For Partial Summary Judgment On The Pleadings

A. Whether Pfizer Is Entitled To Dismissal Of Ranbaxy's First Counterclaim And Third Affirmative Defense On The Basis Of Res Judicata

With respect to its Motion To Dismiss And For Partial Summary Judgment On The Pleadings, Pfizer requests the Court to dismiss Ranbaxy's First Counterclaim and its Third Affirmative Defense, both of which relate to the '893 patent. Specifically, Ranbaxy's First Counterclaim and Third Affirmative Defense allege that the '893 patent and its patent term extension are invalid as obvious under 35 U.S.C. § 103. Pfizer contends that the First Counterclaim and Third Affirmative Defense are barred by the doctrine of res judicata and/or collateral estoppel as a result of the final judgment entered in the prior Lipitor® litigation. According to Pfizer, Ranbaxy knew about the prior art upon which it now bases its obviousness claim, but declined to assert that art in the Lipitor® litigation. Thus, Pfizer contends that Ranbaxy is precluded from now raising its obviousness claim.

Ranbaxy contends that res judicata principles should be more narrowly applied in this case because the issue of obviousness was never presented at trial or adjudicated in the Lipitor® litigation, and significant factual and legal changes have occurred since the Lipitor® litigation that fundamentally alter the obviousness analysis of the '893 patent. With respect to the legal landscape, Ranbaxy contends that the Supreme Court's

decision in KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. (2007), "dramatically lowered the bar of 35 U.S.C. § 103" by removing the teaching, suggestion or motivation to combine the prior art test from the obviousness inquiry. (D.I. 19 at 2, 9-12.) With respect to the factual landscape, Ranbaxy contends that Pfizer withheld "critical information" about the test data it relied upon to gain the issuance of EP 247 633, the European counterpart to the '893 patent. (Id. at 2, 13-14.) Ranbaxy asserts EP 247 633 as the prior art over which the '893 patent is obvious. According to Ranbaxy, it could not have presented an obviousness challenge to the '893 patent in the Lipitor® litigation because it was unable to timely analyze and compare the relevant data as a result of Pfizer's actions.

The doctrine of res judicata is considered 'a rule of fundamental and substantial justice,' and not merely a 'matter of technical practice or procedure.'" Equal Employment Opportunity Commission v. U.S. Steel Corp., 921 F.2d 489, 492 (3d Cir. 1990) (quoting Hart Steel Co. v. Railroad Supply Co., 244 U .S. 294 (1917)). "Res judicata avoids the expense and vexation attending multiple lawsuits, conserves judicial resources, and fosters reliance on judicial action by minimizing the possibility of inconsistent decisions." Id.

Res judicata, also known as claim preclusion, "requires a showing that there has been (1) a final judgment on the merits in

a prior [law]suit involving (2) the same claim and (3) the same parties or their privies." Id. at 493 (citing United States v. Athlone Industries, Inc., 746 F.2d 977, 983 (3d Cir. 1984)).

Ranbaxy does not dispute that the third element of the res judicata analysis is met here. However, Ranbaxy suggests that this proceeding does not involve the same claim or a final judgment on the merits of that claim, because obviousness was neither raised nor adjudicated in the Lipitor® litigation.

Res judicata requires "that a plaintiff present in one suit all of the claims for relief that he may have arising out of the same transaction or occurrence." Lubrizol v. Exxon Corp., 929 F.2d 960, 963 (3d Cir. 1991). In this regard, the operative question is not whether the issue was actually litigated, but whether it "could have been raised in the earlier proceeding." Board of Trustees v. Centra, 983 F.2d 495, 504 (3d Cir. 1992); Gregory v. Chehi, 843 F.2d 111, 116 (3rd Cir. 1988).

In the Lipitor® litigation, Ranbaxy challenged the validity of the '893 patent. As a result, Ranbaxy was required to raise all of its invalidity defenses at that time, including its challenge based on obviousness. Although Ranbaxy concedes that it was aware of the prior art it now asserts against the '893 patent, Ranbaxy contends that it was unable to appreciate the impact of that prior art due to certain facts which Pfizer allegedly withheld. The Court does not find the grounds asserted

by Ranbaxy to be sufficient to avoid the effects of res judicata in the circumstances of this case.[1] Ranbaxy was informed about the mislabeled data upon which it bases its change of fact argument at least as early as July 19, 2004, during the deposition of Francis J. Tinney, Ph.D. (D.I. 21, Ex. A at 48-50.) Mr. Tinney's deposition occurred more than one hundred days before trial. The parties then entered into a stipulation concerning the mislabeled data on September 3, 2004, nearly three months before trial. (D.I. 191 in Civ. Act. No. 03-209.) That Ranbaxy may have needed more time to evaluate this data is not a change in the factual landscape which should affect this litigation. Rather, Ranbaxy's appropriate remedies rested in the previous Lipitor® litigation through either extensions of time there, or applications for a new trial and/or relief from judgment under Federal Rule of Civil Procedure 60(b).

To the extent that Ranbaxy directs the Court to case law suggesting that a change in factual circumstances precludes the application of res judicata, the Court concludes that those cases have little relevance to the present action. In addition to the

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[1] Where the circumstances suggest a fraud or negligent misrepresentation by a party, some courts have declined to apply res judicata. See James Wm. Moore, et al., Moore's Federal Practice § 131.21[1]. However, Ranbaxy's allegations regarding Pfizer's conduct do not, in the Court's view, rise to the level of either fraud or negligent misrepresentation, particularly where, as here, Ranbaxy was informed of the labeling error well prior to trial. Indeed, even Ranbaxy does not go so far as to characterize Pfizer's conduct as fraudulent or negligent.

fact that Ranbaxy was aware of the change in fact it now asserts during the previous Lipitor® litigation, the cases to which Ranbaxy cites arise in factual and legal contexts dissimilar to the circumstances here. See e.g., Brown v. Felsen, 442 U.S. 127, 132-134 (1979) (noting in a bankruptcy case that "respondent's res judicata claim is unlike those customarily entertained by the courts); Commissioner v. Sunnen, 333 U.S. 591 (1948) (discussing the operation of res judicata in the unique circumstances of tax cases where each tax year presents a new claim and inequities among taxpayers would result if determinations which are erroneous or obsolete are permitted to perpetuate); In re Bose Corp., 476 F.3d 1331 (Fed. Cir. 1997) (recognizing in the context of administrative proceedings that courts should "exercise caution in applying claim preclusion in an ex parte proceeding"). Accordingly, the Court is not persuaded that the case law cited by Ranbaxy counsels against the application of res judicata here.

Ranbaxy also contends that res judicata is precluded in this case, because the Supreme Court's KSR decision represents a change in the controlling law. However, a change in the law does not ordinarily affect the res judicata effect of a judgment. Indeed, the Supreme Court has declined to recognize an exception to res judicata based upon a change in the controlling law. Federated Dept. Stores, Inc., v. Moitie, 452 U.S. 394, 398-399 (1981). As the Supreme Court explained in Federated:

> Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case. Angel v. Bullington, 330 U.S. 183, 187, 67 S. Ct. 657, 659, 91 L. Ed. 832 (1947); Chicot County Drainage District v. Baxter State Bank, 308 U.S. 371, 60 S. Ct. 317, 84 L. Ed. 329 (1940); Wilson's Executor v. Deen, 121 U.S. 525, 534, 7 S. Ct. 1004, 1007, 30 L. Ed. 980 (1887). As this Court explained in Baltimore S.S. Co. v. Phillips, 274 U.S. 316, 325, 47 S. Ct. 600, 604, 71 L. Ed. 1069 (1927), an "erroneous conclusion" reached by the court in the first suit does not deprive the defendants in the second action "of their right to rely upon the plea of res judicata.... A judgment merely voidable because based upon an erroneous view of the law is not open to collateral attack, but can be corrected only by a direct review and not by bringing another action upon the same cause [of action]." We have observed that "[t]he indulgence of a contrary view would result in creating elements of uncertainty and confusion and in undermining the conclusive character of judgments, consequences which it was the very purpose of the doctrine of res judicata to avert." Reed v. Allen, 286 U.S. 191, 201, 52 S. Ct. 532, 534, 76 L. Ed. 1054 (1932).

Id.

To the extent Ranbaxy relies on a contrary statement by the Supreme Court in State Farm Mut. Auto. Ins. Co. v. Duel, 324 U.S. 154 (1945), the Court concludes that State Farm's discussion of res judicata is dicta, and in any event, State Farm has been superseded by Federated. See e.g., Forsman v. Chater, 1996 WL 396718, *1 (9th Cir. July 12, 1996). The Court's conclusion is consistent with the prevailing view by courts and commentators alike that a change in the law is insufficient to bar the

application of res judicata.[2] See e.g. Wilson v. Lynaugh, 878 F.2d 846, 850-851 (5th Cir. 1989), Precision Air Parts, Inc. v. Avco Corp., 736 F.2d 1499, 1503 (11th Cir. 1984) ("The general rule in this circuit, and throughout the nation, is that changes in the law after a final judgment do not prevent the application of res judicata and collateral estoppel, even though the grounds on which the decision was based are subsequently overruled."); Barzin v. Selective Service Local Board No. 14, 446 F.2d 1382, 1383 (3d Cir. 1971) (recognizing that "a prior decision may serve as res judicata even if a contrary judicial decision on the legal issues involved intervenes between the first and second suits."); see also 18 Wright, Miller & Cooper, Federal Practice and Procedure: Jurisdiction § 4403 (2d ed. 2002). Accordingly, the Court concludes that Ranbaxy has not demonstrated that res judicata is precluded in this action by a change in controlling law.

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[2] Courts have recognized an exception to this principle in the case of momentous legal changes invoking important and fundamental changes in constitutional rights. For example, the Court of Appeals for the Eleventh Circuit did not apply res judicata to a state court judgment because three months after that judgment was issued the Supreme Court overruled the separate but equal doctrine in Brown v. Bd. of Education, 347 U.S. 483 (1954). See Precision Air, Inc., 736 F.2d at 1504 (discussing Christian v. Jemison, 303 F.2d 52, 54 (5th Cir. 1962)). Whatever can be said of the changes in patent law that may flow as a result of the Supreme Court's decision in KSR, the Court cannot conclude that KSR stands on par with such precedent shifting cases as Brown v. Bd of Education.

In sum, the Court concludes that Pfizer is entitled to the dismissal of Ranbaxy's First Counterclaim and Third Affirmative Defense. Ranbaxy's First Counterclaim and Third Affirmative Defense implicate the validity of the '893 patent, a claim which was raised and litigated to a final judgment on the merits in the Lipitor® litigation between these same parties and/or their privies. Any failure by Ranbaxy to assert the obviousness claim it seeks to raise here does not diminish the res judicata effect of the final judgment in the Lipitor® litigation. Accordingly, the Court will grant Pfizer's Motion To Dismiss.

B. Whether Pfizer Is Entitled To A Judgment Of Infringement Of the '893 Patent Based Upon The Doctrine Of Collateral Estoppel

By its Motion, Pfizer also requests the Court to enter judgment on the pleadings in its favor on the question of whether Ranbaxy infringes the '893 patent under 35 U.S.C. § 271(e)(2). Specifically, Pfizer contends that Ranbaxy is collaterally estopped from denying infringement of the '893 patent based on the inclusion of atorvastatin calcium in its new ANDA product.

The party seeking to invoke the doctrine of collateral estoppel must demonstrate four elements: (1) the previous determination was necessary to the decision; (2) the identical issue was previously litigated; (3) the issue was actually decided in a decision that was final, valid, and on the merits; and (4) the party being precluded from relitigating the issue was

adequately represented in the previous action. See e.g., Novartis Pharms. Corp. v. Abbott Labs., 375 F.3d 1328, 1333 (Fed. Cir. 2004); Henglein v. Colt Indus. Operating Corp., 260 F.3d 201, 209 (3d Cir. 2001). The Third Circuit also considers whether the party being estopped had a full and fair opportunity to litigate the issue to a final and valid judgment in the prior litigation. Seborowski v. Pittsburgh Press Co., 188 F.3d 163, 169 (3d Cir. 1999); National R.R. Passenger Corp. v. Pennsylvania Pub. Util. Comm'n, 288 F.3d 519, 525 (3d Cir. 2002).

Ranbaxy does not contest infringement of the '893 patent, but contends that the Court should not enter a final judgment of infringement while invalidity is being contested. However, the Court has concluded that Ranbaxy is barred by the doctrine of res judicata in light of the Lipitor® litigation from contesting the validity of the '893 patent. Accordingly, the Court will grant Pfizer's Motion For Partial Summary Judgment and enter judgment against Ranbaxy and in favor of Pfizer on Pfizer's claim that Ranbaxy infringed the '893 patent under 35 U.S.C. § 271(e)(1) by filing an ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a product containing atorvastatin calcium as an active ingredient prior to the expiration of the patent.

CONCLUSION

For the reasons discussed, the Court will grant Pfizer's Motion To Dismiss In Part Declaratory Judgment Counterclaims and its Motion To Dismiss And For Partial Judgment On The Pleadings Pursuant To Federal Rule Of Civil Procedure 12(c). A judgment of infringement based on the '893 patent will be entered in favor of Pfizer and against Ranbaxy.

An appropriate Order will be entered.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER LIMITED, C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, WARNER LAMBERT COMPANY LLC, and WARNER-LAMBERT EXPORT, LTD.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 07-138-JJF
RANBAXY LABORATORIES LIMITED and RANBAXY INC.,	:	
Defendants.	:	

O R D E R

At Wilmington, this 29th day of November 2007, for the reasons set forth in the Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Plaintiffs' Motion To Dismiss In Part Declaratory Judgment Counterclaims (D.I. 14) is **GRANTED**.

2. Plaintiffs' Motion To Dismiss And For Partial Judgment On The Pleadings Pursuant To Federal Rule Of Civil Procedure 12(c) (D.I. 16) is **GRANTED**.

Joseph J. Farnan, Jr.

UNITED STATES DISTRICT JUDGE