UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	Civil Action No. 07-811-JJF-LPS
Plaintiffs,	**REDACTED VERSION DI 23**
v.	
COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES INC.,	
Defendants.	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COUNT II OF THE COMPLAINT OR TERMINATE THE AUTOMATIC STAY OF APPROVAL

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Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") oppose the motion of Cobalt Pharmaceuticals Inc. ("Cobalt Pharma") and Cobalt Laboratories Inc. ("Cobalt Labs") (collectively "Cobalt") to dismiss Count II of the complaint or terminate the automatic 30-month stay of approval for reasons set forth below.

I. THE NATURE AND STAGE OF THE PROCEEDING

This is an action for infringement of U.S. Reissue Patent RE37,314 ("the '314 patent") under 35 U.S.C. § 271(e)(2)(A) and for a declaratory judgment under 35 U.S.C. § 271(a) based on threatened infringement. The action results from Cobalt filing Abbreviated New Drug Application (ANDA) No. 79-167 with the US Food and Drug Administration ("FDA") to market generic versions of AstraZeneca's highly successful drug CRESTOR®, before the '314 patent expires.

Cobalt is one of seven generic pharmaceutical companies to challenge the '314 patent by seeking FDA approval to sell generic CRESTOR® before the patent's expiration date. In an effort to resolve the multiple challenges to its patent rights, AstraZeneca filed seven related patent infringement actions in the District of Delaware on December 11, 2007 (C.A. Nos. 07-805, 07-806, 07-807, 07-808, 07-809, 07-810, and 07-811). AstraZeneca's action against Cobalt Pharma and Cobalt Labs in Delaware is Civil Action No. 07-811.

II. SUMMARY OF ARGUMENT

Declaratory judgment jurisdiction is proper over Cobalt's anticipated acts of infringement under 35 U.S.C. § 271(a), because the parties' controversy is sufficiently immediate and real to present an actual controversy, and the Court should exercise its discretion to hear the matter for reasons of policy and judicial economy. Moreover, Cobalt has itself invoked the Court's declaratory judgment jurisdiction in counterclaims, alleging invalidity of the '314 patent.

Cobalt's insistence that the Court cannot exercise declaratory judgment jurisdiction over AstraZeneca's Count II is, therefore, at odds with its own pleadings and the case law.

III. STATEMENT OF FACTS

This case relates to AstraZeneca's CRESTOR® pharmaceutical product, and Cobalt's efforts to sell a generic version of CRESTOR® before the pioneer patent on the active ingredient, rosuvastatin calcium, expires. The discovery of rosuvastatin calcium resulted in one of the most potent cholesterol-lowering drugs now available. Over 11 million patients have been treated with CRESTOR® in the United States, and over 110 million prescriptions have been written worldwide. (D.I. 1 at ¶ 9.)

On October 29, 2007, Cobalt Pharma notified AstraZeneca of its ANDA and intentions "to obtain approval to engage in the commercial manufacture, use or sale of rosuvastatin calcium" before the '314 patent expires, alleging that the '314 patent is invalid. (Ex. 1 at 2.) Cobalt's ANDA relies on the years of clinical testing conducted by AstraZeneca to demonstrate the safety and efficacy of its proposed generic version of CRESTOR®, without the need to duplicate that testing. *See, e.g.*, 21 C.F.R. §§ 314.94 and 320.21. Cobalt Pharma, the Canadian parent, will make that generic product, and Cobalt Labs, the U.S. subsidiary, will sell it in the United States.

IV. ARGUMENT

A. Count II Should Not Be Dismissed

In this action, Cobalt moved to dismiss Count II, alleging that there is no subject matter jurisdiction to decide infringement of the '314 patent under 35 U.S.C. § 271(a). There is no question that jurisdiction over patent matters rests with federal courts. *See* 28 U.S.C. § 1338(a). The question raised, then, is whether Count II presents a case of actual controversy under the Declaratory Judgment Act. *See* 28 U.S.C. § 2201(a); *MedImmune, Inc. v. Genentech, Inc.*, 127

S. Ct. 764, 771 (2007) ("[T]he phrase 'case of actual controversy' in the [Declaratory Judgment] Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III.")

1. Recent Controlling Authority Confirms Declaratory Judgment Jurisdiction

The "actual controversy" needed to sustain declaratory judgment jurisdiction arises from Article III of the Constitution, and requires that "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, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). In *MedImmune*, the Supreme Court rejected the Federal Circuit's "reasonable apprehension of suit" test for declaratory relief, finding that the test contradicts or conflicts with four prior Supreme Court decisions. *Id.* at 774 n.11; *recognized by SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1379 (Fed. Cir. 2007) and *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007). Post-*MedImmune*, the Federal Circuit has acknowledged that the boundaries of declaratory judgment jurisdiction are expanded, stating "where a patentee asserts rights under a patent based on certain identified ongoing or *planned activity* of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise . . . ." *SanDisk*, 480 F.3d at 1381 (emphasis added).

Under the expanded *MedImmune* standards, there is a justiciable controversy over Count II: Cobalt notified both the FDA and AstraZeneca that it intends to sell generic rosuvastatin calcium without license before the '314 patent expires, and AstraZeneca has asserted its patent rights to prevent that activity.

2. Cobalt Has Itself Invoked the Courts' Declaratory Judgment Jurisdiction over the '314 Patent

Cobalt urges the Court to dismiss Count II, alleging that the parties' dispute over the '314 patent is insufficiently real or immediate to exercise declaratory judgment jurisdiction. Simultaneously, however, Cobalt invokes the Court's declaratory judgment jurisdiction in counterclaims filed in this action, alleging that the same facts, involving the same ANDA, and the same patent, necessarily create an actual, justiciable controversy.[1] (D.I. 4 at ¶ 13.) Specifically, Cobalt alleges,

> There is an actual, substantial and continuing justiciable case and controversy between Defendants/Counterclaim-Plaintiffs and Plaintiffs/Counterclaim-Defendants regarding infringement, invalidity, and unenforceability of the '314 and '460 patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

Id. (Emphasis added.)

Accordingly, Cobalt's counterclaim acknowledges an actual controversy, regarding infringement of the '314 patent – the same controversy alleged by AstraZeneca. The Federal Circuit has instructed that "[i]t logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." *Teva*, 482 F.3d at 1342. Thus, if the courthouse doors are open to Cobalt, they are open to AstraZeneca as well.

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[1] Under § 271(e)(5), a generic drug company is authorized to file a declaratory judgment action on patents listed in the FDA's Orange Book that are not asserted within the 45-day period, following notice to the patent owner of the ANDA submission. AstraZeneca sued Cobalt on the '314 patent within the 45-day period. In filing its declaratory judgment counterclaim on the '314 patent, therefore, Cobalt has not invoked the Court's declaratory judgment jurisdiction under § 271(e)(5).

3. Activities that Might Be Protected from Infringement Under the § 271(e)(1) Safe-Harbor Provision Are Relevant to the Inquiry

Cobalt argues that "it is undisputed that Defendants' conduct to date falls squarely within the 'safe harbor' provisions of 35 U.S.C. § 271(e)(1)" and cannot create a case or controversy. (D.I. 15 at 2.) The Federal Circuit has already addressed this issue. In *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997), the Federal Circuit expressly ruled that the courts may exercise declaratory judgment jurisdiction even where the case or controversy is "premised in part on actions protected under § 271(e)(1)." *See also Amgen, Inc. v. F. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 276 (D. Mass. 2006) (safe harbor activities may establish an actual controversy). Significantly, the day before this brief was due, the Federal Circuit reaffirmed its decision in the *Glaxo* case, that conduct otherwise protected by the safe harbor may support the Court's exercise of declaratory judgment jurisdiction. *See Amgen, Inc. v. ITC*, No. 2007-1014, slip op. at 14 (Fed. Cir. March 19, 2008) (analyzing the jurisdiction of the International Trade Commission).[2]

Here, Cobalt misapplied the § 271(e)(1) safe harbor, because "the protected status of [defendant's] activities leading to its submissions to the FDA does not by itself prevent the district court from considering [plaintiff's] request for declaratory relief because such relief is directed to the time after the ANDA is approved, when § 271(e)(1) no longer provides a shelter against infringement liability." *Glaxo,* 110 F.3d at 1571. Though immune from liability, Cobalt's preparations to sell generic rosuvastatin calcium demonstrate, as in *Glaxo*, threatened

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[2] Although the underlying infringement allegations in *Glaxo* and *Amgen v. ITC* were based on § 271(g) (importing a product made overseas by a patented process), the analysis applies with equal force to § 271(a) infringement, because the § 271(e)(1) safe harbor applies to conduct within the scope of both statutes.

future infringement when the safe harbor will no longer apply and an actual, justiciable controversy.

4. The Controversy Is Real and Immediate

Cobalt contests Count II under Rule 12(b)(1) and therefore does not factually challenge the allegations of the Complaint. Thus, Cobalt must show that the controversy is not real and immediate, even assuming the truth of AstraZeneca's allegation that "Cobalt Pharma and Cobalt Labs intend to commence sale of Cobalt Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA." (D.I. 1 ¶29); *see Turicentro, S.A. v. American Airlines Inc.*, 303 F.3d 293, 300 n.4 (3d Cir. 2002) (When addressing a facial attack, the court must consider all the allegations of the complaint as true). Here, there is a real and immediate controversy.

a) Cobalt Plans to Enter the Market as Soon as Legally Possible

The immediacy of the threatened infringement is confirmed by the substantial preparations involved in preparing and filing an ANDA[3] and the significant market value of generic rosuvastatin calcium. Given these efforts and the money at stake, Cobalt is unlikely to abandon its plan to sell generic CRESTOR® before the '314 patent expires. In similar circumstances, the court in *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1009 (N.D. Ill. 2001) found:

> [T]he enormous amount of money at stake [] leads to the inescapable conclusion that defendant plans to enter the market as soon as possible . . . . To hold [there is no declaratory judgment jurisdiction], as defendant requests, would be to close one's eyes to the economic realities of the situation. [The product-at-issue's] sales last year alone amounted to $610,000,000 worldwide.

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[3] An ANDA requires, *at least*: (1) a product formulated for human consumption; (2) completion of manufacturing control testing; (3) human bioequivalency clinical trials; and (4) a generic product label complete with prescribing information, warnings, and precautions. 21 C.F.R. § 314.94(a)(1)-(13).

Id. at 1009 (citations omitted.) *See also Abbott Labs. v. Baxter Healthcare Corp.*, No. 04-C-836, 2004 WL 1878291, *6 (N.D. Ill. Aug. 16, 2004) ("[T]ime and cost involved in filing an ANDA indicate an intent to market [the generic product at issue]").

b) FDA Approval Is Not Required for Jurisdiction

According to Cobalt there is no immediate controversy, because FDA's approval of Cobalt's ANDA has neither occurred nor is imminent. (D.I. 15 at 4.) FDA approval, however, is not a prequisite to declaratory judgment jurisdiction. The filing of an ANDA itself can create an actual case or controversy. *See Glaxo v. Novopharm*, 110 F.3d at 1571; *Glaxo v. Apotex*, 130 F. Supp. 2d at 1008; *Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004); *see also Amgen*, No. 2007-1014, slip op. at 15. Cobalt's submission of its ANDA demonstrates an actual and immediate controversy, concerning Cobalt's significant, systematic, and deliberate actions to obtain FDA approval to sell a generic rosuvastatin calcium product.

c) The 30-Month Stay of Approval Does Not Negate Jurisdiction

Cobalt proposes a *per se* rule for ANDA cases that the 30-month stay of FDA approval precludes declaratory judgment jurisdiction.[4] However, the cases on which Cobalt relies to support that proposition were governed by Federal Circuit precedent decided before the Supreme Court's *MedImmune* ruling, which rejected the Federal Circuit's prior narrow construction of declaratory judgment jurisdiction. *See, e.g., Teva*, 482 F.3d at 1334 (reversing a district court

[4] Cobalt has argued that "Plaintiff could not present any specific factual allegations of 'immediacy,' because they knew that their assertion of infringement under § 271(e)(2) in Count I triggered a two and a half year stay of FDA approval under the Hatch-Waxman Act. *See* 21 U.S.C. § 355(j)(5)(B)(iii)." (D.I. 15 at 3.)

under the *MedImmune* standard, where the district court applied the reasonable apprehension of suit standard).

Cobalt cites *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925 (N.D. Ill. 1995), as ruling that a period even shorter than 30 months is not sufficiently immediate for declaratory judgment jurisdiction. In that case, unlike here, there was a significant possibility that the specification for the accused product would change, diminishing the immediacy of the controversy until the final specification of the product was known. *Id.* at 937. The patent at issue in that case covered only certain crystal forms of the active ingredient. *Id.* at 927. Because the FDA permits alternative crystal forms of an active ingredient to be used interchangeably,[5] it was possible for the defendant in *Abbott* to avoid the patent by specifying a non-infringing crystal form.

Here, however, the '314 patent claims the underlying FDA-approved active ingredient in CRESTOR®, rosuvastatin calcium. There is no possibility of designing around or otherwise changing the active ingredient to avoid infringement. Cobalt must use rosuvastatin calcium in its product. This aspect of Cobalt's product will not change, and the controversy, therefore, is ripe for adjudication.

More recently, the same court that decided *Abbott* held that little more than filing an ANDA creates a sufficient controversy for declaratory judgment jurisdiction in circumstances similar to this one. *See Glaxo v. Apotex,* 130 F. Supp. 2d at 1008-09. In that case, the court

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[5] *See* FDA "Guidance for Industry: ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information", available at http://www.fda.gov/CDER/guidance/7590fnl.pdf (visited Mar. 1, 2008) ("[D]ifferences in drug substance polymorphic forms do not render drug substances different active ingredients for the purposes of ANDA approvals within the meaning of the Act and FDA regulations.") (citing 57 FR 17958, Apr. 28, 1992).

exercised its declaratory judgment jurisdiction upon finding that the "defendant has filed and the FDA has accepted for filing the ANDA, which, as both parties recognize, means that the defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product." *Id.* at 1008.

Cobalt selectively quoted *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590, 2006 WL 2375035, at *3 n.3 (D. Del. Aug. 16, 2006), to suggest that "the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate." Cobalt, however, omitted the court's preceding sentence, which states, "The court agrees with the argument [patent holder] makes in its answering brief, namely that FDA approval is not the standard by which it should evaluate whether an actual controversy existed at the time the complaint was filed." *Id.*

In fact, the absence of FDA approval in that case was not the reason for the court's declining to exercise declaratory judgment jurisdiction. Instead, the controversy was not ripe, because the final specification of the likely product was not known when the case was filed. *Id.* The FDA submission at issue was not an ANDA, but a premarket approval application for a medical device with viable non-infringing design alternatives. *Id.* at *1. Unlike generic drugs which must use the approved active ingredient,[6] the court in *Abbott Diabetes Care* found that the "[patent holder] has not demonstrated that [defendant] produced or has prepared to produce a product that would be subject to an infringement charge under 35 U.S.C. § 271." *Id.* at *3. Significantly, the court further found that the "[patent holder] did not, and could not, allege with any certainty that 'the device when approved would be the same device that began clinical trials . . . .'" *Id.*

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6 *See* 21 C.F.R. § 314.94(a)(5).

In contrast, the active ingredient at issue in this case, rosuvastatin calcium, must be used in Cobalt's generic drug product. There is, therefore, a ripe and immediate controversy as to whether Cobalt's product infringes the '314 patent.

5. Exercising Jurisdiction over Count II Will Promote Judicial Economy and Is Consistent with the Purpose and Policy of the Hatch-Waxman Act

After finding a justiciable controversy, a court has discretion to exercise declaratory judgment jurisdiction if it "would settle the legal relations in dispute and afford relief from uncertainty or insecurity . . . ." *See SanDisk*, 480 F.3d at 1383 (citing *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993)).

a) Exercising Jurisdiction Will Not Undermine the Purpose and Policy of the Hatch-Waxman Act

Cobalt mistakenly claims that AstraZeneca's "Count II is an attempt to circumvent the protection from infringement suits afforded by the Hatch-Waxman Amendments *until after premarket approval by the FDA*." (D.I. 15 Brief at 6 (emphasis added).) There is no such protection for generic drug products. The safe harbor provided by § 271(e)(1) provides an immunity from suit for activities related to an ANDA submission to the FDA for drug approval. However, the Hatch-Waxman Amendments expressly contemplate that an ANDA applicant may be sued upon submitting an ANDA that certifies the applicant's intention to market the drug product before patent expiration. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). As a result, patent infringement litigation concerning generic drug products may commence well before "premarket approval by the FDA." *See, e.g., Glaxo v. Novopharm*, 110 F.3d at 1570 (future infringement under § 271(g)); *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331-32 (Fed. Cir. 2003) (induced infringement under § 271(e)(2)); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (induced infringement under § 271(b)).

The case upon which Cobalt principally relies, *Intermedics, Inc. v. Ventritex*, Inc., 775 F. Supp. 1269, 1277-78 (N.D. Cal. 1991), is distinguishable, because it involved an application to the FDA for approval of a medical device, for which the implications of the § 271(e)(1) safe harbor are quite different than for generic drug products. In that case, the patent owner asked the court to disregard the § 271(e)(1) safe harbor upon a showing that the accused infringer intended to market the medical device before patent expiration. *Id.* at 1273. The court declined to read an intent element into § 271(e)(1), noting the impracticality of ascertaining a company's intentions. *Id.* at 1274. As a result, the court ruled that "a case and controversy could arise only if either defendants [exceeded the scope of the safe harbor] or the FDA granted pre-market approval of the [medical device] and defendants began attempting to sell it in the general commercial market."[7] *Id.* at 1289.

The practical effect of § 271(e)(1) is, however, different for generic drug products. The FDA statute and regulations require an ANDA applicant to certify its intentions – whether it will market the generic drug product before patent expiration or wait until the patent expires. *Eli Lilly*, 496 U.S. at 677. If the applicant certifies its intention to market the product before patent expiration, the applicant loses its immunity from patent infringement suits. *See* 35 U.S.C § 271(e)(2). Thus, Cobalt wrongly asserts that § 271(e)(1) immunizes it from suit "until after premarket approval by the FDA," and the purposes and policies of the Hatch-Waxman Amendments are not undermined when ancillary claims of patent infringement under § 271(a) are brought in connection with related claims under § 271(e)(2).

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[7] Unlike the situation here, the court declined to exercise declaratory judgment jurisdiction because it found that "the FDA could require defendants to make changes in the [medical device] as a condition to approval. If so, the content of the dispute between these parties could change." *Intermedics*, 775 F. Supp. at 1290.

Indeed, prompt resolution of all disputes regarding infringement of the '314 patent and Cobalt's drug product is consistent with the purpose underlying both the declaratory judgment and Hatch-Waxman statutes. *See Teva*, 482 F.3d at 1344 ("the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes." (quoting Sen. Kennedy during debate of Medicare Modernization Act. 149 Cong. Rec. S15885 (Nov. 25, 2003))). Adjudicating AstraZeneca's declaratory judgment count for threatened infringement under § 271(a) at the same time as the infringement issues under § 271(e)(2) furthers this purpose and imposes no additional burdens on Cobalt.

Finally, Cobalt wrongly argues that *Abbott*, 934 F. Supp. 925, prevents this Court from exercising declaratory judgment jurisdiction over AstraZeneca's § 271(a) infringement. In *Abbott*, the court dismissed the patent owner's § 271(e)(2) count, because it had failed to properly list the underlying patent in the FDA's "Orange Book"—a prerequisite to a § 271(e)(2) action. *Id.* at 936. The court then dismissed the patent owner's claims under § 271(a) for threatened infringement explaining, "Because § 271(e)(2) cannot be invoked, the 'safe haven' provided by § 271(e)(1) remains in force until Defendant begins to market its [generic drug product]." *Id.* at 939.

Unlike the situation in *Abbott*, where "§ 271(e)(2) cannot be invoked," AstraZeneca has properly invoked § 271(e)(2), and the § 271(e)(1) immunity from suit is no longer in force. Accordingly, § 271(e)(1) does not preclude the court from exercising declaratory judgment jurisdiction to efficiently and simultaneously adjudicate both the § 271(e)(2) and § 271(a) counts, and resolve all patent infringement and validity issues between AstraZeneca and Cobalt in this litigation.

b) The Remedy Under Count I May Not Be Adequate

The exercise of jurisdiction under the Declaratory Judgment Act is appropriate "whether or not further relief is or could be sought." 28 U.S.C. § 2201; *Lang v. Pacific Marine and Supply Co., Ltd.*, 895 F.2d 761, 764 (Fed. Cir. 1990) ("[T]he fact that the patent owner, unlike the accused infringer, will have an express statutory remedy for infringement at a later time is irrelevant."). Nevertheless, Cobalt argues that the Court should decline to exercise declaratory judgment jurisdiction because no further relief is available for infringement under 35 U.S.C. § 271(a) beyond the relief available for § 271(e)(2) infringement. AstraZeneca disagrees.

The relief under § 271(e)(2) requested in Count I focuses primarily on the subject matter of Cobalt's ANDA. The relief under § 271(a) requested in Count II would prohibit all forms of infringement of the '314 patent, whether or not associated with this ANDA. It would prohibit active inducement of importation into the United States of unapproved rosuvastatin calcium from Canada or other countries where it may be marketed. It would also prohibit Cobalt from entering into an agreement to market rosuvastatin calcium which is the subject of some other entity's ANDA.

It is because such declaratory judgment counts are necessary in order to fully resolve the controversy between the parties that they are regularly included in ANDA complaints and routinely litigated without incident. *See, e.g., Forest Labs., Inc. v. IVAX Pharms., Inc.*, 438 F. Supp. 2d 479 (D. Del. 2006) (Complaint included claim for patent infringement due to ANDA filing under § 271(e) and future infringing acts under § 271(a)). Cobalt's motion to dismiss Count II should be denied so that the parties can proceed to completely resolve this dispute.

V. CONCLUSION

For the forgoing reasons, the Court should deny Cobalt's motion to dismiss Count II of the Complaint, and the Court should continue the stay of FDA approval of ANDA No. 79-167.

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I, hereby certify on this 27th day of March, 2008 I electronically filed the foregoing Redacted Version DI 23, PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COUNT II OF THE COMPLAINT OR TERMINATE THE AUTOMATIC STAY OF APPROVAL with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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The undersigned counsel further certifies that, on March 27, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

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EXHIBIT 1
FULLY REDACTED