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/Counterclaim-Defendants, v.	)	Civil Action No. 07-138 (JJF)
RANBAXY LABORATORIES LIMITED, and RANBAXY INC.,	)	
Defendants/Counter-Claimants.	)	

PFIZER'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(1), RANBAXY'S COUNTERCLAIMS WITH RESPECT TO THE '995 PATENT

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I. INTRODUCTION

In its Answering Brief, Ranbaxy concedes that its counterclaims with respect to non-infringement and invalidity of the '995 patent are moot as a result of Pfizer's grant of a covenant not to sue and Ranbaxy, therefore, acknowledges that these counterclaims should be dismissed without prejudice.[1] Notwithstanding this concession of non-justiciability, Ranbaxy maintains that its counterclaim with respect to alleged unenforceability of the '995 patent on the ground of inequitable conduct still presents a case or controversy, and should be permitted. This is the same assertion of unenforceability previously rejected by this Court and deemed moot on appeal following the declaration of invalidity of the '995 patent pursuant to 35 U.S.C. § 112 ¶ 4. Ranbaxy is wrong.

A declaratory judgment of unenforceability for inequitable conduct cannot be sustained in the absence of a case or controversy over potentially infringing conduct. No such actionable infringing conduct exists with respect to the '995 patent, and any ruling with respect to a potential future reissue patent, should it issue, is speculative. Declaratory judgment on such an inchoate claim would constitute a purely advisory opinion. For these reasons, Ranbaxy also lacks standing regarding its inequitable conduct contentions, and Pfizer's motion to dismiss should be granted in its entirety.

II. ARGUMENT

As established in our opening brief, the test for a justiciable controversy applied by the Supreme Court in *MedImmune* and followed by the Federal Circuit in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1337

[1] Dismissal without prejudice is appropriate because dismissal for lack of subject matter jurisdiction is not a determination on the merits.

(Fed. Cir. 2007) "is whether 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." Quoting *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 766 (2007); *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

In *MedImmune*, the Supreme Court also stated that Article III requires:

> that the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] 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."

127 S. Ct. at 771 (citation omitted); *See also, Merck & Co. v. Apotex, Inc.*, --- F.Supp.2d ----, 2007 WL 1470453, *4 (D. Del. 2007) (covenant not to sue moots actual controversy under *Medimmune* standard).

No facts or arguments asserted by Ranbaxy support declaratory judgment jurisdiction over the enforceability of the '995 patent under this standard.

A. The Court Lacks Subject Matter Jurisdiction Over Ranbaxy's Unenforceability Counterclaim Directed to the '995 Patent

Ranbaxy cannot dispute that the '995 Claim 6, which directly claims the active ingredient, atorvastatin calcium, has been declared invalid by the Federal Circuit, and that the remaining claims of the '995 patent, are the subject of a covenant not to sue in Ranbaxy's favor. See Exhibit "A" to Opening Brief. Ranbaxy also cannot dispute that whether the '995 patent might reissue sometime in the future is uncertain at this time, and Ranbaxy has sought to prevent reissue by filing a Protest in the Patent Office. Ranbaxy is also enjoined until March 24, 2010 by this Court's Final Judgment in the first Lipitor litigation from selling any atorvastatin calcium product based on the '893 patent.

Ranbaxy asserts, however, that: (1) its counterclaim for unenforceability of the '995 patent does not depend upon the scope of any future reissued '995 patent claims and thus this lone counterclaim is ripe for adjudication, while at the same time conceding that its other counterclaims must be dismissed for the lack of a case or controversy; (2) the Supreme Court's decision in *MedImmune* undermines all preexisting precedent from the Federal Circuit on declaratory judgment jurisdiction, most particularly those cases holding that a covenant not to sue moots any controversy over the infringement, validity and enforceability of a patent covered by the covenant; (3) notwithstanding Pfizer's covenant not to sue on the claims of the '995 patent (excepting claim 6, previously adjudged invalid), a case or controversy still exists over the '995 patent because Pfizer has applied for reissue of the patent and Ranbaxy has standing to assert claims of unenforceability of the potential future reissued patent; and (4) this Court should exercise its discretion to entertain Ranbaxy's counterclaim. All of these arguments are meritless.

1. Ranbaxy's Inequitable Conduct Counterclaim Previously Rejected By This Court Presents No Case Or Controversy.

The enforceability of the '995 patent was previously adjudicated by this Court and was appealed by Ranbaxy to the Federal Circuit. *Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284, 1286 (Fed. Cir. 2006). After finding claim 6 to be an improper dependent claim, the Federal Circuit declined Ranbaxy's invitation to consider any other issues regarding the validity and enforceability of the '995 patent, deeming them "moot". *Id.* at 1292. Ranbaxy's Petition for Rehearing on this precise point was denied without dissent. Now, however, Ranbaxy would have this Court re-adjudicate these "moot" issues on the premise that an application for reissue resurrects them. Presumably, since this Court has already once flatly rejected Ranbaxy's charges, Ranbaxy is really seeking, once again, to obtain Federal Circuit review. Ranbaxy grounds this contorted position on

the assertion that its counterclaim is unaffected by any potential reissue because it does not implicate claim scope and thus is ripe for adjudication. Ranbaxy's Brief in Opposition, p. 10.

Regardless of whether Ranbaxy's inequitable conduct arguments could be impacted by reissue of the patent, it is clear that Ranbaxy's inequitable conduct claim presents no current case or controversy. An assertion of inequitable conduct demands that there be a patent capable of being enforced, and nothing in *MedImmune* alters this fundamental and logical precept of justiciability. As the Federal Circuit observed in the *GAF* case:

> We therefore hold that a threat is not sufficient to create a case or controversy unless it is made with respect to a patent that has issued before a complaint is filed. Thus, the district court correctly held that there was no justiciable case or controversy in this case at the time the complaint was filed. *See Spectronics*, 940 F.2d at 636, 19 USPQ2d at 1549 ("[T]he existence of issued patent claims, presently enforceable against [the declaratory judgment plaintiff], are a requisite to litigation of a declaratory judgment action."); *Muskegon Piston Ring Co. v. Olsen*, 307 F.2d 85, 89, 134 USPQ 471, 474 (6th Cir.1962) (If there is no issued patent, "no controversy under the patent laws exists, upon which [the accused infringer] can bring an action for declaratory judgment."), *cert. denied*, 371 U.S. 952, 83 S.Ct. 508, 9 L.Ed.2d 500 (1963).

GAF Building Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 482-83 (Fed. Cir. 1996).

GAF cannot be disregarded on the alleged ground that it was decided under the "reasonable apprehension" standard prior to *MedImmune*. The *GAF* decision explicitly states that the "reasonable apprehension" standard is insufficient to determine justiciability of a declaratory judgment claim on an unissued patent. The *GAF* court thus applied general Supreme Court precedent on case or controversy. *Id.* at 482. Moreover, the Federal Circuit in *GAF* went even further in finding that the jurisdictional defect could not be cured by issuance of the patent after filing of the complaint. *Id.* at 483. It

follows that Ranbaxy can assert no claim for declaratory judgment predicated upon a reissue patent yet to be reissued.

In short, until the '995 patent is reissued, the question of whether inequitable conduct bars enforcement of a reissued '995 patent is purely hypothetical. Ranbaxy does not and cannot allege any injury arising from the '995 patent currently. What Ranbaxy seeks is a determination that **if** a reissue patent were to issue, the patent would not be enforceable against it. This Court is without jurisdiction to answer such a question. *See, e.g., Calderon v. Ashmus,* 523 U.S. 740, 747 (1998).

2. A Reissued '995 Patent Could Impact Such Allegations.

Ranbaxy's further assertion that unenforceability based upon the prosecution of the original '995 patent application cannot be cured in reissue proceedings is also inapposite. The Court has already made substantial factual findings, undisturbed by an appellate court, rejecting Ranbaxy's allegations of inequitable conduct on both materiality and intent with respect to the prosecution of the '995 patent. While reissue will not normally cure previously established (i.e. adjudicated) inequitable conduct,[2] where no deceptive intent exists, reissue can be had over previously unadjudicated information. *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1563 (Fed. Cir. 1989), cited by Ranbaxy for the proposition that "reissue is not available" to "rehabilitate the patent," concerned the impact of established inequitable conduct in the reissue application. In footnote 7, the *Hewlett-Packard* court cites to *In re Clark*, 522 F.2d 623, 627 (C.C.P.A. 1975) to support the proposition. However, *In re Clark* reserved the situation where inequitable conduct has not been previously established by virtue of

[2] However, some courts have applied the test for cure of inequitable conduct during original prosecution to reissued patent claims. *See, e.g., Bristol-Meyers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2002 WL 59429 (S.D.N.Y. 2002) (applying *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571-72 (Fed. Cir. 1983) test for cure of inequitable conduct to a reissued patent).

the withholding of material information.

> This case does not require us to decide, and we do not decide, whether it is proper to seek reissue in order to disclose uncited prior art where no holding of invalidity has arisen from the patentee's failure to have disclosed the prior art.

Id. at 627 n. 4. The question of whether Pfizer might by reissue application cure purported inequitable conduct as alleged by Ranbaxy is therefore not foreclosed as a matter of law under the circumstances of this case. More importantly, this alleged basis for jurisdiction fails for the same reasons as Ranbaxy's other arguments – at bottom, it is a request for an improper advisory opinion on a patent application.

3. MedImmune Does Not Abrogate The Federal Circuit's Previous Holdings On Lack Of Jurisdiction Where A Covenant Not To Sue Is Provided.

The holding of the Supreme Court in the *MedImmune* case does not undermine the rationale in all cases determined by the Federal Circuit in which the "reasonable apprehension" test was applied. Courts addressing the issue have been loath to invoke such a sweeping implication from MedImmune. *See Merck & Co. v. Apotex, Inc.*, supra. (applying *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995) post *Medimmune*); *Prasco, LLC v. Medicis Pharm. Corp.*, No. 1:06CV313, 2007 WL 928669, at *2 (S.D. Ohio Mar. 27, 2007) ("The Court's decision may call into doubt the use of the 'reasonable apprehension of suit' test, but it did not overrule the line of cases that rely upon the "reasonable apprehension of suit" test outside of this factual scenario.").

Moreover, *MedImmune* does not and should not alter *Super Sack* and its progeny, which do not depend upon the "reasonable apprehension of suit" test. As stated in *Super Sack*:

> The long established rule of law is that a declaratory judgment plaintiff

must establish an actual controversy on the 'totality of the circumstances.'

Id., *citing Spectronics*, 940 F.2d at 634 (*quoting Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 272 (1941)).

Thus, the rationale of the *Super Sack* line of cases relating to the impact of a covenant not to sue is grounded in the "totality of the circumstances" required by *MedImmune* and survives as good law. This is because the issuance of a covenant not to sue defeats declaratory judgment jurisdiction under even the broadest Supreme Court standards for a case or controversy. Where the declaratory judgment plaintiff can not be harmed by the existing patent, no court has ever found a case or controversy to exist.

4. Ranbaxy Lacks Standing

The Third Circuit has articulated clear standards for a case or controversy to exist.

> The constitutional component derives from the Article III "case or controversy" requirement and has three elements:
>
> (1) the plaintiff must have suffered an injury in fact-an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) there must be a causal connection between the injury and the conduct complained of-the injury has to be fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court; and (3) it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.
>
> *Trump Hotels & Casino Resorts v. Mirage Resorts*, 140 F.3d 478, 484-85 (3d Cir.1998) (*citing Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). "These requirements ensure that plaintiffs have a personal stake or interest in the outcome of the proceedings" sufficient to justify federal court intervention. *Joint Stock Soc'y v. UDV N. Am., Inc.*, 266 F.3d 164, 175 (3d Cir. 2001) (internal quotation marks omitted).

Township of Piscataway v. Duke Energy, --- F.3d ----, 2007 WL 1614614, at *3 (3d Cir. June 6, 2007).

Ranbaxy has no current stake in whether the '995 patent is unenforceable and it is enjoined under the '893 patent until March 24, 2010. Ranbaxy has suffered no injury in

fact, and can show no causal connection to any such injury. It has no interest that is capable of being harmed by the '995 patent. Ranbaxy lacks standing and seeks only an advisory opinion on a patent not yet issued.

Additionally, Ranbaxy's argument that *MedImmune* has abrogated the line of cases[3] cited in our Opening Brief establishing that submission for reissue does not create any justiciable issue between the parties is wrong. These cases rest on the simple proposition that pending applications create no rights and no actual controversy exists until there is an assertion of infringement, and this precedent existed long before explication of the "reasonable apprehension" test. *See Treemond Co. v. Shering Corp.*, 122 F.2d 702, 705 (3d Cir. 1941). ("There can be no doubt that an 'actual controversy' does not exist until the patentee makes some claim that his patent is being infringed.")

5. Public Policy Cannot Create An Article III Case Or Controversy Or Supply Standing

Ranbaxy next asserts that the public interest in the patent system and the Hatch-Waxman Act should be considered in determining whether a case or controversy exists. Again, Ranbaxy is wrong. *See Whitmore v. Arkansas,* 495 U.S. 149, 161 (1990) ("The short answer to this suggestion is that the requirement of an Art. III 'case or controversy' is not merely a traditional 'rule of practice,' but rather is imposed directly by the Constitution. It is not for this Court to employ untethered notions of what might be good public policy to expand our jurisdiction in an appealing case."); *Fair Housing Council of Suburban Philadelphia v. Main Line Times,* 141 F.3d 439, 444 (3d Cir. 1998) ("[T]he most impassioned public policy arguments cannot eliminate the case or controversy

[3] *See, e.g., Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 637 (Fed. Cir. 1991); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 856 (Fed. Cir. 1999); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d at 1058; *GAF Bldg. Materials Corp. v. Elk Corp.*, 90 F.3d 479 (Fed. Cir. 1996); *see also Czarnik v. Illumina, Inc.*, 437 F. Supp. 2d 252, 259 (D. Del. 2006).

requirement from the Constitution. If anything, the appeal to public policy should highlight ... the separation of powers rationale from which the case or controversy doctrine flows. Adjudicating actual controversies, not legislating social policy, is the province of the judiciary.").

The Federal Circuit in *Teva* recognized that under the Hatch-Waxman Act not every patent claim was capable of resolution within the case or controversy limitation of Article III. *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d at 1343-44. The present situation is precisely the case contemplated by the Federal Circuit in *Teva* as providing no declaratory judgment jurisdiction. *Id, citing*, 149 Cong. Rec. S15885 (Nov. 25, 2003). No case or controversy presently exists over the enforceability of the '995 patent. Public policy, without more, cannot create one.

III. CONCLUSION

For the reasons stated above, defendants/counterclaimants' Fourth, Fifth, Sixth, and Seventh Counterclaims with respect to the '995 patent should be dismissed for lack of subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and/or the Court should, in the exercise of its discretion, decline to exercise jurisdiction over the counterclaims.

RESPECTFULLY SUBMITTED,

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Case 1

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Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2002 WL 59429 (S.D.N.Y.)
(Cite as: Not Reported in F.Supp.2d)

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Bristol-Meyers Squibb Company v. Rhone-Poulenc Rorer, Inc.
S.D.N.Y.,2002.
Only the Westlaw citation is currently available.

United States District Court, S.D. New York.

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff,
v.
RHÔNE-POULENC RORER, INC., Centre National De La Recherche Scientifique, and Rhône-Poulenc Rorer, S.A., Defendants.

No. 95 CIV 8833(RPP).

Jan. 16, 2002.

Fitzpatrick, Cella, Harper & Scinto, New York, By Thomas H. Beck, Esq., Counsel for Plaintiff.
Clifford Chance Rogers & Wells LLP, New York, By Philip E. Roux, Esq., Counsel for Defendants.

OPINION AND ORDER:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

PATTERSON, D.J.

***1** This opinion constitutes the findings of fact and conclusions of law of the Court relating to the contention of Plaintiff Bristol-Myers Squibb Company ("Bristol") that Defendants Rhône-Poulenc Rorer, Inc., Centre National De La Recherche Scientifique, and Rhône-Poulenc Rorer, S.A. (collectively, "RPR") obtained U.S. Patent No. 4,924,011 (issued May 8, 1990) (" '011 patent") and U.S. Patent Re. No. 34,277 (issued June 8, 1993) (" '277 patent") by inequitable conduct by intentionally withholding material information (the JACS article) FN1 from the U.S. Patent & Trademark Office during the prosecution of the '011 patent and the '277 reissue patent.

> FN1. The JACS article is a scientific article written by the named inventors of the '011 patent titled "A Highly Efficient, Practical Approach to Natural Taxol." The article was published in the Journal of the American Chemical Society in August, 1998.

After hearing evidence on the interpretation of the JACS article, the Court previously determined by clear and convincing evidence that (1) "the inventors omitted to provide material information by not providing the Patent Office with the JACS article during the prosecution of the '011 patent"; and (2) "that the examiners did not review the JACS article prior to issuing the '011 patent." (Opinion and Order dated Oct. 2, 2001.) On November 13-16, 2001, the Court held a hearing on the issue of RPR's intent to mislead the U.S. Patent & Trademark Office.

Applicable Law

"[T]o reach a finding of inequitable conduct, the district court must determine that information known to the inventors or their representatives was both material and intentionally withheld." *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed.Cir.2001). "Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue." *Precision Instruments Mfg. Co., et al. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 818, 65 S.Ct. 993, 999, 89 L.Ed. 1381, *petition for clarification denied,* 325 U.S. 843, 65 S.Ct. 1561, 89 L.Ed. 1967, *rehearing denied,* 325 U.S. 893, 65 S.Ct. 1189, 89 L.Ed. 2005 (1945); *see also* 37 C.F.R. § 1.56(a) (2001) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.")

"This duty of candor applies equally to the applicant and his attorney, even where a foreign attorney has primary responsibility for the prosecution of the application and acts only through a correspondent attorney in the United States." *Gemveto Jewelry Co., Inc. v. Lambert Bros., Inc.*, 542 F.Supp. 933, 938-39 (S.D.N.Y.1982) (citations omitted); *see also* Manual of Patent Examining Procedure ("MPEP") § 2004(7) (1986) ("It is also important that an attorney or agent

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make sure that foreign clients, including foreign applicants, attorneys, and agents understand the requirements of the duty of disclosure, and that the U.S. attorney or agent review any information disclosure statements or citations to ensure that compliance with [the duty of disclosure] is present").

***2** Bristol has the burden of proving by clear and convincing evidence that RPR acted with intent to mislead the U.S. Patent & Trademark Office. *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed.Cir.1987). "Intent to deceive can not be inferred solely from the fact that information was not disclosed," *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed.Cir.1996), nor from the fact that the information was material, *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed.Cir.1990). "[T]here must be a factual basis for a finding of deceptive intent." *Hebert*, 99 F.3d at 1116. Proof of intent, however, does not require "direct evidence of admitted deceitful conduct;" rather, it is generally "proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred." *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed.Cir.2001); *see also Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed.Cir.1989) ("Intent need not, and rarely can, be proven by direct evidence. It is most often proven by 'a showing of acts the natural consequences of which are presumably intended by the actor.' ").

The Inventors' Semi-Synthesis of Taxol

The '011 and '277 patents cover a semi-synthesis of taxol from 10-deacetylbaccatin III ("10-DAB") or baccatin III (collectively, "taxane core") utilizing a (2R, 3S) 3-phenylisoserine side chain. Starting with 10-DAB, a hydroxy-protecting group is introduced at the C-7 hydroxyl position on the taxane core to form the C-7 protected intermediate. (Dr. Martin, Transcript ("Tr.") at 292.) Second, an acetyl group replaces the hydrogen atom that is bonded to the oxygen atom at the C-10 position on the taxane core. (Dr. Martin, Tr. at 291, 292.) The resulting product is referred to as protected baccatin III. (Dr. Martin, Tr. at 304.) Third, the side chain is protected by a hydroxy-protecting group at the C-2' position and then esterified (or coupled) with the protected baccatin III at the C-13 position. (Dr. Martin, Tr. at 303-04.) Finally, the hydroxy-protecting groups at the C-7 and C-2' positions are deprotected (removed) to form taxol. (Dr. Martin, Tr. at 306.) In the '011 and '277 patents, the hydroxy-protecting group at C-2' is referred to as R_2 and the hydroxy-protecting group at C-7 is referred to as R_3. (PX 4.)

Chronology

On or around November 3, 1987, Jacques Pilard, a patent agent in the employ of RPR in France, was sent a draft article ("draft JACS article") authored by Drs. Jean-Noel Denis, Andrew E. Greene, Daniel Guenard, Francoise Gueritte-Voegelein and Pierre Potier entitled "Highly Efficient, Practical Approach to Natural Taxol," which the authors hoped to publish for the purposes of sharing their discovery with their peers in the scientific community.[FN2] (PX 162, Greene, Tr. at 51.) In the draft JACS article, which was written in English, the authors described the semi-synthetic process for making taxol that they had discovered. The authors stated that

> FN2. Pursuant to a joint research agreement between RPR and CNRS, the authors could not publish the draft JACS article until they received approval from RPR. (*See* Order and Opinion dated February 5, 1998 (docketed February 9, 1998); Greene, Tr. at 184.)

***3** The required differentiation of the similarly reactive C-7 and C-10 hydroxyl functions and the selective esterification of the difficultly accessible C-13 hydroxyl group with the bulky (suitably protected) N-benzoylphenylisoserine side chain of taxol, in practice, could be successfully achieved only with specific protecting groups and under unique reaction conditions.
(PX 162 at 2.)[FN3] Further on, the authors stated that

> FN3. The published version of the JACS article changed "under unique reaction conditions" to "under specially developed reaction conditions, as described below." (PX 21.)

None of the various esterification procedures that are

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generally successful with hindered substrates was able to produce, even to a modest degree, the desired coupling. Subsequent extensive investigation, however, led to the development of a powerful protocol, which proved effective: 7-triethylsilyl baccatin III(3b) in the presence of 6 equiv of readily available, optically pure (2R, 3S)-N-benzoyl-O-(1-ethoxyethyl)-3-phenylisoserine (5) [16] ....

(PX 162 at 3.) In footnote 16 cited in the previous passage, the authors stated that "[a] methoxymethyl ["MOM"] protecting group at C-2' could not be removed from the molecule." (PX 162 at n. 16.) In footnote 13, relative to the triethylsilation of the C-7 hydroxyl, the authors stated that

The trimethylsilyl [("TMS")] group could also be selectively introduced at C-7, but it proved unstable to the subsequent esterification conditions. The t-butyldimethylsilyl [("T-BDMS")] group could not be cleanly introduced.

(PX 162 at n. 13.)

On November 13, 1987, Mr. Pilard suggested to Dr. Guenard "that the process described in the draft publication should [could?] be the subject of a patent application, but it would be desirable to have applied this process to the synthesis of 56979 RP [taxotere, RPR's taxol derivative] before filing ... and publishing." (PX 162.) [FN4]

> FN4. The named inventors are Drs. Denis, Greene, Guenard, and Gueritte-Voegelein. Although Pierre Potier was listed as one of the authors of the draft JACS article provided to Mr. Pilard in November, 1987, Mr. Potier was not listed as one of the named inventors on the French or U.S. patent applications or as one of the named authors of the published JACS article. In all other respects, the substance of the draft JACS article and the JACS article are the same.

In a letter sent to Mr. Pilard (among others) dated January 29, 1988, P.E. Simon of RPR's Grants and Licenses Department, suggested that a patent application covering the inventors' semi-synthesis of taxol be filed in consideration of an exclusive license to RPR. (PX 130.) In that letter, Mr. Simon described RPR's interest in the inventors' discovery:

Although we are not interested in exploitation of Taxol, our Research Management would not consider it appropriate to leave this process without industrial protection.

For if a source of Taxol should become available by reason of this process, that would facilitate pursuit of [ ]clinical studies and, hence, the marketing of this anti-cancer agent before that of the derivatives we are now investigating. We are quite aware that a patent on this process would not constitute an absolute bar to third parties.

(PX 130.)

On or around March 7, 1988, Drs. Greene and Denis provided Mr. Pilard their resumes and an invention disclosure, entitled "Modes Operatoires," which described their semi-synthesis of taxol in detail. (PX 71.) In the Modes Operatoires, the inventors described their experimental success using TES as the hydroxy-protecting group at the C-7 position and EOE as the hydroxy-protecting group at the C-2' position. (PX 71.) In footnotes relating to the protection of the hydroxyl at C-7, the inventors stated that

***4** The regioselective protection of the hydroxyl at C7 in 10-deacetyl baccatin III, *4,* was also obtained with trimethylsilyl chloride in pyridine at O C . 7-trimethylsilyl 10-deacetyl baccatin III was obtained with 72-76% yield. However, this trimethylsilyl group proved too fragile in the esterifying reaction with the protected side chain *3* (see esterifying reaction *3 + 6-7*)

and

The protection reaction does not go forward with the t-butyl dimethylsilyl chloride. (PX 71 at RPR 4200018.) In a footnote relating to the protection of the hydroxyl at C-2', the inventors stated that

The hydroxyl function of the side chain *1* was also protected with a wide variety of protective groups, such as the methoxymethyl group, benzyloxymethyl, (9-trimethyl ... tetroxy)methyl, and tetrahydropyranyl (THP). The corresponding acetals were obtained in

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excellent yields.

(PX 71 at RPR 4200014.)

On March 10, 1988, Mr. Pilard began to draft a patent application for the semi-synthesis of taxol that had been discovered by the inventors. (PX 177 at Tab 3, pp. 14-15.) In claim 1 of the draft patent application, Mr. Pilard claimed the process as one "in which R_2 is a hydroxy-protecting group ... [and] in which R_3 is a hydroxy-protecting group," without any limitation as to the hydroxy-protecting groups that could be utilized in the process. (PX 168.)

In claim 2 of the draft patent application, Mr. Pilard claimed the process according to claim 1 "in which R2 is chosen from methoxymethyl ... and R_3 is chosen from trialkylsilyl groups in which each alkyl portion contains one to three carbon atoms." (PX 168.) In addition to specifying that MOM and TMS FN5 were permissible hydroxy-protecting groups in claim 2, Mr. Pilard wrote in the specification of the draft patent application that "R_2 denotes, more especially, a methoxymethyl ... radical" and that "[p]referably, R_3 is a trimethylsilyl ... radical." (PX 168.)

> FN5. TMS is a trialkylsilyl in which each alkyl portion contains one carbon atom. It therefore comes within claim 2's definition of R_3. (Martin, Tr. at 327.) The alkyl portion of T-BDMS contains four carbon atoms and does not come within claim 2's definition of R_3. (Denis, Tr. at 95.)

On or around March 18, 1988, Mr. Pilard sent his draft of the French patent application to Drs. Greene and Denis, asking them to "review carefully this draft, adding all the complements and modifications that you deem necessary." (PX 168.) Mr. Pilard also asked the inventors "to specify, in both the general part of the description and in the examples, the configuration of carbon atoms in the 2 and 3 positions of the 3-phenylisoserine derivatives." (PX 168.)

On or around March 23, 1988, Drs. Greene and Denis submitted their suggested changes to the French patent application to Mr. Pilard. (PX 163.) Drs. Greene and Denis specified the configuration of the carbon atoms in the 2 and 3 positions of the 3-phenylisoserine derivatives, in accordance with Mr. Pilard's request, and made several minor changes to the chemistry in the patent's example, but made no changes to the substantive scope of the claims in either the specification or the claims. (PX 163.) Drs. Greene and Denis also requested that Mr. Pilard approve the draft JACS article for publication by April 4. (PX 163.)

***5** On or around March 24, 1988, Mr. Pilard advised Dr. Denis that the filing of the French Patent Application could not be done by April 4, but would be done before April 15. (PX 163.)

On April 6, 1988, Mr. Pilard filed the French Patent Application. (PX 134.)

On April 20, 1988, the draft JACS article was received at the Journal of the American Chemical Society for publication. (PX 21.)

On August 17, 1988, the JACS article was published. (PX 21.)

On or around November 17, 1988, F. Lavelle, Officer in Charge of RPR's Anticancer Research Program, wrote to Mr. Pilard about the inventors' semi-synthesis of taxol, stating:
In view of the importance of this subject and the risks of competition, we consider it indispensable that the widest possible scope be sought at the time of filings abroad.

(PX 143.)

In March, 1989, Mr. Pilard sent a copy of the French patent application and a search report dated November 24, 1988 generated by the French National Institute of Industrial Property to J.A. Kemp & Co. for translation into English and forwarding to Mr. Ellsworth H. Mosher, RPR's U.S. patent attorney. (Pilard, PX 177, tab 3 at 36-40, 43.) The search report did not list the JACS article and Mr. Pilard did not send a copy of the JACS article, the Modes Operatoires, or any of the inventors' test results to J.A. Kemp & Co. or Mr. Mosher. (PX 177, tab 3 at 39-40, 44-45.) There is no evidence that Mr. Pilard

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sought advice from Mr. Mosher regarding whether the JACS article should be submitted to the U.S. Patent & Trademark Office.

On April 3, 1989, the '011 patent application was filed with the U.S. Patent & Trademark Office by Mr. Mosher. (PX 171(a) at pp. 2-25 .) The filed patent application (except for the abstract) is an English translation of the French patent application previously prepared and filed by Mr. Pilard. (PX 171(a) at 3-25.) Mr. Mosher, who never received a copy of the JACS article from Mr. Pilard, did not disclose the JACS article to the U.S. Patent & Trademark Office.[FN6] (PX 171(a).)

> FN6. Excerpts of the depositions of Mr. Mosher and Dr. Guenard, both of whom were unable to testify at the hearing, were offered into evidence by Bristol as PX 159 and PX 157 and not objected to by RPR. (Tr. at 270-72.) However, these exhibits were not formally admitted into evidence at the hearing due to an oversight by the Court. (Tr. at 270-72.) Accordingly, both depositions are admitted into evidence *nunc pro tunc.*

On or around December 12, 1989, Mr. Mosher wrote to J.A. Kemp & Co., enclosing a formal Notice of Allowance for the '011 patent. (PX 135.) Mr. Mosher advised that:

You and the applicant are required by 37 CFR Sect. 1.99 "Updating of Prior Art Statement" to disclose any additional Prior Art *or other information you are aware of which is "material to the examination of the application."* Please furnish us with such information including copies of publications and patents or complete identification including date of publication so we can locate them on the PTO microfilm. Such prior art must be immediately submitted to be considered by the PTO before issuance. Please note the requirements of the *Manual of Patent Examining Procedure* (MPEP) when submitting prior art after a Notice of Allowance is issued.

(PX 135 (emphasis added).)

On May 8, 1990, without further communication with the U.S. Patent & Trademark Office, the '011 patent issued. (PX 171(a) at p. 1.)

***6** On or around January 31, 1991, Mr. Pilard wrote to the European Patent Office, acknowledging that "[t]aking into account the complexity of the initial and final products, it is necessary to find specific conditions of use of the process in order to avoid secondary reactions involving, in particular, an excessive consumption of baccatin III," and withdrawing the claims previously drawn in the counterpart European patent application. (PX 142, Tr. at 282.) Mr. Pilard replaced those claims with a single claim (similar to claims 2-7 of the '011 patent) for the inventors' process "wherein R_2 represents a hydroxy-protecting group selected from the group comprising the methoxymethyl, 1-ethoxyethyl, benzyloxymethyl, (trimethylsilylethoxy)methyl and 2,2,2-trichloroethoxycarbonyl radicals" and "wherein R_3 represents a hydroxy-protecting group selected from among the trialkylsilyl radicals wherein each alkyl part contains 1 to 3 carbon atoms" using "a condensation agent selected from among the carbodiimides and reactive carbonates" and "an activating agent chosen from the dialkylaminopyridines in an aromatic organic solvent chosen from among benzene, foluene, xylenes, ethylbenzene, isopropylbenzene and chlorobenzene, at a temperature of between 60 and 90 C ." (PX 142.)

On June 11, 1991, Mr. Pilard sent Frederick F. Calvetti, a U.S. patent attorney in a different firm, a letter by fax and post about seeking a reissue patent with "additional claims directed to the intermediates of formula IV and V" of the '011 patent. (PX 136.) Attached to Mr. Pilard's June 11, 1991 fax/letter to Mr. Calvetti was a copy of the '011 patent and a copy of the JACS article with footnote 16 circled[FN7]. (PX 136; Calvetti, Tr. at 469-70.)

> FN7. Footnote 16 is the footnote that states, among other things, "A methoxymethyl protecting group at C-2' could not be removed following esterification." (PX 21, PX 136.)

On June 13, 1991, Mr. Calvetti replied to Mr. Pilard's letter, stating that the JACS article would not affect

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the grant of the patent "because the Journal publication was filed less than one year prior to the filing of the '011 patent" in compliance with 35 U.S.C. § 119 [FN8], and that a reissue patent application could be filed. (DX 54.)

> FN8. Mr. Calvetti described Section 119 to Mr. Pilard as stating "that, 'No patent is to be granted on any application for patent for an invention which had been ... described in a printed publication in any country more than one year before the date of the actual filing of the application in this country.' " (DX 54 at ICR 0623.)

On or around June 24, 1991, Mr. Calvetti wrote Jacques Savina, Mr. Pilard's supervisor at RPR, regarding Mr. Pilard's request that he seek a reissue patent with additional claims directed to the intermediates of formula IV and V of the '011 patent.FN9 (PX 138; Calvetti, Tr. at 478.) Mr. Calvetti stated that he had reservations about the patentability of the intermediate of formula IV. (PX 138 at ICR 0734.) Mr. Calvetti noted that the intermediate of formula IV is "derived from naturally occurring 10 deacetylbaccatine III by trialkylsilylation followed by acetylation" and opined that "[s]uch modification of a naturally occurring compound may not be considered nonobvious." (PX 138 at ICR 0736.)

> FN9. Mr. Calvetti's letter also discussed infringement considerations with regards to European Patent Applications 400,971 and 428,376. (PX 138.) Those patents were filed by Bristol on behalf of Professor Holton and covered a semi-synthetic process for making taxol using a beta-lactam side chain coupled with the protected 10-DAB core. (Calvetti, Tr. at 478.)

On or around July 25, 1991, Mr. Pilard sent a letter to Mr. Calvetti replying to Mr. Calvetti's letter of June 24, 1991. (PX 139 .) Mr. Pilard attached to that letter a document, written in English, which discussed the reasons that Mr. Pilard believed that the intermediates were patentable and included a draft of the proposed additional claims. (PX 139; Calvetti, Tr. at 496.) In Mr. Pilard's discussion of the reasons he felt the intermediates to be patentable, he stated:

*7 It would be advisable to protect selectively the C-7 hydroxyl function prior to acetylation without protection of the C-10-hydroxyl function with a protecting group which can be easily remove [sic] only after the esterification of the C-13 -hydroxyl function.... Particularly, when taxol has to be prepared from 10-deacetylbaccatine III, it is necessary to protect only hyroxyl [sic] function at the C-7, in order to acetylate selectively the C-10 without acetylating the C-13. *The protecting group at C-7 has to be stable under the acetylating conditions and to the subsequent esterifying conditions. Furthermore, the elimination of the protecting groups has to be made under conditions which do not conduct to an epimerisation at the C-13 or at the C-2':* it is important that the protecting group at the C-7 to do not be cleavable under basic conditions. *Even if protecting groups are known, it is difficult to select an appropriate protecting group without undue experimentation.*

(PX 139 at ICR 0731 (emphasis added).) [FN10]

> FN10. Other correspondence between Mr. Pilard and Mr. Calvetti was sent on or around 6/17/91 (PX 59), 8/23/91 (PX 175) and 9/3/91 (PX 140).

On November 1, 1991, Mr. Calvetti filed the reissue application ("the '277 patent application"). (DX 83 at pp. 2-3; Calvetti, Tr. at 510.) In addition to all the claims in the '011 patent, the reissue application claimed three intermediates of the '011 patent: (1) 10-DAB protected at the C-7 position by a trialkylsilyl group containing one to three carbon atoms; (2) protected baccatin III; and (3) the coupled side chain and protected baccatin III protected in the C-7 and C-2' positions. (DX 83 at 14.) In addition, the reissue application contained two additional process claims. (DX 83 at 15-16.) Mr. Calvetti did not disclose the JACS article to the U.S. Patent & Trademark Office upon filing the '277 patent application. (DX 83; Calvetti, Tr. at 510.)

On or around January 28, 1992, Mr. Calvetti submitted an information disclosure statement to the

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U.S. Patent Office. (DX 83 at 37.) Mr. Calvetti did not disclose the JACS article to the U.S. Patent Office at that time. (Calvetti, Tr. at 511.)

On April 8, 1992, Mr. Calvetti went to the U.S. Patent & Trademark Office for an interview with the patent examiner handling the '277 patent application. (DX 83 at 36.) Mr. Calvetti did not disclose the JACS article at that time. (Calvetti, Tr. at 511.)

On or around April 17, 1992, Mr. Calvetti filed a response to an Official Action from the examiner but did not mention the JACS article. (DX 83 at 58-67; Calvetti, Tr. at 512.)

On or around July 17, 1992, Mr. Pilard sent a letter to Mr. Calvetti stating that the JACS article is irrelevant. (DX 160.)

On October 20, 1992, Mr. Calvetti interviewed with the patent examiner again regarding the '277 patent application. (DX 83 at 144.) Mr. Calvetti did not disclose the JACS article at that time. (Calvetti, Tr. at 513.)

On or around December 14, 1992, Mr.Calvetti filed another response to an Official Action from the examiner but did not mention the JACS article. (DX 83 at 182-91; Calvetti, Tr. at 513-14.)

***8** By letter dated December 15, 1992, Mr. Calvetti submitted an information disclosure statement to the U.S. Patent & Trademark Office listing the JACS article as one of six references (and providing a copy of the JACS article) pursuant to instructions from Mr. Pilard. (DX 83 at 38, 72-73, Calvetti, Tr. at 517-518; Pilard, PX 177 at tab 2, p. 157.) A receipt stamp of the U.S. Patent & Trademark Office on the information disclosure statement from Mr. Calvetti bears the date January 14, 1993. (DX 83 at 38, 72-73.) The copy of the JACS article that Mr. Calvetti provided to the Patent Office did not have footnote 16 circled. (DX 83 at 125, Calvetti, Tr. at 520-21.)

On January 28, 1993, the patent examiner indicated to Mr. Calvetti that an allowance would be issued for the reissue application in due course. (DX 83 at 159.)

In February, 1993, subsequent to indicating that the reissue application would be allowed, the patent examiner reviewed the information disclosure statement listing the JACS article. (DX 83 at 72-73.)

On March 11, 1993, the U.S. Patent & Trademark Office issued a notice of allowability for the '277 reissue patent. (DX 83 at 192.)

On June 8, 1993, the '277 patent was issued. (DX 83 at cover page .)

A. Mr. Pilard Intentionally Drafted The French Patent Application In An Overly Broad Manner

Mr. Pilard did not appear at the hearing. Bristol and the Court had requested Mr. Pilard's appearance but RPR was unable to persuade him to appear. (Savina, Tr. at 413-15.) Accordingly, the Court had to rely on the portions of Mr. Pilard's videotaped depositions submitted by the parties and a transcript of his depositions to evaluate his credibility.

Mr. Pilard testified that he prepared the French patent application based on the invention disclosure, Modes Operatoires, provided by the inventors. (Pilard, PX 177 at tab 3, pp. 15-16.) The Modes Operatoires, however, did not provide support for the breadth of the patent application drafted by Mr. Pilard. In the Modes Operatoires, the inventors described a very specific reaction utilizing EOE as a protecting group for R_2 and TES as a protecting group for R_3. (PX 71.) In footnotes, the inventors mentioned some of their results with other hydroxy-protecting groups and other solvents and reactants. (PX 71.) In one footnote, the inventors stated that "[t]he protection reaction does not go forward with the t-butyl dimethylsilyl chloride [T-BDMS]" protecting group. (PX 71 at RPR 4200018.) In another, the inventors stated that TMS could be used to protect the hydroxyl at the C-7 position of 10-DAB, but the "trimethylsilyl group proved too fragile in the esterifying reaction with the protected side chain." (PX 71 at RPR 4200018.) Nonetheless, in claim 1 of the French patent application, Mr. Pilard claimed the inventors' process to make taxol utilizing any hydroxy-protecting group [FN11], and in claim 2, Mr. Pilard claimed the inventors' process utilizing TMS as a

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hydroxy-protecting group. (PX 168.) In addition, Mr. Pilard wrote in the specification of the French patent application that "Preferably, R_3 is a trimethylsilyl ... radical." (PX 168.)

> FN11. Mr. Pilard's statement to Mr. Calvetti in his letter dated July 25, 1991, that "[e]ven if protecting groups are known, it is difficult to select an appropriate protecting group without undue experimentation," cannot be reconciled with claim 1 of Mr. Pilard's draft patent application, which states that R_2 and R_3 could be any hydroxy-protecting group. (PX 139.)

***9** Also in claim 2 of the French patent application, Mr. Pilard claimed that MOM could be used as a hydroxy-protecting group in the C-2' position on the side chain in the process to make taxol. (PX 168.) Mr. Pilard also stated in the specification of that patent application that "R_2 denotes, more especially, a methoxymethyl ... radical." (PX 168.) The Modes Operatoires does not support the claim that MOM could be successfully used to make taxol or the statement it is a more especially preferred hydroxy-protecting group. In the Modes Operatoires, the inventors made reference to MOM only once, in a footnote stating that the hydroxyl function of the side chain (C-2') had also been protected by MOM and a wide variety of other protective groups to obtain the corresponding acetals in excellent yield. (PX 71 at RPR 4200014.) No statement in the Modes Operatoires indicated that MOM could be successfully used in the subsequent esterification with the protected baccatin III or that it could be removed following esterification without damaging the molecule. (PX 71.)

Mr. Pilard was given a motive for drawing the patent application broadly. He had been advised by Mr. Simon's letter dated January 29, 1988 that RPR wanted a patent for the inventors' semi-synthesis of taxol in order to block competitors from using taxol before RPR had concluded investigation of other derivatives that it was then pursuing. (PX 130.) A patent application based on the inventors' successful use of EOE and TES as the hydroxy-protecting groups for R_2 and R_3, respectively, to obtain taxol, as set forth in the Modes Operatoires, would not have accomplished that objective. The clear inference is that Mr. Pilard was attempting to satisfy RPR's Mr. Simon by drawing claim 1 to state that the process could be used to make taxol with any hydroxy-protecting group; by drawing claim 2 to state that the process could be used to make taxol utilizing MOM or TMS as hydroxy-protecting groups; and by making the statements in the specification that MOM and TMS were preferred hydroxy-protecting groups.

The JACS Article

Mr. Pilard had read the draft JACS article and had it in his possession at the time he drafted the French patent application in March, 1988. (PX 162.) That article provided no scientific support for claims 1 and 2 or the statements that MOM and TMS were preferred hydroxy-protecting groups. In the draft article, the inventors had stated that the process used to produce taxol "could be successfully achieved *only* with specific hydroxy protecting groups and under unique reaction conditions," not with any hydroxy-protecting group; that TMS could "be selectively introduced at C-7, but it proved *unstable* to the subsequent esterification conditions"; and that a MOM "protecting group at C-2' *could not be removed* following esterification." (PX 162 (emphasis added).)

Mr. Pilard has testified that it was his practice to read the whole text of a publication before permitting it to be published. (PX 177 at tab 3, p.11.) Thus, Mr. Pilard had notice that the inventors had written in the JACS article that the process worked only with specific protecting groups and under unique reaction conditions, that TMS had proved to be unstable to the subsequent esterification conditions, and that a MOM protecting group at C-2' could not removed from the molecule.

Mr. Pilard's Files

***10** Although it was standard RPR procedure in 1988 for the patent agent to collect the scientific tests and other documentation supporting the claims in a patent application (Savina, Tr. at 420), Mr. Pilard's files on the patent application contained no scientific tests

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FN12, no notes, no memoranda or any other documents which would support claims 1 and 2 of the French patent application. Nothing in the files indicated that Mr. Pilard asked the inventors whether the process could be used to produce taxol with any hydroxy-protecting group or whether TMS or MOM could be successfully used to produce taxol.

> FN12. Though Mr. Pilard's files contained no scientific tests, Dr. Guenard testified he had provided experimental data to Mr. Pilard:
> Q: In what form did you provide the experimental data to Pilard?
> A: Written form.
> (Guenard, DX 501, 9/9/97 at 389.)

The Inventors' Testimony

None of the inventors could recall any communication with Mr. Pilard informing him that R2 and R_3 could be defined as a hydroxy-protecting group, that R_2 was preferably MOM, or that R_3 was preferably TMS. (Denis, Tr. at 46, 48; Gueritte-Voegelein, Tr. at 108; Greene, Tr. at 165.)

The inventors' testimony showed, moreover, that even if Mr. Pilard had asked them in March, 1988 whether the process could work with any hydroxy-protecting group or whether TMS could be used to make taxol, they could not have provided him with any reasonable scientific basis for so believing. The inventors have not testified that their semi-synthesis of taxol could work with all hydroxy-protecting groups or that their statement in the Modes Operatoires that the "protection reaction does not go forward with the [T-BDMS]" is not accurate. Accordingly, there is no evidence that Mr. Pilard had any scientific basis for claiming that the process could be used to produce taxol with any hydroxy-protecting group as he did in claim 1.

In addition, the inventors never conducted an experiment in which they successfully coupled a 7-TMS protected taxane core with a protected side chain to produce taxol. (Denis, Tr. at 98.) The inventors conducted only one experiment in which they tried to produce taxol using TMS ("the E141 experiment"). (Denis, Tr. at 78 .) It was a failure. (PX 69(a) at 13.) Dr. Denis' lab notes on this experiment state "No desired ester." (PX 74(a).) The experiment was abandoned without further analysis of the products obtained. (PX 74(a).) Dr. Denis admitted that, on the basis of the E141 experiment, "one cannot conclude" that TMS is useful for making taxol.FN13 (Denis, Tr. at 74.)

> FN13. Drs. Denis and Greene described the E141 experiment as a failure in an internal report prepared in November, 1989. (PX 69(a) at 13.) In an October, 1993 report, Drs. Denis and Greene described the E141 experiment with the statement that TMS was "unstable under conditions of esterification used." (PX 165 at 3.) In her speaking notes from the 1990s, Dr. Gueritte-Voegelein wrote that "the trimethylsilyl group could ... be selectively introduced at C-7, but it proved unstable to the subsequent esterification conditions." (PX 153 at RPR 028651.)

Though Dr. Denis testified that he was convinced that the E141 experiment yielded monoprotected taxol as a product, thereby giving him a basis to believe that TMS could be successfully used in the process, this testimony was not credible. (Denis, Tr. at 68.) Not only did Dr. Denis not make any notation in his lab notebook indicating a conviction that he had obtained monoprotected taxol, he wrote "No desired ester." (PX 74(a).) Dr. Denis also did not make any notation in any other contemporaneous document of his conviction that he had obtained monoprotected taxol. Even RPR's own expert witness, Dr. Stephen Martin, stated that, based on the records of the experiment, a scientist "could not reliably conclude that one of those spots [on the TLC plate] was the monoprotected taxol because there is no evidence for that.... It's speculation in any direction." (Martin, Tr. at 323.) Dr. Elias J. Corey, Bristol's expert witness, agreed with Dr. Martin that it would be speculative to claim any particular product based on the records of the E141 experiment and opined that the experiment's abrupt termination (without analysis) indicated that it was a failure:

***11** Q: Doctor, reviewing the record of that

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experiment [E141] and results, what conclusions would you draw?
A: There are several conclusions that I would draw. One of them is that this experiment was so unpromising and negative in its results that it was basically abandoned without thorough analysis.
At the very bottom of the [E141 lab notebook] page, which I am trying to point to, the experiment was terminated. That would be a premature termination by anybody's standards, which indicates that, in the judgment of the people or the individual who did this experiment, it was a failed experiment.
There is no workup or isolation of any reaction product. The reaction mixture was just thrown away because it didn't seem profitable to pursue it. That TLC may be one of the reasons that the experiment was terminated.
In such a terminated experiment, it is very difficult for anyone to claim any particular result. I don't see the basis on which any conclusion can be drawn from this experiment other than it was a failed experiment.

(Corey, Tr. at 212-13.) Dr. Denis, like the other inventors, is an interested witness who stands to receive significant royalties if Bristol is determined to have infringed RPR's '277 patent. (Gueritte-Voegelein, Tr. at 132.) The only conclusion to be drawn is that his testimony is a rationalization or wishful thinking.[FN14] [FN15]

FN14. Dr. Martin's testimony about Dr. Leone's experiments in 1996 lacked a sufficient evidentiary foundation and, in any case, was not persuasive as to the issue of inequitable conduct. (Martin, Tr. at 330-49, 370-80, 387-89.)

FN15. The inventors may have had a basis to think that MOM could be used to produce taxol. In March of 1987, Dr. Gueritte-Voegelein successfully deprotected MOM, in poor yield, from deacetyl taxol (the taxol compound minus the acetyl group in the C-10 position of the taxane core) using an iodine TMS reagent in experiment FG 1457. (PX 73, PX 148.) This experiment might have furnished the inventors' with a reason to believe that MOM could be successfully used to make taxol, but if so they did not make such a claim in the draft JACS article in November, 1987. The evidence is that (1) Dr. Gueritte-Voegelein never attempted to deprotect MOM from taxol (Gueritte-Voegelein, Tr. at 108); (2) Drs. Greene and Denis were unsuccessful in all their attempts to deprotect MOM from taxol (PX 72); and (3) Dr. Gueritte-Voegelein had used a reagent in experiment 1457, iodo-TMS, that is different from the reagents specified in the '011 or '277 patents (Gueritte-Voegelein, Tr. at 112-13).

Mr. Pilard's Testimony

Mr. Pilard's deposition by Bristol on January 8-9, 1998, following three days of preparation by RPR's counsel (Pilard, PX 177 at tab 1, pp. 34-35), confirmed that he had no scientific basis for drafting the patent claims in the manner in which he drew them. Mr. Pilard could not recall any support whatsoever for having claimed that TMS or MOM could be used to produce taxol or for stating that they were preferred hydroxy-protecting groups:
Q: Sir, with respect to the U.S. patent application ... What basis did you have at the time the U.S. application was prepared and filed for representing to the patent office that the methoxymethyl protecting group was a more specially preferred group-stop there.
Mr. Roux: Object to the form of the question.
A: I don't recall.
Q: As you sit here today, do you have any information that would support the assertion to the patent office that the methoxymethyl group was a more specially preferred protecting group?
A: No.
Q: ... At the time the U.S. patent application ... was prepared and filed, what basis did you have for representing to the U.S. Patent Office that the trimethylsilyl protecting group was a preferred protecting group for the C-7 position?
A: I don't recall.
....
Q: As you sit here today, sir, are you aware of any support for the view that the trimethylsilyl protecting group at the 7 position is a preferred protecting group

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in the process described in [the U.S. patent application]?
Mr. Roux: Same objection [to the form of the question]. You may answer if you can.
*12 A: No.

(Pilard, PX 177 at tab 1, p. 113-15.)

In Mr. Pilard's deposition by RPR on September 22-23, 1999, Mr. Pilard again could not provide any support for having claimed that MOM could be used to make taxol in claim 2 or stating that MOM is a preferred hydroxy-protecting group:
Q: And as you sit here today do you have any information that MOM protecting group could be used to make any amount of taxol?
Mr. Roux: Objection. That question has been asked and answered. You may answer again.
A: As far as I remember, I didn't get any information on this point.

(Pilard, PX 177 at tab 3, p. 83.) He also could not provide any support for having claimed that TMS could be used to make taxol or that TMS was a preferred hydroxy-protecting group.Q. And the question, sir, is did you have any basis then or now to believe that it did work? That is, the T.M.S. could be used in any other reaction?
Mr. Roux: Object to the form of the question.
A: The reaction concerns a function which is other than the protected-than the protected group. Therefore, it is not-we cannot believe-
Ms. Rose: It is not impossible.
A: It is not impossible to believe that the reaction-it is not impossible to think that the reaction can occur even badly.
Q. Well, sir, when you prepared the patent application, did you check with the inventors to see what their actual results were when they used the 7-TMS group?
A. I do not remember.
Q. And you didn't check with the inventors to see whether they thought 7-TMS could be used in other coupling reactions, right?
A. I do not remember.

(Pilard, PX 177 at tab 3, p. 88.)

Accordingly, the evidence is clear and convincing that Mr. Pilard intended to draft the French patent application in an overly broad manner to block competing synthetic processes making taxol, despite his knowledge that he had no scientific basis for drafting the claims so broadly.[FN16]

FN16. The inventors' review of the draft patent application in March, 1988 is insufficient to show that Mr. Pilard had grounds for drawing the patent so broadly. None of the inventors could recall their actual review of that patent application. (Denis, Tr. at 86-91, 98; Gueritte-Voegelein, Tr. at 151; Greene, Tr. at 188-89; Guenard, DX 501, Dep. dated 9/9/97 at 422-23.) Dr. Greene has testified that, generally, his review of patent applications involves a scrutiny of the chemistry involved to make sure that the chemistry is correct. (Greene, Tr. at 188.) The inventor's response was confined to Mr. Pilard's question concerning the configuration of the carbon atoms in the 2 and 3 positions of the 3-phenylisoserine derivatives and making small changes relating to the chemistry in the example. (PX 163.)
The inventors did not suggest any changes to the legal definitions in the specification or the claims. (PX 163.) The inventors indicated that they trusted Mr. Pilard to draft the legal claims. Dr. Denis testified that:
Q: When you signed the declaration, having read the patent application, did it occur to you that you should tell the patent examiner, as you told Mr. Pilard, that TMS was unstable or too fragile?
A: Mr. Pilard is my lawyer, and I think that in my logic it wasn't incumbent upon me to tell the examiner, to tell him whatsoever. I told Mr. Pilard, and I trusted Mr. Pilard. Me, I am a scientist. And Mr. Pilard, he is a patent agent. He knows about patents. So I trusted him.
(Denis, Tr. at 98.) Similarly, Dr. Gueritte-Voegelein testified that:
Q: Doctor, when you signed the declaration

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for the U.S. patent application, did anything in the patent application at that time seem scientifically inaccurate?
A: No, at the time I wasn't struck by that. The patent had been written by Mr. Pilard and I trusted Mr. Pilard to write the patent.
(Gueritte-Voegelein, Tr. at 152.) Dr. Guenard testified that:
Q: As of the time that patent application was filed, do you believe those claims fully described your invention?
A: That was Mr. Pilard's job to draw up these claims and our task was simply to-and we would reread them afterwards.

Q: So your specific testimony is that you don't have any understanding as to why Mr. Pilard included the BOM group in the R2 [position] on the patent application?
A: It is the work of the man of art and I trust him.
Q: And when you say you trust him, that means you trust Mr. Pilard, right?
A: Yes.
(Guenard, DX 501, Dep. dated 9/9/97 at 422-23 (Mr. Roux's objection omitted); PX 157, Dep. dated 7/27/99 at 176.)
As an experienced patent agent, Mr. Pilard would have known that inventors would rely on his expertise in drawing the legal claims. Accordingly, Mr. Pilard's provision of the French patent application to the inventors for review is not sufficient to counterbalance the strong evidence that Mr. Pilard intentionally drew the patent claims too broadly.

B. Mr. Pilard Intentionally Engaged in Inequitable Conduct During The Prosecution Of The '011 Patent and the '277 Reissue Patent

Mr. Pilard was the person at RPR responsible for providing all relevant information to Mr. Mosher, RPR's U.S. patent attorney, in conjunction with Mr. Mosher's filing of the '011 patent application. (Pilard, PX 177 at tab 1, pp. 74-75, Savina, Tr. at 419-20.) Mr. Pilard has testified that he understood the U.S. duty of disclosure at that time:

Q: Now, at the time you gave this form [acknowledging the duty of disclosure to the U.S. Patent & Trademark Office] to the inventors for signature, did you have an understanding of what was material information as referred to in that sentence?
A: Yes.
Q: What did you understand "material information" to mean?
A: It's the duty to furnish to the U.S. Patent Office information that would permit the examiner which would facilitate, which would help the examiner in facilitating his work to determine their patentability of the invention.
***13** Q: And that duty encompassed both prior art and experimental test results, right?
Mr. Roux: Object to the form of the question. You may answer, if you can.
A: What do you mean by experiments?
Q: Scientific test results which were important to determine patentability.
Mr. Roux: Object to the form of the question. You may answer it, if you can.
A: Yes.

(Pilard, PX 177 at tab 1, p. 85-86.) FN17

FN17. Mr. Mosher also testified that Mr. Pilard was knowledgeable in U.S. patent law and the duty of disclosure:
Q: Now with respect to the dealings that you had with Mr. Pilard, do you recall his background or experience in connection with prosecution?
A: He's very skilled in prosecution as evidenced by his instructions.
Q: And was Mr. Pilard familiar with the duty of disclosure in connection with U.S. patent applications?
Mr. O'Shea: Objection.
A: Well, I assume he was since he was told a sufficient number of times.
Q: And you told him about the duty of disclosure; correct?
Mr. O'Shea: Objection.
A: Yes.
(Mosher, PX 159, Dep. dated 11/17/97 at 37.) Mr. Pilard had sufficient fluency in U.S. patent law to draft, in English, an

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application for the intermediates to be claimed in the '277 reissue application. (PX 139.)

Mr. Pilard supplied Mr. Mosher with a copy of the French patent application that he had filed, and a copy of the French search report generated by the National Institute of Industrial Research but did not provide Mr. Mosher with a copy of the JACS article or the Modes Operatoires. (Pilard, PX 177 at tab 3, p. 40.) The French search report did not list the JACS article. (Pilard, PX 177 at tab 3, pp. 44-45.)

Having drawn the '011 patent too broadly, Mr. Pilard had a reason not to submit the Modes Operatoires and the JACS article. Each contained information which was not consistent with the claims which Mr. Pilard had drawn. Submission of the JACS article, which was not prior art, could have informed the examiner that the inventors had made a contemporary scientific disclosure stating that the semi-synthesis of taxol worked "only with specific protecting groups and under specially developed reaction conditions";[FN18] that the TMS group "proved unstable" as a protecting group during esterification; and that the MOM protecting group at the C-2' position "could not be removed" from the protected taxol molecule. (PX 162 at 5918, n. 13, n. 16.)

FN18. Mr. Pilard subsequently wrote to the European Patent Office in January, 1991 that the process could only work with specific protecting groups and under specific conditions. (PX 142.) He also informed Mr. Calvetti that "[e]ven if protecting groups are known, it is difficult to select an appropriate protecting group without undue experimentation" in his correspondence of July 25, 1991. (PX 139.)

Mr. Pilard has never suggested that his failure to disclose the JACS article was a mere oversight or that he forgot about the JACS article when the application was made for the '011 patent. Instead, Mr. Pilard has contended that the JACS article was irrelevant because (1) the article only applies to an efficient synthesis of taxol and is intended for a different audience; (2) footnotes 13 and 16 are not inconsistent with his patent application because they do not state that the process did not work at all with TMS or MOM; and (3) that it is possible that the inventors continued to work with MOM subsequent to drafting the JACS article and achieved better results.[FN19] (Pilard, PX 177 at tab 1, pp. 104-011; tab 3 at 74-88 .) None of these proffered explanations are grounds for not submitting the JACS article to the U.S. Patent and Trademark Office nor were the explanations credible.

FN19. Mr. Pilard initially refused to answer whether footnotes 13 and 16 were adverse to the positions taken by RPR in the patent application:
Q: As you sit here today, sir, do you understand that the statements in footnotes 13 and 16 concerning the trimethylsilyl group and the methoxymethyl method protecting group are adverse to the positions taken during the prosecution of the U.S. patent application, right?
Mr. Roux: Object to the form of the question. No foundation. And it's plainly incorrect. But you may answer, if you can.
Mr. Beck: Don't obstruct and don't coach.
Mr. Roux: I'm not obstructing. I'm not obstructing. Stating my objections. You may answer, if you can.
A: I'm not answering it.
(Pilard, PX 177 at tab 1, p. 100-01).

(1) The Title of the JACS Article

Mr. Pilard testified that he might have concluded that the JACS article applied only to efficient syntheses of taxol based on the title of the JACS article, "A Highly Efficient, Practical Approach to Natural Taxol":
Q: Now, is that view, that the article speaks of an efficient approach, is that an understanding you arrived at on your own or did you have discussions with others?
A: No. Actually, I read it in the article, in the title.

***14** (Pilard, PX 177 at tab 1, p. 105.) However, the inventors did not suggest in the JACS article that its underlying experiments had been limited to efficient

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syntheses of taxol. (PX 21.) Footnote 13 states that TMS "proved unstable to the subsequent esterification conditions" without any qualification as to yield or efficiency. (PX 21 at n. 13.) Footnote 16 stated that a MOM "protecting group at C-2' could not be removed following esterification" without qualification as to yield or efficiency. (PX 21 at n. 16.) If the inventors had produced any taxol using TMS or MOM, they could have stated that MOM could only be partially removed or that TMS' instability resulted in reduced yield.

In addition, Mr. Pilard's contention that he believed the article only applied to an efficient synthesis of taxol was a hypothesis and therefore is irrelevant. Mr. Pilard testified that he could not remember what he could conclude or even what his intellectual approach was in 1988:

Q: Do you specifically recall today that back in 1988 when you were preparing the patent application, that you concluded that the statements in the JACS article could be disregarded [on the basis that the JACS article is a scientific publication and it has a different objective and a different audience than a patent does]?

A: I do not remember what I could do or what I could conclude in 1988.

Q: Is your answer that you don't recall specifically what you thought about the JACS article in 1988?

A: I don't know what-I don't remember what was my intellectual approach in 1988.

(Pilard, PX 177 at tab 3, pp. 84-85 (objections and other exchanges omitted.)

(2) The Expert Reading of the JACS Article

The two independent experts that testified at the hearing, Dr. Martin and Dr. Corey, both indicated that a person of ordinary skill in the art (a "POSA") in 1988 reading footnote 16 would have concluded that MOM was an unsuitable protecting group at any yield.[FN20] (Corey, Tr. at 253-55, Martin, Tr. at 328.)

FN20. Dr. Corey testified:

The Court: Reading footnote 16 in the context of the article, would a POSA read footnote 16-"methoxymethyl protecting group at C-2' could not be removed following esterification"-as meaning that a methoxymethyl protecting group could well be removed following esterification but not with a highly efficient practical approach? Do you follow my question?

A: Yes. I think that the intent of this footnote was to emphasize-

The Court: I don't want to know the intent of the footnote. I am asking how a POSA would read the footnote.

A: I think a person of ordinary skill or patent examiner would read it-

Mr. Roux: Objection, your Honor.

A: -to mean exactly what it said. Under the usual conditions for removing a methoxymethyl protecting group, the group could not be removed after esterification without loss of material due to side reactions, any conditions that would suffice for cleaving. A methoxy protecting group would do violence somewhere else in the molecule. Therefore, this warns the reader against-teaches the reader against the use of that particular protecting group.

The Court: Only teaches it against the use of that protecting group when the POSA is engaged in trying to have a highly efficient and practical approach to making taxol?

A: There is a certain ambiguity. It says "could not be removed."

The Court: What is the ambiguity?

A: You can interpret it in different ways.

The Court: To a POSA is what I'm getting at.

A: Yes. I would read it to mean-I think a person of ordinary skill would read it to mean as unsatisfactory as a protecting group.

(Corey, Tr. at 253-55.) Dr. Martin agreed with Dr. Corey's assessment of footnote 16:

Q: The first sentence there recites, "A methoxymethyl protecting group at C-2' could not be removed following esterification." Do you see that?

A: I do.

Q: To a person of ordinary skill in the art in

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> 1988, what would that footnote mean, have meant?
> A: That would mean I think that under the conditions that were examined that they couldn't remove it cleanly after the esterification, that there were probably-there was something wrong, perhaps side reactions that occurred when they tried to remove it. I think Professor Corey said it yesterday, it wasn't satisfactory, and that suggests also that it couldn't be removed cleanly, that there were some problems apparently with it.
> (Martin, Tr. at 328.)

Dr. Corey also testified that a POSA would read footnote 13 to state that TMS was not a suitable protecting group at any yield, while Dr. Martin testified that a POSA would find footnote 13 unclear as to whether TMS yielded any taxol.[FN21] (Corey, Tr. at 255-56; Martin, Tr. at 324-35.)

> FN21. Dr. Corey testified that:
> The Court: What about the statement about TMS in footnote 13? Reading footnote 13, would [a POSA] believe that "the trimethylsilyl group proved unstable to subsequent esterification conditions" meant that if you were only trying to get a small yield, that trimethylsilyl could be selectively introduced and would result in a yield? Are you following me?
> A: Yes. There wouldn't be any point in having that footnote if the trimethylsilyl group-if there was any evidence that the trimethylsilyl group gave a reasonable yield, there wouldn't be any point in putting the footnote in.
> The Court: My problem is good yield, reasonable yield.
> A: Given the background of the experiment that we have just been talking about, the Denis experiment, where there didn't seem to be any sign of success in that experiment, where in fact the experiment was abandoned because it looked so unpromising, given that, I think the statement in footnote 13 can only mean one thing. That is, it is not a suitable protecting group.
> (Corey, Tr. at 255-56.) Dr. Martin testified that:
> Q: Sir, how would a person of ordinary skill in the art in 1988 understand [footnote 13]?
> A: That sentence would to me mean that the trimethylsilyl group was unstable to the esterification conditions, and I would infer that the term "subsequent esterification conditions" referred to those described in the article.
> The word "unstable," I think to one of ordinary skill, would suggest that it comes off to some degree during the stated esterification conditions. It doesn't indicate how unstable. It leaves that open. There is no way of knowing exactly how unstable it was, but certainly some of it would have come off during those conditions.
> (Martin, Tr. at 324-25 (objection omitted.)

Mr. Pilard received a degree in chemical engineering from the Higher School of Science at Lyonnes in 1961, and a doctorate in (chemical) engineering from the University of Paris in 1964, and was employed as a chemical engineer at RPR from 1961 through 1978, and, after receiving one year of legal training in patent law at the Strasbourg International Center, Institute for Industrial Property, he acted as a patent agent at RPR from 1978 through his early retirement in August, 1996. (Pilard, PX 177 at tab 1, pp. 6-8, 14-15, 24.) Accordingly, Mr. Pilard would have known that a POSA would read the statements in the JACS article either to apply to TMS and MOM at any yield or, at the very least, to be unclear. As a person familiar with U.S. patent law and the duty of disclosure, Mr. Pilard would have known that he had an obligation to disclose this material to the U.S. Patent & Trademark Office.[FN22] *Brasseler,* 267 F.3d at 1386 ("Moreover, we have repeatedly warned practitioners that in close cases, where the materiality of the information is uncertain, disclosure is required"); *U.S. Ind., Inc. v. Norton Co.,* 210 U.S.P.Q. 94, 107 (N.D.N.Y.1980) ("In short, the question of relevancy in close cases, should be left to the examiner and not the applicant").

> FN22. At the very least, Mr. Pilard should

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have inquired of a U.S. patent attorney whether the JACS should be produced.

***15** In light of Mr. Pilard's floundering testimony and inconsistent explanations of his reasons why the patent application and the JACS article are not inconsistent; the consistencies between statements made by the inventors in the JACS article and in the Modes Operatoires; and the expert testimony that a POSA would not have interpreted footnotes 13 and 16 of the JACS article to mean that the use of TMS or MOM as protecting groups would produce taxol, Mr. Pilard's suggestion that he disregarded the JACS article because it applied only to efficient syntheses of taxol is best characterized as a post-litigation fabrication for the benefit of his long-time employer.FN23

FN23. Moreover, if Mr. Pilard had thought that, based on the title of the JACS article, the article applied only to efficient synthesis, he should have sought to confirm his belief with the inventors. However, Mr. Pilard could not recall ever having asked the inventors whether the statements in the JACS article were limited to efficient syntheses of taxol:
Q: And prior to today, have you had any discussions with anyone concerning the significance of the title with respect to its use of the word "efficient"?
A: I don't recall.

Q: Well, sir, did you ask the inventors whether the statement in the JACS article that the MOM group could not be removed was merely a science statement and not a patent statement?
A: I don't remember.
(Pilard, PX 177 at tab 1, p. 105; tab 3 at 79-80.)

(3) The Inventors Did Not Continue To Experiment With MOM

Mr. Pilard's third reason for not submitting the JACS article was that, with regard to footnote 16, "[i]t is possible that the inventors continued to work on this topic and that they obtained some results." (Pilard, PX 177 at tab 3, p. 76.) Not only does this answer fail to explain the statements in the Modes Operatoires, but it is an implicit admission that the JACS article's statements were inconsistent with the patent application (see subsection (4) below). Moreover, RPR did not produce any evidence that the inventors did further tests involving MOM and Mr. Pilard could not recall receiving any further information regarding MOM:
Q: As you're sitting here today, sir, are you aware of any such results? Namely, results in which 2'-MOM was successfully removed to yield taxol?
A: I cannot answer.
Q: Are you aware of any notes or comments you wrote on any other papers concerning the inventors telling you that they had successful results with 2'-MOM?
Mr. Roux: Object to the form of the question. Object to the form of the question. I object to the form of the question. You may answer if you can.
A: I don't remember.
Q: And do you recall as you sit here today any conversations with any of the inventors in which they told you they had successful results with 2'-MOM?
A: I don't remember.

(Pilard, PX 177, tab 1 at 76-77.)

(4) The Adverse Nature of the JACS Article's Statements

On one occasion, Mr. Pilard testified that he did not consider the JACS article's statements to be adverse to the patent application but this testimony does not constitute grounds for withholding the JACS article from the U.S. Patent & Trademark Office. (Pilard, PX 177 at tab 1, pp. 103-05) Mr. Pilard testified that footnote 13 was not adverse because "[i]t doesn't say that the esterification didn't occur." (Pilard, PX 177 at tab 1, p. 106.) FN24 Mr. Pilard testified that footnote 16 is not adverse because "[n]othing, nothing that says that elimination is total or partial." (Pilard, PX 177 at tab 1, p. 109.) Though footnotes 13 and 16 fail to state that the process did not work at all, the plain meaning of their words are that MOM could not be removed after esterification and TMS was unstable during esterification. Thus, Mr. Pilard's testimony relies on 'non-statements' in the footnotes for which

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he had no support based on other evidence. As a person who had been advised about the U.S. duty of disclosure, Mr. Pilard had to know that he was obligated to inform the U.S. patent office of the JACS article's footnotes in view of its inconsistencies with the patent application. *Brasseler*, 267 F.3d at 1386; *U.S. Ind., Inc. v. Norton Co.*, 210 U.S.P.Q. at 107.

> FN24. Mr. Pilard gave the same answer when confronted with the inventors' statement from the Modes Operatoires that TMS "proved too fragile in the esterifying reaction with the protected side chain." (Pilard, PX 177 at tab 1, pp. 86-87.)

***16** Mr. Pilard could not provide any basis for his belief that the esterification reaction would occur even though TMS was unstable:
Q: Sir, can you give me whatever information you have supporting your belief that the esterification continued notwithstanding that the trimethylsilyl group was unstable, any information whatsoever?
Mr. Roux: Object to the form of the question. The question has been answered now twice. If you have anything new to add, please do so.
A: I have nothing to add.

(Pilard, PX 177 at tab 1, p. 108.) FN25

> FN25. Having been advised of the U.S. duty of disclosure, Mr. Pilard also must have known that he had a duty to ask the inventors about the meaning of footnotes 13 and 16. As stated in the Manual of Patent Examining Procedures regulations applicable in 1989:
> Case law supports that there exists a duty of reasonable inquiry .... Certainly, "the duty of reasonable inquiry" such as represented by the above cited cases is an integral part of and included in the duty of disclosure. For instance, if an applicant or applicant's attorney is aware of facts which indicate a reasonable possibility that a bar to patenting or information material to examination may exist, they are expected to make reasonable inquiries to ascertain such information and submit such to the Office.
> MPEP § 2001.02 (1986), Tab 2; *see also Brasseler*, 267 F.3d at 1383 ("Once an attorney, or an applicant, has notice that information exists that appears material and questionable, that person cannot ignore that notice in an effort to avoid his or her duty to disclose"). Neither Mr. Pilard nor the inventors could recall any conversation regarding the meaning of footnotes 13 and 16. (Pilard, PX 177 at tab 3, pp. 77, 79-80, 88; Denis, Tr. at 46, 48; Gueritte-Voegelein, Tr. at 108; Greene, Tr. at 165.)

Mr. Pilard also could not give any basis for stating that MOM was a more preferred hydroxy-protecting group in the patent application:
Q: Let me just ask you, sir, how do you square [footnote 16] with a patent application which states that the methoxymethyl protecting group is one of an especially, more especially preferred group?
Mr. Roux: Object to the form of the question. Object to the form of the question. Mischaracterized the patent's language and that question has been answered already. It's also irrelevant. But the witness may answer, if he can.
A: I can't go any further than that.

(Pilard, PX 177 at tab 1, pp. 110-11.)

In addition, Mr. Pilard's subsequent correspondence with Mr. Calvetti indicates that he knew that footnotes 13 and 16 were adverse. (PX 139.) Contained in his draft patent application for the protected intermediates, Mr. Pilard wrote:
Particularly, when taxol has to be prepared from 10-deacetylbaccatine III, it is necessary to protect only hyroxyl [sic] function at the C-7, in order to acetylate selectively the C-10 without acetylating the C-13. *The protecting group at C-7 has to be stable under the acetylating conditions and to the subsequent esterifying conditions. Furthermore, the elimination of the protecting groups has to be made under conditions which do not conduct to an epimerisation at the C-13 or at the C-2':* it is important that the protecting group at the C-7 to do not be cleavable under basic conditions. *Even if protecting groups are known, it is difficult to select*

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an appropriate protecting group without undue experimentation.

(PX 139 (emphasis added).) Mr. Pilard's knowledge that "the protecting group at C-7 has to be stable ... to the subsequent esterifying conditions" can not be reconciled with his position that the statement, TMS "proved unstable to the subsequent esterification conditions," was not adverse. Similarly, his statement that "the elimination of the protecting groups has to be made under conditions which do not conduct to an epimerisation at the C-2" ' can not be reconciled with his position that the statement, "[a] methoxymethyl protecting group at C-2' could not be removed following esterification," was not adverse. Accordingly, the Court finds Mr. Pilard's testimony that he did not consider footnotes 13 and 16 of the JACS article to be adverse was intentionally misleading.

(5) Mr. Pilard Committed Inequitable Conduct

***17** Mr. Pilard intentionally drew the '011 patent more broadly than warranted by the information in his possession; he was aware of the JACS article at the time he provided Mr. Mosher with materials for filing the '011 patent; he was aware of the U.S. duty of disclosure; and none of his attempted justifications for not disclosing the JACS article are grounds for not supplying the JACS article to the examiner nor were they credible [FN26]. The only conclusion that can be drawn is, and the Court finds by clear and convincing evidence that, Mr. Pilard intentionally withheld the JACS article from Mr. Mosher and the U.S. Patent and Trademark Office in an attempt to mislead the patent examiner.

FN26. The Court also notes that it found Mr. Pilard to be lacking in credibility for the following reasons:
Mr. Pilard was prepared for three days prior to his initial deposition. (Pilard, PX 177 at tab 1, pp. 34-35.) In light of that preparation, his answers at that deposition were less than candid. (Pilard, PX 177 at tab 1, pp. 30-68.) Only a few examples of his supposed lack of memory are cited below:
Q: Do you recall any of the circumstances concerning your first involvement with patent matters concerning taxol?
A: I don't recall.
Q: Can you describe what you do recall concerning your involvement with patent matters relating to taxol?
Mr. Roux: At this point, I just caution the witness, he may answer generally, but he should be cautious not to disclose any privileged communications, including discussions with U.S. or foreign patent attorneys.
A: I don't recall.
(PX 177 at 40.)
Q: What was the substance or the subject of the patent application?
A: I don't recall.
(PX 177 at 41.)
Q: Do you recall that this patent application concerns a convergent synthesis of taxol in which the side chain is reacted with the taxane core?
A: As you show it to me now, I could say yes, but if I hadn't seen the document, I couldn't say.
(PX 177 at 52-53.)
Q: Well, sir, isn't it an essential point of patent law that you don't tell patent offices that something works when it doesn't?
Mr. Roux: Object to the form of the question; that's a different question. Are you speaking of French law?
Mr. Beck: Let him answer.
Mr. Roux: The witness can answer. If the witness can answer, he may.
A: I don't know.
(PX 177 at 57-58.)
In his second deposition by RPR, his recollection improved somewhat but was marked by extraordinarily long delays in responding to questions. These long delays in answering were not indicative of a lack of recollection but rather indicative of searching to find a response which would not be damaging to the positions taken by his employer. Mr. Pilard had been thoroughly prepared for several days before

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> the deposition so the long delays on answers to questions which would obviously be asked at the deposition are not otherwise explicable.
> Mr. Pilard did not appear to testify at the hearing. His excuse was he had to take care of his wife. However, the consulting fee that he was offered could have been arranged to cover the cost of care during the seventy two hours or less Pilard might have had to be absent. The clear inference is that Mr. Pilard's absence was due to the risk of giving further inconsistent testimony.

C. Mr. Pilard's Inequitable Conduct During The Prosecution of the '011 Patent Application Was Not Cured During The Prosecution of the '277 Reissue Application

Mr. Pilard's failure to disclose the JACS article during the prosecution of the '011 patent was not cured by his subsequent disclosure of the JACS article late in the prosecution of the '277 patent. To the contrary, Mr. Pilard's actions during the prosecution of the '277 patent exacerbated his original misconduct. In his initial fax/letter to Mr. Calvetti dated June 11, 1991, Mr. Pilard enclosed the JACS article with footnote 16 circled. (PX 61, Calvetti, Tr. at 470.) Mr. Pilard did not send his letter with the JACS article to Mr. Mosher, the attorney who was familiar with the '011 patent, but rather chose to proceed through another law firm lacking such familiarity with the prosecution of the '011 patent.[FN27] (Pilard, PX 177 at tab 1, p. 40.) Mr. Pilard testified that he could not recall why footnote 16 was circled in the copy of the JACS article provided to Mr. Calvetti:

> FN27. RPR's instructions to Mr. Mosher, during his deposition, not to answer whether he would have disclosed the JACS article if he had had it in his possession in 1989, were in violation of Rule 30(d)(1) of the Federal Rules of Civil Procedure. (Opinion and Order dated January 6, 1998.) This violation effectively denied Bristol of Mr. Mosher's answer because he subsequently became unable to testify. Although unnecessary to the conclusions drawn in this opinion, in view of RPR's violation of Rule 30(d)(1), the inference is drawn that Mr. Mosher would have testified he would have submitted the JACS article to the examiner if it had been in his possession.

Q: And if you look at the JACS article, you note that footnote 16 is circled?
A: Yes.
Q: Do you know who circled that and why?
A: I have no-I don't know.

(PX 177 at tab 4, p. 167.)[FN28] Mr. Pilard's awareness of the significance of the JACS article at the time of preparation of the '277 reissue patent application is evidenced not only by footnote 16 having been circled but also by his remarks on patentability enclosed with his July 25, 1991 letter to Mr. Calvetti where he stated that "it is difficult to select an appropriate protecting group without undue experimentation," "the protecting group at C-7 has to be stable ... to the subsequent esterifying conditions," and that "the elimination of the protecting groups has to be made under conditions which do not lead to an epimerization at the C-13 or C-2" 'positions. (PX 139.) Not only are these statements consistent with the statements in the JACS article about TMS, MOM and the inventors' difficulties in finding the appropriate hydroxy-protecting groups, which Mr. Pilard chose to disregard, but they demonstrate that claims I's definitions of R_2 and R_3 as "a hydroxy-protecting group" were overbroad.[FN29] (PX 139, PX 21, PX 4.)

> FN28. Although Mr. Pilard did not ask for an opinion concerning the JACS article in his fax/letter of June 11, 1991, Mr. Calvetti opined in his letter of June 13, 1991 that the JACS article would not affect the reissue application because it was published less than one year prior to the filing of the '011 patent. (DX 54.)
>
> FN29. In fact, Mr. Pilard had already withdrawn that claim from the counterpart patent application in the European Patent Office for those reasons. (PX 142.)

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***18** Nonetheless, on or around July 17, 1992, Mr. Pilard specifically instructed Mr. Calvetti that persons at RPR had evaluated the JACS article and determined it to be irrelevant. (DX 160) No disclosure was made at that time. (DX 83) The JACS article was finally disclosed, pursuant to Mr. Pilard's instructions (Pilard, PX 177 at tab 2, p. 157), in an information disclosure statement that was stamped as received by the U.S. Patent Office on January 14, 1993, and only reviewed by the examiner after he had informed Mr. Calvetti that the patent would issue.FN30 (DX 83 at 72-73.) In the information disclosure, the JACS article was listed as one of six articles disclosed. (DX 83 at 72-73.) Mr. Pilard did not advise Mr. Calvetti of the significance of the JACS article (Calvetti, Tr. at 508-09), and Mr. Calvetti, in turn, did not notify the patent examiner of the JACS article's significance.FN31 (Calvetti, Tr. at 518.) Mr. Pilard testified that he could not recall why he had decided to submit the JACS article to the U.S. Patent & Trademark Office at that time. (Pilard, PX 177 at tab 2, p. 159.)

> FN30. Patent file letters from Mr. Calvetti pre-dating and post-dating January 14, 1993 bear the same stamp date. (DX 83 at 157, 177-91.)
>
> FN31. Mr. Calvetti's unfamiliarity with his correspondence with Mr. Pilard was troubling to the Court. (Calvetti, Tr. at 464-522, 528-29 .) He had been made aware he would be called as a witness for two weeks in a case involving a claim that he participated in inequitable conduct. (Calvetti, Tr. at 490-91, 523.) Full familiarity with the documents would be expected of an attorney.

Under *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571-72 (Fed.Cir.1983), a patent applicant who is aware of misrepresentation in the prosecution of his or her application and desires to overcome it must (1) advise the Patent Office of the existence of the misrepresentation and state specifically wherein the misrepresentation resides; (2) make the Patent Office aware of what the actual facts are and make clear that further examination in light thereof may be required; and (3) establish patentability of the claimed subject matter on the basis of the new and factually accurate record. Mr. Calvetti's mere listing of the JACS as one of six disclosed articles in a December, 1992 information disclosure statement and provision of a clean copy of the JACS article is insufficient under *Rohm & Haas Co.* to cure Mr. Pilard's inequitable conduct in the prosecution of the '011 patent application.

D. Conclusion

The Court finds by clear and convincing evidence that Mr. Pilard intended to draw the patent claims of the '011 and '277 patent more broadly than warranted by the scientific evidence; that Mr. Pilard failed to disclose the JACS article in order to hide the adverse statements in the JACS article from the '011 patent examiner; and that, although he was clearly aware of the significance of the JACS article, he did not advise Mr. Calvetti of that significance so the patent examiner would not become aware of its adverse statements during the prosecution of the '277 reissue patent.FN32 Consequently, the Court concludes that there is clear and convincing evidence that Mr. Pilard failed to disclose the JACS article with intent to mislead the patent office in connection with the '011 patent application and the '277 reissue patent application. In view of the ex parte nature of the patent prosecutions and Mr. Pilard's awareness of the duty of disclosure, Mr. Pilard's actions in intentionally withholding the JACS article from the U.S. Patent & Trademark Office are found to be a fraudulent action in furtherance of an effort to obtain the '011 patent. The Court further concludes that, combined with its previous determinations that the JACS article was material and not submitted to the patent office during the prosecution of the '011 patent, RPR has committed inequitable conduct in the prosecution of the '011 patent and the '277 patent. The Court therefore decrees that the asserted claims of the '277 reissue patent are invalid, void and unenforceable and may not be asserted in this matter or any other, including cases numbered 96-CV-2346 and 98-CV-0356 which are pending in this Court. Plaintiff shall serve a notice of entry of judgment on five days notice to the Defendants.

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FN32. The Court rejects RPR's contention that Mr. Pilard's approval of the JACS article for publication belies any notion that Mr. Pilard intended to mislead the U.S. Patent & Trademark Office. Publishing the JACS article is not equivalent to disclosing the JACS article to the patent office.

***19** IT IS SO ORDERED.

S.D.N.Y.,2002.
Bristol-Meyers Squibb Company v. Rhone-Poulenc Rorer, Inc.
Not Reported in F.Supp.2d, 2002 WL 59429 (S.D.N.Y.)

END OF DOCUMENT

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Case 2

Westlaw.
--- F.Supp.2d ----
--- F.Supp.2d ----, 2007 WL 1470453 (D.Del.)
(Cite as: --- F.Supp.2d ----)

Merck & Co., Inc. v. Apotex, Inc.
D.Del.,2007.
Only the Westlaw citation is currently available.
United States District Court,D. Delaware.
MERCK & CO., INC., Plaintiff,
v.
APOTEX, INC., Defendant.
C.A. No. 06-230(GMS).

May 21, 2007.

Background: Pioneer drug company brought patent infringement action against generic competitor. Competitor counterclaimed for declaratory judgment of invalidity and noninfringement. Pioneer drug company moved to dismiss complaint, and generic manufacturer moved to amend its answer.

Holdings: The District Court, Sleet, J., held that:

(1) court lacked jurisdiction over counterclaim, and

(2) pioneer drug company's alleged manipulation of Drug Price Competition and Patent Term Restoration Act did not violate federal antitrust laws.

Pioneer drug company's motion granted.

[1] Declaratory Judgment 118A 0

118A Declaratory Judgment
Declaratory Judgment Act requires actual controversy between parties before federal court may exercise jurisdiction over action for declaratory judgment. 28 U.S.C.A. § 2201.

[2] Declaratory Judgment 118A 0

118A Declaratory Judgment
Actual controversy requirement in declaratory judgment action is met when facts alleged, under all circumstances, show that there is substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant issue of declaratory judgment. U.S.C.A. Const. Art. 3, § 2, cl. 1; 28 U.S.C.A. § 2201.

[3] Declaratory Judgment 118A 0

118A Declaratory Judgment
District court lacked subject matter jurisdiction over generic drug manufacturer's counterclaim against pioneer drug company for declaratory judgment of patent invalidity and noninfringement, despite generic manufacturer's contentions that dismissal would operate to deny it right to compete with pioneer drug company for want of triggering event under Drug Price Competition and Patent Term Restoration Act, and would injure it by delaying its entry into market, where pioneer drug company presented generic manufacturer with comprehensive covenant not to sue and then voluntarily dismissed its patent infringement suit, and there was no evidence that generic manufacturer's delayed entry into market was any different than what it would have been had pioneer drug company never sued it. Federal Food, Drug, and Cosmetic Act, § 505(j)(5), 21 U.S.C.A. § 355(j)(5).

[4] Antitrust and Trade Regulation 29T 0

29T Antitrust and Trade Regulation
When determining whether party has standing to bring private action under antitrust laws, courts should consider: (1) causal connection between antitrust violation and harm to plaintiff and intent by defendant to cause that harm, with neither factor alone conferring standing; (2) whether plaintiff's alleged injury is of type for which antitrust laws were intended to provide redress; (3) directness of injury, which addresses concerns that liberal application of standing principles might produce speculative claims; (4) existence of more direct victims of alleged antitrust violations; and (5) potential for duplicative recovery or complex apportionment of damages.

[5] Antitrust and Trade Regulation 29T 0

29T Antitrust and Trade Regulation
Pioneer drug company's alleged manipulation of Drug Price Competition and Patent Term Restoration Act by filing patent infringement action against generic drug manufacturer after it filed abbreviated

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new drug application (ANDA) and then voluntarily dismissing suit after offering comprehensive covenant not to sue did not violate federal antitrust laws, even though pioneer drug company's actions placed generic manufacturer at competitive disadvantage, where pioneer drug company's actions were expressly sanctioned by Act or contemplated by its legislative history, and consequences to generic manufacturer were specific products of Act. Federal Food, Drug, and Cosmetic Act, § 505(j)(5), 21 U.S.C.A. § 355(j)(5).

[6] Antitrust and Trade Regulation 29T ⚿0

29T Antitrust and Trade Regulation
When patentees attempt to extend their legal monopoly beyond that which is permitted by their statutory grants, such actions can trigger antitrust liability.

[7] Antitrust and Trade Regulation 29T ⚿0

29T Antitrust and Trade Regulation
Any adverse effects within scope of patent or statutory right to exclude cannot be redressed by antitrust law.

Mary B. Graham, Esquire, and James W. Parrett, Jr., Esquire, of Morris, Nichols, Arsht & Tunnell LLP, Wilmington, Delaware, and John DeQ. Briggs, Esquire, John F. Lynch, Esquire, Kenneth W. Donnelly, Esquire, Aaron Myers, Esquire, of Howrey LLP, Washington, D.C., and Nicholas G. Barzoukas, Esquire, Suzy S. Harbison, Esquire, Jason C. Abair, Esquire, of Weil, Gotshal & Manges, Houston, Texas, and Paul D. Matukaitis, Edward W. Murray, Gerard M. Devlin, of Merck & Co., Inc. Attorneys for Plaintiff.
Richard L. Horwitz, Esquire, and Kenneth L. Dorsney, Esquire, of Potter Anderson & Corroon, LLP, Wilmington, Delaware, and A. Sidney Katz, Esquire, Robert B. Breisblatt, Esquire, Louise T. Walsh, Esquire, Michael Krol, Esquire, of Welsh & Katz, Ltd., Chicago, Illinois. Attorneys for Defendant.

OPINION

SLEET, District Judge.

I. INTRODUCTION

*1 The plaintiff Merck & Co., Inc. ("Merck") filed suit against the defendant Apotex, Inc. ("Apotex") in the above-captioned matter, alleging that Apotex committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Merck moves to dismiss its complaint for lack of subject matter jurisdiction because, since filing suit, it has given Apotex a comprehensive covenant not to sue, which removed the controversy between the parties. For the reasons that follow, Merck's motion is granted.

II. SUMMARY OF STATUTORY FRAMEWORK

The provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") govern the generic drug approval process.[FN1] The Food and Drug Administration ("FDA" or "Agency"), provides the following summary explanation of the Act's statutory provisions, at http://www.fda.gov/cder/about/smallbiz/generic-exclusivity.htm, which the court incorporates in pertinent part:

The Hatch-Waxman Amendments are intended to balance two important public policy goals. First, drug manufacturers need meaningful market protection incentives to encourage the development of valuable new drugs. Second, once the statutory patent protection and marketing exclusivity for these new drugs has expired, the public benefits from the rapid availability of lower priced generic versions of the innovator drug.

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic ("FD & C") Act and created section 505(j). Section 505(j) established the abbreviated new drug application ("ANDA") approval process, which permits generic versions of previously approved innovator drugs to be approved without submission of a full new drug application ("NDA"). An ANDA refers to a previously approved new drug application (the "listed drug") and relies upon the Agency's finding of safety and effectiveness for that drug product. The timing of an ANDA approval depends in part on patent protections for the

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innovator drug. Innovator drug applicants must include in an NDA information about patents for the drug product that is the subject of the NDA. The FDA publishes patent information on approved drug products in the Agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." The FD & C Act requires that an ANDA contain a certification for each patent listed in the Orange Book for the innovator drug. This certification must state one of the following: (i) that the required patent information relating to such patent has not been filed; (ii) that such patent has expired; (iii) that the patent will expire on a particular date; or (iv) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.

A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved on the patent expiration date. A paragraph IV certification begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent. The ANDA applicant who files a paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent, and therefore, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA sponsor or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt of notice, the FDA may not give final approval to the ANDA for at least 30 months from the date of the notice. This 30-month stay will apply unless the court reaches a decision earlier in the patent infringement case, or otherwise orders a longer or shorter period for the stay.

***2** The statute provides an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a paragraph IV certification and running the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first. These two events-first commercial marketing and a court decision favorable to the generic-are often called "triggering" events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days. But 180-day exclusivity can begin to run, with a court decision, even before an applicant has received approval for its ANDA. In that case, some, or all, of the 180-day period could expire without the ANDA applicant marketing its generic drug. Conversely, if there is no court decision and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period. Approval of an ANDA has no effect on exclusivity, except if the sponsor begins to market the approved generic drug. Until an eligible ANDA applicant's 180-day exclusivity period has expired, the FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the sponsors are willing to immediately begin marketing. Therefore, an ANDA applicant who is eligible for exclusivity is often in the position to delay all generic competition for the innovator product.

III. BACKGROUND

Merck is the owner of nine patents listed in the Orange Book for the drug alendronate sodium, which Merck markets and sells under the trademark Fosamax.[FN2] On February 24, 2006, Apotex sent

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Merck a letter informing Merck that Apotex filed ANDA No. 077-982, seeking approval from the FDA to market a generic version of Merck's Fosomax tablets. Apotex certified in its ANDA submission that certain Merck patents were invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's generic version. Apotex was not the first generic filer to challenge Merck's patents on the Fosamax drug.

In the absence of any further information than what Apotex provided in its February 2006 letter, on April 7, 2006, Merck filed this action to protect its rights under the Hatch-Waxman Act. Apotex counterclaimed for a declaratory judgment of invalidity and noninfringement of the nine patents at issue. In August 2006, after receiving more detailed information from Apotex regarding its generic version of Fosamax, Merck granted Apotex a comprehensive covenant not to sue.

IV. LEGAL STANDARD

***3** [1][2] The exercise of judicial power under Article III of the United States Constitution requires the existence of a case or controversy. The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996). The actual controversy requirement is met when, "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issue of a declaratory judgment." *Id.* (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 213 U.S. 270, 273 (1941)). When an actual controversy does exist sufficient to warrant subject matter jurisdiction, however, "the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp.*, 89 F.3d at 810.

V. DISCUSSION

Merck argues that, as a result of its covenant not to sue Apotex on the asserted patents, this action is moot and the court lacks subject matter jurisdiction over the purported controversy. Conversely, Apotex asks that the court deny Merck's motion for the following reasons: (1) a dismissal without a finding of invalidity and/or noninfringement would operate to deny Apotex "its right to compete with Merck for want of a 'triggering event' " and that Apotex would be injured by delayed entry into the market; (2) the court should not sanction Merck's "manipulating the court's jurisdiction" by filing a patent infringement suit, later presenting a covenant not to sue, and then attempting to dismiss Apotex's counterclaims for lack of subject matter jurisdiction; and (3) the court has subject matter jurisdiction because this case satisfies the Supreme Court's test for determining an actual case or controversy. (D.I. 19 at 2.)

Existence of an Actual Case or Controversy

In *Teva v. Novartis,* the Court of Appeals for the Federal Circuit ("Federal Circuit") acknowledged that the Supreme Court, in *MedImmune v. Genentech,* --- U.S. ----, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007), disagreed with the Federal Circuit's "reasonable apprehension of suit" test, and refocused the declaratory judgment jurisprudence on earlier Supreme Court precedent. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed.Cir.2007). Thus, "the question in each case is whether 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 v. Genentech,* 127 S.Ct. at 771 (citing *Md. Cas. Co.*, 312 U.S. at 273). In support of its argument that an actual case or controversy exists in this case, Apotex points to the Federal Circuit's observation in *Teva v. Novartis:*

***4** A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV

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certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

482 F.3d at 1344. The court agrees with the Federal Circuit's observation about what ***establishes*** a justiciable declaratory judgment controversy in the Hatch-Waxman context. Further, the court recognizes that, when filed, this case also presented a justiciable controversy. A significant distinction between the scenario in *Teva v. Novartis* and the case here is that Novartis had declined to give Teva a covenant not to sue. Here, after the case was filed, and Merck received further information upon which it could evaluate the infringement action, Merck presented Apotex with a comprehensive covenant not to sue. The actual controversy must be in existence at all stages of the litigation and cannot merely be present at the filing of the complaint. *Super Sack v. Chase,* 57 F.3d 1054, 1058 (Fed.Cir.1995).

[3] Article III standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright,* 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984). Here, having received a covenant not to sue, Apotex does not and cannot allege "*unlawful* conduct" attributable to Merck in connection with its declaratory judgment claim. Further, Apotex's articulated injury-delayed entry to the market-is not fairly traceable to Merck. There is no evidence to conclude that Apotex's delayed entry into the market is any different than what it would have been had Merck never sued it. Thus, Apotex's advancement of this case against Merck becomes merely a means to an end, where the desired "end" is a triggering event but the means to that end, the litigation itself, is not sanctioned under the current legal framework. To proceed to a substantive "court decision" on the merits of Apotex's claims of noninfringement or invalidity would amount to an impermissible advisory opinion. *See Preiser v. Newkirk,* 422 U.S. 395, 401, 95 S.Ct. 2330, 45 L.Ed.2d 272 (1975) (holding that courts may not render advisory opinions or decide questions that do not affect the rights of the parties to the case).

Merck's covenant not to sue removes any cause for concern that Apotex could be held liable for infringement of the patents in suit. *See Super Sack,* 57 F.3d at 1059. Moreover, " '[i]t is well-established that a trial court may be divested or deprived of subject matter jurisdiction over a particular patent claim if the patentee covenants not to assert an infringement claim against a putative infringer.' " *Crossbow Tech., Inc. v. YH Tech., Inc.,* No. C 03-04360, 2007 WL 174422, at *2 (N.D.Cal. Jan.22, 2007) (quoting *Eli Lilly & Co. v. Zenith Goldline Pharms.,* 101 F.Supp.2d 1139, 1142 (S.D.Ind.2000)). Federal Rule of Civil Procedure 12(h)(3) states "*[w]henever* it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter, the court shall dismiss the action." Accordingly, the court must dismiss this action for lack of subject matter jurisdiction.[FN3]

Manipulation of Court Jurisdiction

***5** Notwithstanding the body of law that mandates dismissal, the court is sensitive to Apotex's argument that Merck is manipulating the court's jurisdiction. Indeed, the court must guard its jurisdiction jealously. Apotex highlights an interesting yet troublesome practice that has emerged from the interplay of the Hatch-Waxman regulatory scheme, covenants not to sue, subject-matter jurisdiction, and the typical time cycle of a patent litigation. This lawsuit exposes the ability of pioneer drug companies to potentially hold generics at bay by suing them, as they are authorized to do when a paragraph IV certification is made in an ANDA, and then granting a covenant not to sue, which divests the court of subject-matter jurisdiction. In this way, district courts can be viewed as unwitting agents in a pioneer drug company's ability to defer competition for as long as possible. As unfortunate as it may be for Apotex, this is the framework that the Hatch-Waxman Act created.[FN4] The legislative history suggests that, in fact, Congress contemplated the use of covenants not to sue as a means of resolving any controversy created by the filing of an ANDA:

The provision [a "civil action to obtain patent certainty"] ... is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution.

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We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. ***We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.***

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee) (emphasis added)).

ANDA litigation reaches the federal courts through specialized legislation enacted by Congress, perhaps without the prescience of the maze it would be creating, and the ingenuity of motivated business persons and lawyers to capitalize on its imperfections. These cases represent the intersecting roles of all three branches of government and the pharmaceutical industry: the court's interest in interpreting the existing law so that it can provide justice and equity to injured parties; congressional interest in making laws that will encourage research and development, as well as to speed entry of generic drugs into the market; a regulatory agency's interest in advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and the pharmaceutical industry's interest in protecting its bottom line. This court is without the power, however, to ameliorate the problems that have emerged from this interplay.

***6** Apotex argues that the Federal Circuit, in *Teva v. Novartis,* recognized that a patentee's actions of only suing on one of its patents frustrated the central purpose behind Hatch-Waxman, and that this court should similarly recognize the gamesmanship behind suing, covenanting not to sue, and moving to dismiss without a decision on the merits. In finding a justiciable controversy in *Teva v. Novartis,* however, the Federal Circuit found frustration of the Hatch-Waxman Act's purpose to be just one of numerous circumstances, in the "totality of circumstances" analysis, that warranted a finding of an actual controversy. 482 F.3d at 1344. Moreover, in the past, both innovator and generic companies have been accused of "gaming" the Hatch-Waxman regulatory regime to their respective benefit.[FN5] Congress responded through legislation. *See* 149 Cong. Rec. S15882-03, S15885 (Nov. 25, 2003) ("[I]n recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the [ ] Act ... will stop these abuses.") (remarks of Sen. Kennedy, ranking member of the Senate HELP committee regarding the 'civil action to obtain patent certainty' provision under 21 U.S.C. § 355(j)(5)(C)). Likewise, if it is the view of Congress that pharmaceutical companies are abusing the Act in the way that Apotex complains here, Congress can reform the Hatch-Waxman Amendments as it deems necessary.

Right to Competition-Antitrust Claim

Apotex's argument that a dismissal without a finding of invalidity or noninfringement would operate to deny Apotex "its right to compete with Merck for want of a 'triggering event' ' coincides with its proposed antitrust counterclaim presented in its motion to amend. As such, the court will address this argument and Apotex's motion together.

Recognizing that motions to amend shall be granted freely under Federal Rule of Civil Procedure 15(a), the court has discretion to deny leave to amend when there is undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile. *See Foman v. Davis,* 371 U.S. 178, 182, 83 S.Ct. 227, 9 L.Ed.2d 222 (1962); *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1434 (3d Cir.1997). In assessing futility, the court applies the same standard of legal sufficiency as applies under Rule 12(b)(6). *Id.* Thus, the court looks to whether Apotex's antitrust claim, if allowed, would survive a motion to dismiss.

[4] The Supreme Court has outlined the factors that

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courts should consider when determining whether a party has standing to bring a private action under the antitrust laws: (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 (3d Cir.1998) (citing *Associated Gen. Contractors of California v. California State Council of Carpenters,* 459 U.S. 519, 537-45, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983)).

*7 Apotex argues, both in its opposition to Merck's motion to dismiss and in Apotex's motion to amend, that if the court grants Merck's motion to dismiss, the 30-month stay on Apotex's ANDA application will not be terminated, the 180-day exclusivity period will not be triggered, and Apotex, as well as the other secondary generic applicants, will be prevented from entering the generic market until 180 days after the first generic applicant enters the market. With these consequences in mind, Apotex asserts that Merck's actions of filing suit, covenanting not to sue, and moving to dismiss for lack of subject matter jurisdiction, are an unlawfully anticompetitive and monopolistic scheme to delay entry by Apotex and other generic filers into the market for generic alendronate sodium.

One material aspect of this discussion is whether the FDA's 30-month stay on Apotex's ANDA will terminate upon the court's dismissal of the action. The 30-month stay was introduced to give the generic applicant and NDA holder the opportunity to resolve patent issues prior to commercial marketing. Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf, at 39. 21 U.S.C. § 355(j)(5)(B)(iii)(2003) provides:
If such an action is brought before the expiration of [45 days after the date that the paragraph IV notice is received], the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that-
(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on-
(aa) the date on which the court enters judgment reflecting the decision; or
(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

Merck argues that the parenthetical clause of § 355(j)(5)(B)(iii)(I), "(including any substantive determination that there is no cause of action for patent infringement or invalidity)," instructs that a dismissal for lack of subject matter jurisdiction would lift the 30-month stay on an ANDA. Apotex contends that the FDA has not yet construed the provision, and that the FDA's construction of similar, previously disputed language suggests that nothing less than a court decision of invalidity, noninfringement or unenforceability would affect the stay.[FN6] Neither the parties nor the court can be certain of how the provision will be applied to Apotex. Moreover, the matters pending before the court do not mandate this court's interpretation of the statute. It is noteworthy, however, that the FDA considered a precise answer, by way of a proposed rule, but later withdrew it without comment. The FDA's proposed rule § 314.107(g) provided in pertinent part:
*8 *Effect of dismissal of litigation on 30-month stay.* If the patent litigation between the ANDA applicant and the patent owner or NDA holder described in paragraph (b)(3)(A) of this section is dismissed without a court decision on the merits of the patent claim, whether the dismissal is with or without prejudice, the agency may immediately approve the

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ANDA that was the subject of the litigation, if it is otherwise eligible for approval.

180-Day Generic Exclusivity for Abbreviated New Drug Applications, 64 Fed.Reg. 42873, 42886 (1999) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999), withdrawal of proposed rule reflected in 67 Fed.Reg. 66593 (2002).

Certainly, if the mere filing of a patent infringement suit can result in an irrevocable 30-month stay on an ANDA application, except in the limited circumstances of a "substantive decision" on the merits or other narrower circumstances where a court may shorten the stay, then Apotex has a legitimate concern about how such a policy is susceptible to abuse by pioneer drug companies. Ultimately, however, the court cannot remedy every harm or prejudice a party endures. Moreover, not every business disadvantage is appropriately deemed legal injury. The fiercely competitive pharmaceutical industry does not escape these realities. The existing law does not provide an absolute right of a generic drug company to enter the market in which a pioneer drug company and a first-filing generic applicant have legally achieved some market exclusivity.

[5] The court understands that Apotex is at a competitive disadvantage, but as to the harm it claims to have endured, and the relief it seeks, the court's hands are tied. In *Teva v. Pfizer,* the Federal Circuit stated:

The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer.

395 F.3d 1324, 1338 (Fed.Cir.2005), *abrogated by MedImmune v. Genentech,* --- U.S. ----, 127 S.Ct. 764, 166 L.Ed.2d 604 (2007). Notwithstanding the Supreme Court's abrogation of the Federal Circuit's reasonable apprehension test, the Federal Circuit's analysis of the distinction between a business disadvantage and an Article III controversy applies with equal force to Apotex's opposition to Merck's motion to dismiss, as well as its motion to add an antitrust counterclaim on the same grounds.

Apotex attempts to distinguish its case from *Teva v. Pfizer* by emphasizing that, unlike Pfizer, Merck chose to sue Apotex, knowing there was no infringement, and then covenanted not to sue. The court will not engage in fact finding as to the disputed accounts of what Merck knew about the merits of an infringement claim against Apotex at the time it filed suit, and whether and under what circumstances, Merck attempted to glean further information before filing suit. The court does not need to resolve these issues because the mere filing of a paragraph IV certification in an ANDA constitutes infringement. *See* 35 U.S.C. § 271(e)(2)(A). Accordingly, Apotex's filing of its ANDA on Merck's Fosamax drug was an act of infringement that afforded Merck the right to sue. The statutory provisions that allow suit under these circumstances render the patentee's subjective motivations for filing suit irrelevant.[FN7]

***9** [6] Intellectual property law and principles foster the creation of market power and antitrust law and principles respond to market power abuses, however, both systems operate to advance consumer welfare by allocating resources, cultivating innovation, and promoting technological progress. *See, e.g.,* Lawrence A. Sullivan & Warren S. Grimes, *The Law of Antitrust: An Integrated Handbook,* (West Group 2000), §§ 15.1 at 800-801. A patent "is an exception to the general rule against monopolies and to the right to access to a free and open market." *See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.,* 324 U.S. 806, 816, 65 S.Ct. 993, 89 L.Ed. 1381 (1945). Thus, "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present." *Schering-Plough v. Federal Trade Comm'n,* 402 F.3d 1056, 1065-1066 (11th Cir.2005). When patentees attempt to extend their legal monopoly beyond that which is permitted by their statutory grants, such actions can trigger antitrust

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liability. *Andrx Pharms., Inc. v. Biovail Corp. Intern.*, 256 F.3d 799, 813 (D.C.Cir.2001) ("[E]ven a patent-right holder is not immune from antitrust liability.").

[7] Any adverse effects within the scope of a patent or statutory right to exclude, however, cannot be redressed by antitrust law. *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C.Cir.1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent *and is otherwise legal.*") (emphasis added). The existing body of case law involving antitrust allegations in the context of ANDA litigation tends to fall within two categories: cases in which the parties bilaterally entered into a collusive agreement that exceeded the scope of a patent grant, thus warranting antitrust scrutiny,[FN8] and cases in which the patentee was considered to have lawfully enforced its patent right, albeit with the consequence of delaying or inhibiting competition. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir.2003) and *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir.2003) (involving agreements among innovator and generic drug companies that incurred antitrust liability).

The futility of Apotex's proposed amendment is further demonstrated by previously unsuccessful efforts to attach antitrust liability to pharmaceutical companies acting within the Hatch-Waxman regulatory framework and patent grant. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514, 524 (E.D.N.Y.2005) (holding that conduct within the scope of the patent grant is exempt from antitrust scrutiny); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir.2006) (affirming district court decision, which held that the claimed injury was not "antitrust injury," which must be caused by something other than the regulatory action limiting entry to the market); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F.Supp.2d 21, 23-25 (D.Mass.2000) (dismissing an antitrust counterclaim of second ANDA filer against pioneer drug company because the counterclaimant failed to show antitrust injury where the statutory scheme, and not the pioneer drug company, prevented it from entering the market).

***10** Thus, Merck's challenged conduct-filing suit upon notice of Apotex's paragraph IV certification and covenanting not to sue-are expressly sanctioned by the Hatch-Waxman Amendments or contemplated by its legislative history. Likewise, the consequences to Apotex-delayed entry in the market for alendronate sodium tablets-are specific products of the statute. Having failed to establish antitrust injury and causal connection between Merck's legal actions and Apotex's alleged harm, which are necessary requirements for antitrust standing, the court considers Apotex's requested amendment to be futile.

VI. CONCLUSION

Accordingly, Merck's motion to dismiss (D.I.15) is granted as Apotex has failed to establish the existence of an actual case or controversy under the current state of the law. The Clerk of the Court shall mark this action closed and all other pending motions are denied.

ORDER

IT IS HEREBY ORDERED that:

1. Merck's motion to dismiss for lack of subject matter jurisdiction (D.I.15) is GRANTED.

2. Apotex's motion for leave to file a surreply (D.I.26) is DENIED.

3. Apotex's motion for leave to file its first amended answer, affirmative defenses, and counterclaims (D.I.28) is DENIED.

4. Apotex's motion for leave to substitute corrected exhibits to its pending motion for leave (D.I.36) is DENIED as moot.

5. Merck's motion to stay (D.I.68) is DENIED as moot.

6. All claims in Merck's Complaint (D.I.1) are DISMISSED.

7. All counterclaims in Apotex's Answer, Affirmative Defenses, and Counterclaims (D.I.8) are DISMISSED.

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8. Each party shall bear its own costs and attorneys' fees.

FN1. The Hatch-Waxman Amendments were modified by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pub.L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat.2066 (amended 2003). Herein, all references to the Hatch-Waxman Amendments and its regulatory framework include the scope of the provisions as later modified.

FN2. The patents listed in Merck's NDA, which are the patents-in-suit, are U.S. Patent Nos. 5,358,941; 5,681,590; 5,849,726; 6,008,207; 6,090,410; 6,194,004; 5,994,329; 6,015,801; and 6,225,294.

FN3. Apotex also contends that the collateral consequences doctrine permits the court to retain jurisdiction. The court has considered the parties' arguments and finds Apotex's position to be without merit.

FN4. The court is also troubled by the practical realities of a scheme, which in effect, if left as is, enmeshes the district courts in unnecessary, and in this court's opinion, improper involvement in business competition. This cycle not only contributes to court congestion but it wastes the court's valuable time and limited resources by conducting the business it must for these cases, until it reaches the merits of such contested motions to dismiss. The time-triggered provisions of the statute unrealistically presuppose the time in which the district courts are to manage their cases. While the court endeavors to be efficient and expeditious in resolving the matters pending before it, time proscriptions such as those that Congress has assumed in the Hatch-Waxman provisions, and those upon which the litigants press the court, are idealistic at best and unfeasible in practice. The joint effort of the branches of government to balance the interests of consumers with those of innovator and generic drug companies should not be so tunnel-visioned as to facilitate litigants in their attempts to catapult ANDA litigation as a priority in the district courts.

FN5. The Federal Trade Commission issued studies in 2002 and 2003 that examined and commented on the conduct of drug companies in the generic drug approval process. Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

FN6. *See Apotex, Inc. v. FDA,* 449 F.3d 1249 (D.D.C.2006) (upholding FDA's decision finding that dismissal for lack of subject matter jurisdiction did not qualify as a "court decision" sufficient to trigger the 180-day exclusivity period).

FN7. The court is by no means discharging the requirements of Rule 11 in the context of Hatch Waxman litigation. In this case, however, there are no alleged facts from which the court can conclude that, in fact, Merck knew that Apotex's generic version of Fosamax did not infringe Merck's patents at the time it filed suit pursuant to its statutory right to do so upon Apotex's paragraph IV certification. Although the Rule 12(b)(6) standard requires the court to accept all well-pleaded allegations as true, and to view them in the light most favorable to plaintiff, the court will not credit bald and conclusory allegations. *See United States v. Vespe,* 868 F.2d 1328, 1340 (3d Cir.1989) (stating conclusory statements need not be credited).

FN8. "It is widely understood that the

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> 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a 'non-entry' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely." Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes,* 87 Minn. L.Rev. 1719, 1755 (2003).

D.Del.,2007.
Merck & Co., Inc. v. Apotex, Inc.
--- F.Supp.2d ----, 2007 WL 1470453 (D.Del.)

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Case 3

Prasco, LLC v. Medicis Parrmaceutical Corp.
S.D.Ohio,2007.
Only the Westlaw citation is currently available.
United States District Court,S.D. Ohio,Western Division.
PRASCO, LLC, Plaintiff,
v.
MEDICIS PHARMACEUTICAL CORP., et al., Defendants.
No. 1:06CV313.

March 27, 2007.

John David Luken, Joshua Allen Lorentz, Dinsmore & Shohl, Cincinnati, OH, Amy Denise Brody, Deanne M. Mazzochi, William Andrew Rakoczy, Rakoczy, Molino, Mazzochi, Siwik, Chicago, IL, for Plaintiff.
Kenneth Franklin Seibel, Jacobs, Kleinman, Seibel & McNally, Cincinnati, OH, Barry J. Coyne, Reed Smith LLP, Pittsburgh, PA, for Defendants.

ORDER

MICHAEL R. BARRETT, Judge.

***1** This matter is before the Court upon Defendants Medicis Pharmaceutical Corporation ("Medicis") and Imaginative Research Associates, Inc.'s ("Imaginative") Motion to Dismiss and Motion to Dismiss the Amended Complaint. (Docs.15, 19) Also before the Court is Plaintiff Prasco's Response in Opposition to Defendants' Motion to Dismiss the Amended Complaint, and Defendants' Reply thereto. (Doc. 20, 21) In addition, the Parties have provided supplemental briefing on the application of the United States Supreme Court's recent decision in *MedImmune, Inc. v. Genetech, Inc., et al,* 127 S.Ct. 764 (January 9, 2007). (Docs.25, 28, 31)

I. *FACTUAL AND PROCEDURAL BACKGROUND*

Defendant Medicis manufactures and markets the product TRIAZ. This product has four patents associated with it: U.S. Patent Nos. 5,254,334 ('334); 5,409,706 ('706); 5,632,996 ('996); and 5,648,389 ('389). Medicis is the assignee for the 389 patent and is the licensee for the 334, 706, and 996 patents. Defendant Imaginative is the assignee for the 334, 706, and 996 patents, and licenses these patents to Medicis.[FN1] TRIAZ is an acne cleanser containing benzoyl peroxide in the concentrations 3%, 6%, and 9%. Medicis commercially markets TRIAZ as being covered by the patents-in-suit, and labels the packaging and labeling with these patent numbers.

FN1. The parties dispute whether Medicis, as licensee, would have the right to enforce the three Imaginative patents. Based on the Court's analysis, *infra,* the Court finds it unnecessary to reach this issue.

On May 5, 2006, Prasco filed its Complaint for declaratory judgment, seeking a declaration that its product OSCION has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the patents-in-suit. OSCION is a generic acne cleanser also containing benzoyl peroxide in the concentrations 3%, 6%, and 9%. OSCION is designed as a fully substitutable generic alternative to TRIAZ and intended to compete directly with it. Prior to the filing of the declaratory action, Prasco had not begun to market OSCION, and Defendants had no knowledge of Prasco's product. (Doc. 15, Ex. 1, Brandon Hokenstad Decl. ¶ 3; Doc. 15, Ex. 2, Mohan Vishnupad Decl. ¶¶ 4-5)

On July 25, 2006, Defendants filed their Motion to Dismiss Prasco's Complaint. (Doc. 15). Prasco did not respond to this motion, but instead filed an Amended Complaint on August 18, 2006. (Doc. 17) The Amended Complaint states that on June 14, 2006, Prasco commercially launched OSCION. (Doc. 17 ¶ 29). Prasco alleges that on July 28, 2006, it provided Medicis and Imaginative with a sample of OSCION, its related labeling, and an ingredient list. (Id.¶ 31) Prasco also alleges that on July 28, 2006 it requested from Medicis and Imaginative a covenant not to sue relating to the 334, 706, 996, and 389 patents; but Medicis and Imaginative have refused this request. (*Id.* ¶¶ 35-38)

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On September 9, 2006, Defendants filed their Motion to Dismiss the Amended Complaint. (Doc. 19) This matter is now ripe for review.

II. *ANALYSIS*

A. *Motion to Dismiss Standard*

Defendants bring their motions to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1). Defendants assert there is no "actual case or controversy" and therefore this court lacks subject matter jurisdiction.

***2** The Sixth Circuit has distinguished between facial and factual attacks among motions to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1). *Pritchard v. Dent Wizard Intern. Corp.*, 210 F.R.D. 591, 592 (S.D.Ohio 2002). A facial attack on the subject matter jurisdiction alleged by the complaint merely questions the sufficiency of the pleading. *Ohio Nat. Life Ins. Co. v. U.S.*, 922 F.2d 320, 325 (6th Cir.1990). Defendants are bringing a factual attack. A factual attack is "not a challenge to the sufficiency of the pleading's allegations, but a challenge to the factual existence of subject matter jurisdiction." *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir.1994). Therefore, this Court must "weigh the conflicting evidence to arrive at the factual predicate that subject matter jurisdiction exists or does not exist." 922 F.3d at 325. The Court may allow affidavits, documents and even a limited evidentiary hearing to resolve disputed jurisdictional facts. *Id.*

B. *The Reasonable Apprehension of Suit Test*

The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction ... any court of the United States ... may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The Supreme Court has explained that under the Act:

> The controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy admitting 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.

Aetna Life Ins. Co v. Haworth, 300 U.S. 227, 240-41 (1937) (citations omitted). However, the Supreme Court has not precisely defined what type of controversies satisfy this standard. *See MedImmune*, 127 S.Ct. at 771 ("Aetna and the cases following it do not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not.")

The Federal Circuit, in determining when a "case" or "controversy" exists in a patent declaratory judgment action, developed the "reasonable apprehension of suit" test:

> There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed.Cir.1993).

In *MedImmune*, the Supreme Court stated that the Federal Circuit's "reasonable apprehension of suit" test contradicts earlier Supreme Court precedent. 127 S.Ct. at 774, n. 11. However, the Court only held that the "reasonable apprehension of suit" test is not the appropriate test to determine subject matter jurisdiction for a declaratory action in the context of a patent licensee paying royalties under protest. *Id.* The Court's decision may call into doubt the use of the "reasonable apprehension of suit" test, but it did not overrule the line of cases that rely upon the "reasonable apprehension of suit" test outside of this factual scenario.[FN2] Therefore, Federal Circuit precedent establishing the "reasonable apprehension of suit" test as the determinative test when evaluating subject matter jurisdiction for a declaratory judgment involving potential infringement, remains binding upon this Court. *Accord BridgeLux, Inc. v. Cree, Inc*, No. 06-6495, 2007 WL 521237, at *2 (N.D.Cal. Feb. 15, 2007) (slip op.); *WS Packaging Group, Inc. v. Global Commerce Group, LLC*, No. 06-674, 2007 WL 205559, at *3 (E.D.Wisc. Jan. 24, 2007) (slip

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op.); *but see Rite-Hite Corp. v. Delta T Corp .*, 2007 WL 725327, *8 (E.D.Wisc. March 7, 2007) (slip op.) ("[t]he Supreme Court has called into serious question the continued viability of the Federal Circuit's 'reasonable apprehension of suit' test in patent declaratory judgment actions. In light of such fact, this court is reluctant to employ that test in ruling on the defendants' motions to dismiss. Indeed, to do so would be to ignore the Supreme Court's clear signal that such test has a limited future life expectancy."); *Highway Equipment Company, Inc. v. Cives Corp .*, 2007 WL 689766, *2 (N.D.Iowa March 7, 2007) (slip op.) (explaining that in *MedImmune,* the Supreme Court abrogated the reasonable-apprehension test).

FN2. The Federal Circuit Court of Appeals has not yet addressed the effect that the Supreme Court's decision in *MedImmune* has had upon the reasonable-apprehension test.

C. *Factual Basis for Jurisdiction*

***3** Defendants argue that Prasco must rely upon the facts that existed at the time it filed its original Complaint in order to support subject matter jurisdiction. The Court disagrees.

Federal Rule of Civil Procedure 15(a) provides that "[a] party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served."

Accordingly, Prasco's amendments were "as a matter of course" because Defendants have not yet served a responsive pleading.

In addition, Federal Rule of Civil Procedure 15(d) provides that a party may "serve a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." Rule 15(d) would permit a party to supplement his or her complaint in order to state a claim and avoid dismissal. *See* Fed.R.Civ.P. 15(d), Advisory Committee Notes (1963) (indicating that Rule 15(d) was intended to overcome "the rigid and formalistic view that where the original complaint fails to state a claim upon which relief can be granted, leave to serve a supplemental complaint must be denied"); *see also* 28 U.S.C. § 1653 ("Defective allegations of jurisdiction may be amended, upon terms, in the trial or appellate courts"). Other district courts have held that when a plaintiff files an amended complaint, the date of that second filing becomes the controlling date for determining subject matter jurisdiction. *Pharmachemie B.V. v. Pharmacia S.p.A.,* 934 F.Supp. 484, 489 (D.Mass.1996), *citing Millipore Corp. v. University Patents,* Inc., 682 F.Supp. 227, 233 (D.Del.1987); *Northern Telecom Inc. v. Wang Laboratories, Inc.,* 543 F.Supp. 1026, 1028 (D.Mass.1982). Therefore, the Court will determine subject matter jurisdiction based on the facts alleged in the Amended Complaint.

D. *Subject Matter Jurisdiction*

A party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy. *Cardinal Chemical Co. v. Morton Intern., Inc.,* 508 U.S. 83, 95 (1993), *citing Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227, 240-241 (1937).

At issue is whether Prasco satisfies the first prong of the reasonable apprehension of suit test.[FN3] "Although the best evidence of a reasonable apprehension of suit comes in the form of an express threat of litigation, an express threat is not required." *Vanguard Research, Inc. v. Peat, Inc.,* 304 F.3d 1249, 1254 (Fed.Cir.2002). There has been no allegation of an express threat of litigation by Defendants. Where a defendant's conduct, including its statements, falls short of an express charge, one must consider the "totality of the circumstances" in determining whether that conduct meets the first prong of the test. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.,* 846 F.2d 731, 736 (Fed.Cir.1988).

FN3. There appears to be no dispute that Prasco meets the second prong.

Prasco contends that the following facts, when viewed in their totality, create a reasonable apprehension of an infringement suit by Defendant Imaginative: (1) Imaginative has sought patent protection for its 334, 706, and 996 patents, and

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licenses these patents to Medicis; and (2) Imaginative has refused to provide Prasco with a covenant not to sue related to these patents.

***4** Owning and licensing a patent alone or in combination does not constitute conduct creating a "reasonable apprehension of suit." More is required for an actual controversy than the existence of an adversely held patent. *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed.Cir.2004).

Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, this factor is not dispositive. *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed.Cir.1993). Plaintiff has not cited case law which would support a finding of a "reasonable apprehension of suit" based solely on the refusal to sign a covenant not to sue. Based on the foregoing, the Court concludes that Prasco has not alleged conduct sufficient to objectively establish a "reasonable apprehension of suit" by Defendant Imaginative.

In regards to Defendant Medicis, Prasco contends that the following facts, when viewed in their totality, create a reasonable apprehension of an infringement suit: (1) Medicis has sought patent protection for its 389 patent and is the licensee of Imaginative's 334, 706, and 996 patents; (2) Medicis marks its acne cleanser product as being "covered" by the patents-in-suit; (3) Medicis has previously sued Prasco for patent infringement; (4) Medicis has made statements indicating a willingness to aggressively pursue patent rights; and (5) Medicis has refused to provide Prasco with a covenant not to sue related to these patents.

The Court is not persuaded that these facts establish a "reasonable apprehension of suit" by Defendant Medicis. First, as explained above, owning and licensing a patent alone does not constitute conduct creating a "reasonable apprehension of suit."

Second, the fact that Medicis has marked its product as being "covered" by the patents-in-suit has no bearing on the issue at hand. The patent marking statute, 35 U.S.C.A. § 287(a) requires that a patentee must provide notice to a potential infringer before damages for infringement will accrue. The fact that Medicis may at some undetermined point in time choose to file an infringement suit against an unspecified potential infringer does not lead to a "reasonable apprehension of suit" by Prasco. *See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed.Cir.2005) (holding that the listing of patent FDA's Orange Book, without more, should not be construed as blanket threat to potential infringers).

Third, even when viewed in combination with the above, Medicis' history of litigation is not sufficient to create a reasonable apprehension of suit. On October 27, 2005 Medicis filed a complaint against Prasco and another generic company in federal court in Arizona seeking a declaration that Prasco's product PRASCION infringed another of Medicis' patents. (Doc. 17, ¶ 40) During the litigation Medicis stated that it would continue to "vigorously pursue" the issue "through additional legal avenues." (Id.) Prasco has alluded to other prior litigious conduct by Medicis, but with no specificity. (Doc. 20, at 11).

***5** In cases where courts have found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, *see, e.g., Arrowhead,* 846 F .2d at 733, 737; *Ivoclar Vivadent, Inc. v. Hasel,* No. 02-CV-0316E(F), 2003 WL 21730520, at *5 (W.D.N.Y. June 30, 2003) (unpublished), or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology, *see, e.g., Goodyear,* 824 F.2d at 955.

Here, there is no evidence that Medicis ever referenced the litigation in its communications with Prasco; and Prasco has not alleged that the Arizona litigation involved the same technology as the patents-in-suit in this action. While Prasco has grouped both products into a category of Medicis' "core products," Prasco has not identified any relationship between the patents. Defendants state that the patent in the Arizona litigation recites a different pharmacological agent than the patents at issue here. (Wortzman Decl. ¶¶ 10-13; Vishnupad Decl. ¶¶ 9-11) In addition, the Court notes that Medicis' statements to the effect that it would

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continue to "vigorously pursue" the issue "through additional legal avenues" was within the context of responding to the denial of a preliminary injunction, and was not in reference to enforcement of the patents which are the subject of this litigation. Therefore, this statement is distinguishable from cases which have held that statements evidencing an intent to enforce patents create "reasonable apprehension." *See, e.g., Plumtree Software, Inc. v. Datamize, LLC,* 473 F.3d 1152, 1158 (Fed.Cri.2006); *Mobil Oil Corp. v. Advanced Environmental Recycling Technologies, Inc.,* 1996 WL 325081, *2 (Fed.Cir.1996) (unpublished).

Finally, Prasco asks the Court to consider Medicis' refusal to concede noninfringement or grant a covenant not to sue relating to these patents. As explained above, a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination, but is not dispositive. The Court finds that the present situation is different from that in *Kos Pharms., Inc. v. Barr Labs., Inc.,* 242 F.Supp.2d 311 (S.D.N.Y.), a case cited by Prasco. In *Kos,* the court found that the failure to provide a covenant not to sue properly added grounds to support a reasonable apprehension of suit. *Id.* at 317. The court explained that other pending litigation between the parties involved patents that were very similar to the patents involved in the declaratory action, which demonstrated that the risk of future litigation was real. *Id.; see also Teva Pharms. USA, Inc. v. Pfizer, Inc.,* 395 F.3d 1324, 1333-34 (Fed.Cir.2005) (defendant's refusal to give covenant not to sue, combined with history of asserting patent rights against other alleged infringers, did not create reasonable apprehension of suit). The Court concludes that based on the facts alleged, Defendants' refusal to provide a covenant-not-to-sue or conceded noninfringement is not dispositive.

***6** When considering the "totality of the circumstances," Prasco has not alleged conduct sufficient to objectively establish a "reasonable apprehension of suit" by Defendants.[FN4] Therefore, Defendants Medicis Pharmaceutical Corporation and Imaginative Research Associates, Inc.'s Motion to Dismiss the Amended Complaint (Docs.19) is **GRANTED;** and Defendants' Motion to Dismiss (Doc. 15) is **DENIED as MOOT.** This matter shall be **CLOSED and STRICKEN** from the docket of this Court.

FN4. The Court finds that even if the reasonable apprehension of suit test is no longer good law after the Supreme Court's decision in *MedImmune,* there is no actual case or controversy present based upon the facts in the record. In *MedImmune,* the Supreme Court explained that their earlier decisions in declaratory judgment actions had required that:
the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what that law would be upon a hypothetical state of facts." ... "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."
Medimmune, 127 S.Ct. at 771 (citations omitted); *see also Rite-Hite,* 2007 W L 725327 at *8. Applying these principles, the Court finds that there is no definite and concrete dispute that touches the legal relations of these parties. Medicis has not stated that its patents have been infringed; and before this litigation commenced, Defendants were not aware of Prasco's product. In addition, Medicis' refusal to provide a covenant-not-to-sue or concede non-infringement is not the type of "substantial controversy" upon which to base this Court's jurisdiction.

IT IS SO ORDERED.

S.D.Ohio,2007.
Prasco, LLC v. Medicis Parrmaceutical Corp.
Slip Copy, 2007 WL 928669 (S.D.Ohio)

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2007, a true copy of the foregoing was hand delivered to the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and the document is available for viewing and downloading from CM/ECF:

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