NOT FOR PUBLICATION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMENDED OPINION
(Correcting Typographical Errors as Noted Below)

ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. APOTEX CORP., Defendant.	Doc. No. 13 Civil No. 10-338 (RBK/KW)
ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED, Defendant.	Doc. No. 13 Civil No. 10-339 (RBK/KW)

ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES INC., Defendants.	Doc. No. 11 Civil No. 10-340 (RBK/KW)
ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. GLENMARK GENERICS INC., USA, Defendant.	Doc. No. 19 Civil No. 10-341 (RBK/KW)
ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	Doc. No. 14 Civil No. 10-342 (RBK/KW)

ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. PAR PHARMACEUTICALS, INC., Defendant.	Doc. No. 13 Civil No. 10-343 (RBK/KW)
ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., Defendant.	Doc. No. 13 Civil No. 10-345 (RBK/KW)
ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Doc. No. 13 Civil No. 10-346 (RBK/KW)

ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC., Defendants.	Doc. No. 14 Civil No. 10-584 (RBK/KW)
ASTRAZENECA PHARMACEUTICALS LP, IPR PHARMACEUTICALS, INC., ASTRAZENECA AB, AND THE BRIGHAM AND WOMEN'S HOSPITAL, INC., Plaintiffs, v. SANDOZ INC., Defendant.	Civil No. 10-344 (RBK/KW)

KUGLER, United States District Judge:

These cases involve ten related patent infringement disputes under the Hatch-Waxman Act. Plaintiffs developed the drug rosuvastatin calcium, which they market as CRESTOR. They hold a patent claiming the chemical compound as well as two patents claiming methods of using the drug to treat certain cholesterol-related conditions. The United States Food and Drug Administration ("FDA") has approved rosuvastatin calcium for the uses claimed by Plaintiffs' two method-of-use patents as well as other non-patented uses. Defendants are generic drug manufacturers that filed Abbreviated New Drug Applications ("ANDA") with the FDA seeking

approval to manufacture and market rosuvastatin calcium for uses not claimed by Plaintiffs' two method-of-use patents but approved by the FDA. Plaintiffs sued Defendants under 35 U.S.C. § 271(e)(2), which makes the submission of an ANDA an act of patent infringement if the applicant seeks approval to market a drug claimed by another person's valid patent. All Defendants except Sandoz Inc. ("Sandoz") now move to dismiss the complaints for lack of subject-matter jurisdiction and failure to state a claim. The moving Defendants argue that Section 271(e)(2) creates a justiciable infringement claim only if a generic manufacturer seeks approval for the specific uses claimed by another's patent. Plaintiffs respond that Section 271(e)(2) creates a justiciable claim whenever a generic manufacturer seeks approval to manufacture a drug that is claimed by a valid FDA-approved method-of-use patent. Because the Court finds that Section 271(e)(2) does not create a justiciable case or controversy if a generic manufacturer excludes from its ANDA all patented methods of use, the Court grants the moving Defendants' motions to dismiss for lack of subject-matter jurisdiction. Additionally, because the Court has an independent obligation to ensure that it has jurisdiction over this matter, the Court orders Plaintiffs to show cause why their claims against Sandoz should not also be dismissed.

I. BACKGROUND[1]

The claims in these cases can be understood only by reference to the statutory and administrative framework regulating the manufacture and marketing of brand-name and generic pharmaceuticals. The Court therefore describes the relevant regulatory framework before presenting the particular facts in these cases.

[1] The facts in this section are from Plaintiffs' complaints and from certain documents submitted by Defendants in support of their respective motions to dismiss. As discussed below, it is appropriate for the Court to consider Defendants' submissions because Plaintiffs expressly reference them in the complaints and because Defendants assert a factual challenge to this Court's subject-matter jurisdiction. See Gould Elecs., Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000) (the court may consider extraneous documents on a factual challenge to its subject-matter jurisdiction); In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997) (the court may consider extraneous documents if the complaint references the documents or if the documents are integral to the plaintiff's claims).

A. The Hatch-Waxman Act

Congress enacted the Hatch-Waxman Act to address several problems related to the development, manufacturing, and marketing of pharmaceuticals. One of the Act's primary purposes was to address impediments to bringing generic drugs to market quickly once an inventor's patent lapsed. Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1357 (Fed. Cir. 2003). All pharmaceutical manufacturers are required to obtain FDA approval prior to marketing a drug. Before the Hatch-Waxman Act, the only means for obtaining FDA approval was to file a New Drug Application ("NDA"), which required independent safety and efficacy data. That requirement was unnecessarily duplicative regarding generic drugs because the same drug had already been tested and approved as part of the pioneering manufacturer's NDA. Id. Additionally, before the Hatch-Waxman Act, the Federal Circuit had held that generic companies could not produce and test patented drugs in anticipation of the patent lapsing without infringing the patent. Id. (citing Roche Prod., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 867 (Fed. Cir. 1984)). "Because it took a substantial amount of time for a second or subsequent manufacturer to obtain data and secure regulatory approval, requiring those manufacturers to wait until after the expiration of the patent to begin testing and other pre-approval activities resulted in" the delayed release of generic drugs and "a de facto extension of the patent term." Id.

To alleviate those problems, the Hatch-Waxman Act created a new regulatory scheme for approval of generic drugs. The Act permits generic manufacturers to apply for approval to market a previously approved drug for a previously approved use (commonly referred to as an "indication") by submitting an ANDA. An ANDA does not require generic manufacturers to "prove the safety and efficacy of a drug that was already the object of an NDA" if the manufacturer proves "bioequivalence" between the generic drug and the previously approved

drug. Id. Because an ANDA does not require production or testing of the drug, a generic manufacturer can submit the ANDA in anticipation of relevant patents lapsing without infringing the patents. Thus, the Hatch-Waxman Act allows generic manufactures to obtain FDA approval immediately upon the patent's expiration by "piggback[ing] on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs." Celgene Corp. v. Teva Pharms. USA, Inc., 412 F.Supp.2d 439, 441 (D.N.J. 2006).

In order to facilitate approval of generic drugs and to ensure that patent holders are protected, the Act requires that pioneering manufacturers "identify all patents that claim the drug or a method of use." Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1361 (Fed. Cir. 2010) (citing 21 U.S.C. § 355(b)(1)(G)). If the brand-name manufacturer holds a method-of-use patent, he must submit a description of each indication claimed by the patent. Id. at 1361 (citing 21 C.F.R. § 314.53). Those descriptions are referred to as "use code narratives." Id. The FDA publishes all patent information related to approved drugs, including the use code narratives, in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). See 21 U.S.C. §§ 355(b)(1), 355(j)(A).

As part of the ANDA process, all applicants must consult the Orange Book and provide one of the following four certifications: (1) that the Orange Book does not contain any patent information relevant to their ANDA (a "Paragraph I Certification"); (2) that relevant patents in the Orange Book have expired (a "Paragraph II Certification"); (3) a request that the FDA not approve the ANDA until relevant patents expire (a "Paragraph III Certification"); or (4) that the applicant believes that relevant patents are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a "Paragraph IV Certification"). 23 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV).

As an alternative to the four certifications listed above, an ANDA applicant may also submit a "section viii statement" declaring that the ANDA does not seek approval for any indications claimed by relevant patents listed in the Orange Book. 21 U.S.C. § 355(j)(2)(A)(viii); see Apotex, Inc. v. FDA, 393 F.3d 210, 213-14 (D.C. Cir. 2004). A section viii statement "indicates that a patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent." Purepac Pharm. Co. v. TorPharm, Inc., 354 F.3d 877, 880 (D.C. Cir. 2004). "For example, if a brand-name manufacturer's patent covers a drug's use for treating depression, and the ANDA applicant seeks approval to use the drug to treat any other condition, then a section viii statement would be appropriate." Id. The Federal Circuit has described a section viii statement as a "carve-out" because it limits the scope of the generic manufacture's ANDA to approved indications that are not claimed by valid patents listed in the Orange Book.[2] Novo Nordisk, 601 F.3d at 1361.

For each implicated patent, an ANDA applicant must "use either a paragraph IV certification or a section viii statement – they may not use both." Purepac Pharm. Co., 354 F.3d at 880; see TorPharm, Inc. v. Thompson, 260 F. Supp. 2d 69, 77 (D.D.C. 2003) ("either the applicant is seeking approval for the use claimed in the patent, or it is not."). When considering an ANDA application based on a section viii statement, the FDA relies on the applicable patent's use code narrative in the Orange Book. Novo Nordisk, 601 F.3d at 1361. The FDA compares the indications described in the patent use code narratives to the indications stated on the generic manufacturer's proposed labeling submitted with the ANDA. Id. "The FDA approves the section viii statement only where there is no overlap between the proposed carve-out label

[2] If the FDA approves such a qualified ANDA, the generic manufacturer may not market its generic drug for any of the nonapproved indications.

submitted by the generic manufacturer and the use code narrative submitted by the pioneering manufacturer." Id.

If an ANDA applicant submits a Paragraph IV Certification, he must give notice to "each owner of the patent that is the subject of the certification . . . and . . . the holder of the approved [NDA]." 21 U.S.C. § 355(j)(2)(B)(iii). Upon receiving notice, a patent-holder has forty-five days to bring a claim in court under Section 271(e)(2). See 21 U.S.C. § 355(j)(5)(B). Section 271(e)(2) creates an "artificial" cause of action for patent infringement. Glaxo Grp. Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004). It makes the filing of an ANDA an act of infringement so that pioneering manufacturers can sue to enforce their patents before the FDA approves the ANDA and the generic manufacturer actually infringes the patent by marketing the drug for patented indications. Id.; Novo Nordisk Inc. v. Mylan Pharms. Inc., No. 09-2445, 2010 U.S. Dist. LEXIS 32569, at *26-27 (D.N.J. Mar. 31, 2010). Once the patent holder institutes an infringement action, there is a 30-month stay of FDA approval regarding the ANDA running from when the patent-holder received notice of the ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii).

B. The Patents In Suit

Plaintiffs are the owners of three patents related to the cholesterol-lowering drug CRESTOR (rosuvastatin calcium). Plaintiffs hold a patent covering the rosuvastatin calcium compound, U.S. Patent No. RE 37,314 ("the '314 patent"). The '314 patent expires on January 8, 2016. Plaintiffs also hold two method-of-use patents regarding rosuvastatin calcium. U.S. Patent No. 6,858,618 ("the '618 patent") claims various methods of using rosuvastatin calcium to treat heterozygous familial hypercholesterolemia ("HeFH"). The '618 patent expressly excludes the use of rosuvastatin calcium to treat homozygous familial hypercholesterolemia ("HoFH").

The ’618 patent expires on December 17, 2021.[3] Plaintiffs’ second method-of-use patent, U.S. Patent No. 7,030,152 (“the ’152 patent”), claims methods of treating a person with normal cholesterol levels but with an elevated level of C-reactive protein by administering rosuvastatin calcium to reduce the risk of developing a future cardiovascular disorder. The ’152 patent claims that indication only as to patients who are nonhypercholesterolemic[4] and who have an above-normal level of C-reactive protein. The ’152 patent expires on April 2, 2018.

The FDA approved Plaintiffs’ NDA regarding rosuvastatin calcium in August 2003. The approval permits the marketing of 5, 10, 20, and 40 mg rosuvastatin calcium tablets for certain indications. Although the ’618 patent claims the use of rosuvastatin calcium to treat only heterozygous familial hypercholesterolemia, the FDA approved its use to treat heterozygous nonfamilial hypercholesterolemia as well as HoFH. (NDA 21-366 Approval Letter dated Aug. 12, 2003).[5] The FDA also approved the use of rosuvastatin calcium to treat elevated serum TG levels, also known as hypertriglyceridemia, a method-of-use not claimed by either the ’618 or ’152 patents. (Id.).

The FDA published the ’618 patent in the Orange Book in August 2007, with the following use code narrative: “USE OF ROSUVASTATIN CALCIUM TO REDUCE ELEVATED TOTAL-C, LDL-C, APOB, NONHDL-C, OR TG LEVELS; TO INCREASE HDL-C IN ADULT PATIENTS WITH PRIMARY HYPERLIPIDEMIA OR MIXED DYSLOPIDEMIA; AND TO SLOW THE PROGRESSION OF ATHEROSCLEROSIS.” The

[3] Plaintiffs also hold a six-month pediatric exclusivity for the ’618 patent that does not expire until June 17, 2022.

[4] According to the ’152 patent, a nonhypercholesterolemic patient is a person with an LDL cholesterol level that is less than 130 mg/dL, or is between 130 mg/dL and 60 mg/dL and who has no more than one cardiovascular risk factor.

[5] As discussed below, it is appropriate for the Court to consider the FDA’s approval letter on this motion to dismiss because the complaints specifically referenced Plaintiffs’ NDA and the FDA’s approval. See In re Burlington Coat Factory Sec. Litig., 114 F.3d at 1426 (on a motion limited to the pleadings, the court may consider documents referenced in a complaint).

FDA published the ’152 patent in the Orange Book in March 2010, with the following use code narrative: “USE OF ROSUVASTATIN CALCIUM FOR THE PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE IN INDIVIDUALS WITHOUT CLINICALLY EVIDENT CORONARY HEART DISEASE BUT WITH INCREASED RISK FACTORS.”

C. The Generic Manufacturers’ ANDAs

In August 2007, all Defendants except Torrent submitted ANDAs to the FDA seeking approval to market 5, 10, 20, and 40 mg rosuvastatin calcium tablets. Torrent notified Plaintiffs in 2010 that it had filed a similar ANDA.

1. Aurobindo’s ANDA (Civ. No. 10-339)

As part of their ANDA, Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively “Aurobindo”) originally submitted a Paragraph IV Certification regarding both the ’314 and ’618 patents. Aurobindo’s Paragraph IV Certification asserted that its application did not infringe the ’618 patent because Aurobindo was not seeking approval to market rosuvastatin calcium to treat HeFH. Aurobindo’s proposed labeling submitted with its ANDA shows that it seeks approval to market rosuvastatin calcium to treat heterozygous nonfamilial hypercholesterolemia, which is not claimed by the ’618 or ’152 patents. In response to Aurobindo’s ANDA, the FDA notified Aurobindo that it could not use a Paragraph IV Certification to “carve out” approved indications and that Aurobindo should submit a section viii statement if it wished to seek approval only for specific nonpatented indications. Aurobindo subsequently amended its ANDA to include a section viii statement regarding the ’618 patent. Aurobindo also submitted a section viii statement regarding the ’152 patent because it did not seek approval to market rosuvastatin calcium for any indications claimed by that patent. In May 2010, the FDA tentatively approved Aurobindo’s ANDA based on its proposed labeling.

"Tentative approval" means that the ANDA satisfies the substantive requirements for approval, but final approval is not appropriate because of outstanding patent issues. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA).

2. Apotex's ANDA (Civ. No. 10-338)

Defendant Apotex Corp. ("Apotex") submitted a Paragraph IV Certification regarding the '314 patent.[6] Regarding the '618 and '152 patents, Apotex submitted a section viii statement declaring that it was seeking approval to market rosuvastatin calcium for indications not claimed by the either the '618 or '152 patents. At no time during the application process did Apotex submit a Paragraph IV Certification regarding either the '618 or '152 patents. Plaintiffs do not specifically allege that Apotex seeks approval for indications claimed by either the '618 or '152 patents or that Apotex's proposed labels include any patented indications.[7]

3. Cobalt's ANDA (Civ. No. 10-340)

Defendants Cobalt Pharmaceuticals Inc. and Cobalt Laboratories Inc. (collectively "Cobalt") submitted a section viii statement regarding both the '618 and '152 patents. Cobalt seeks approval of its ANDA based on indications not claimed by those patents. Cobalt submitted a Paragraph IV Certification regarding the '314 patent. Plaintiffs do not specifically allege that Cobalt seeks approval for indications claimed by either the '618 or '152 patents or that Cobalt's proposed labels include any patented indications. The FDA tentatively approved Cobalt's

[6] Apotex also submitted a Paragraph IV Certification regarding U.S. Patent No. 6,316,460 (the '460 patent), which covers a particular formulation of rosuvastatin calcium. The '460 patent is not at issue in this matter.

[7] Plaintiffs allege that "the labeling associated with the Apotex Rosuvastatin Calcium Tablets causes ANDA No. 79-145 to be an application for a drug the use of which is claimed in the '618 patent . . ." (Apotex Amd. Compl. ¶ 27; see also Apotex Amd. Compl. ¶ 41 (making the same allegation regarding the '152 patent)). This allegation says only that both the ANDA and the '618 patent claim the use of rosuvastatin calcium. It does not say whether the ANDA and the '618 patent claim rosuvastatin calcium for the same indications. All ten complaints contain essentially the same allegations.

proposed labeling. At no time during the application process did Cobalt submit a Paragraph IV Certification regarding either the ’618 or ’152 patents.

4. Glenmark’s ANDA (Civ. No. 10-341)

Defendant Glenmark Generics Inc. (“Glenmark”) submitted a Paragraph IV Certification regarding the ’314 patent. Glenmark submitted a section viii statement regarding the ’618 and ’152 patents. Plaintiffs do not specifically allege that Glenmark seeks approval for indications claimed by either the ’618 or ’152 patents or that Glenmark’s proposed labels include any patented indications. At no time during the application process did Glenmark submit a Paragraph IV Certification regarding either the ’618 or ’152 patents.

5. Mylan’s ANDA (Civ. No. 10-342)

Defendant Mylan Pharmaceuticals Inc. (“Mylan”) submitted a Paragraph IV Certification regarding the ’314 patent. Mylan submitted a section viii statement regarding the ’618 and ’152 patents. Mylan’s proposed labels do not include any indications claimed by either the ’618 or ’152 patents. The labels seek approval only for treatment of hypertriglyceridemia and HoFH. The FDA tentatively approved Mylan’s ANDA based on the proposed labels. At no time during the application process did Mylan submit a Paragraph IV Certification regarding either the ’618 or ’152 patents.

6. Par’s ANDA (Civ. No. 10-343)

Par Pharmaceuticals, Inc. (“Par”) submitted a Paragraph IV Certification regarding the ’314 patent. Par submitted a section viii statement regarding the ’618 and ’152 patents. Par’s proposed labels do not include any indications claimed by either the ’618 or ’152 patents. The labels seek approval for treatment only of hypertriglyceridemia and HoFH. The FDA tentatively

approved Par's proposed labeling and ANDA. At no time during the application process did Par submit a Paragraph IV Certification regarding either the '618 or '152 patents.

7. Sun's ANDA (Civ. No. 10-345)

Defendants Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories Ltd. (collectively "Sun") submitted a Paragraph IV Certification regarding the '314 patent. Sun initially submitted a Paragraph IV Certification regarding the '618 patent. However, in May 2010, Sun amended its ANDA and submitted a section viii statement regarding the '618 patent and withdrew its prior Paragraph IV Certification. Sun has not submitted any form of declaration regarding the '152 patent. Sun's proposed labels do not include any indications claimed by either the '618 or '152 patents. The labels seek approval for treatment only of hypertriglyceridemia and HoFH.

8. Teva's ANDA (Civ. No. 10-346)

Defendant Teva Pharmaceuticals USA, Inc. ("Teva") submitted a Paragraph IV Certification regarding the '314 patent. Teva initially submitted a Paragraph IV Certification regarding '618 patent. However, Teva withdrew that certification in July 2010 and submitted a section viii statement regarding both the '618 and '152 patents. Teva's proposed labels do not include any indications claimed by either the '618 or '152 patents. The labels seek approval for treatment only of hypertriglyceridemia and HoFH.

9. Torrent's ANDA (Civ. No. 10-584)

Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively "Torrent") submitted a Paragraph IV Certification regarding the '314 patent. Torrent submitted a section viii statement regarding the '618 and '152 patents. Plaintiffs do not specifically allege

that Torrent seeks approval for indications claimed by either the ’618 or ’152 patents or that Torrent’s proposed labels include any patented indications.

10. Sandoz’s ANDA (Civ. No. 10-344)

Sandoz has not moved to dismiss Plaintiffs’ Amended Complaint against it. Plaintiffs allege that Sandoz submitted a Paragraph IV Certification regarding the ’618 patent. Plaintiffs do not allege that Sandoz submitted any certification or statement regarding the ’152 patent. Plaintiffs do not specifically allege that Sandoz seeks approval for indications claimed by either the ’618 or ’152 patents or that Sandoz’s proposed labels include any patented indications.

D. The ’314 Patent Litigation

Beginning in December 2007, some of the Plaintiffs brought suit under Section 271(e)(2) against Defendants (except Glenmark and Torent) asserting infringement of the ’314 patent, which claims the chemical compound rosuvastatin calcium. Defendants argued that the ’314 patent was invalid, unenforceable, or not infringed. In June 2009, the district court held that the ’314 patent was valid and enforceable and that Defendants’ ANDAs infringed the patent because Defendants sought approval to manufacture rosuvastatin calcium before the ’314 patent expired. See In re Rosuvastatin Calcium Patent Lit., No. 08-1949, 2010 U.S. Dist. LEXIS 64475, at *54-56 (D. Del. Jun. 29, 2010). All of the losing Defendants (except Sandoz) appealed the district court’s ruling to the Federal Circuit.

E. Plaintiffs’ Claims

In April 2010, Plaintiffs sued Defendants (except Torrent) for infringement of the ’618 and ’152 patents. Plaintiffs sued Torrent in July 2010 on the same basis. Plaintiffs assert claims for infringement under Section 271(e)(2). They allege that this court has subject-matter

jurisdiction under 28 U.S.C. § 1331 and 1338(a) because the matter arises under federal patent law.

Plaintiffs do not[8] specifically allege that any of the proposed labels submitted by Defendants include indications claimed by either the '618 or '152 patents.[9] Rather, they allege that "the label for the [Defendants'] Rosuvastatin Calcium Tablets must be the same as the label for Crestor." (See, e.g., Abotex Amd. Compl. ¶ 24).[10] Based on this assertion, Plaintiffs allege that: (1) "the FDA will require the label for the [Defendants'] Rosuvastatin Calcium Tablets to include information relating to the use to treat pediatric patients 10 to 17 years of age having HeFH", which is an indication claimed by the '618 patent, (id. ¶ 25); and (2) "the FDA will require the label for the [Defendants'] Rosuvastatin Calcium Tablets to include information relating to the use for primary prevention of cardiovascular disease," which is an indication claimed by the '152 patent, (id. ¶ 39). Plaintiffs allege that "if the FDA approves" the Defendants' ANDAs, "the sale of the [Defendants'] Rosuvastatin Calcium Tablets in the United States with their associated labeling before the expiration of the '618 [or '152 patents] will cause infringement of one or more claims of [those patents]." (Id. ¶¶ 29, 42). Although Plaintiffs do not assert separate claims for inducement of patent infringement under 35 U.S.C. § 271(b), they

[8] The Court's original Opinion dated December 15, 2010 inadvertently omitted the word "not."

[9] As noted earlier, Plaintiffs allege that "the labeling associated with the [Defendants'] Rosuvastatin Calcium Tablets causes [Defendants'] ANDA[s] to be . . . application[s] for a drug the use of which is claimed in the '618 patent . . ." (Apotex Amd. Compl. ¶ 27; see also Apotex Amd. Compl. ¶ 41 (making the same allegation regarding the '152 patent)). These allegations say only that the ANDAs and Plaintiffs' patents claim the use of rosuvastatin calcium. It does not say whether the ANDAs and the patents claim rosuvastatin calcium for the same indications. Moreover, when read in the context of the preceding allegations, the phrase "labeling associated with the [Defendants'] ANDA[s]" appears to refer to the amended labeling that Plaintiffs believe the FDA will require. Plaintiffs do not allege that Defendants' actual labeling includes patented indications. Indeed, Plaintiffs' allegation that the FDA will require Defendants to amend their labeling to include patented indications suggests that the actual labeling does not include patented indications. If Plaintiffs believe that Defendants' proposed labeling includes patented indications, they must specifically allege that fact.

[10] For convenience, the Court cites only to Plaintiffs' Amended Complaint against Apotex. The relevant allegations discussed herein are essentially the same in all ten complaints.

nevertheless allege that if the FDA approves the amended labeling, Defendants will be liable for inducing infringement of the ’618 and ’152 patents because rosuvastatin calcium “will be prescribed and administered to human patients” to treat conditions as claimed by the patents. (Id. ¶¶ 29, 43).

F. Defendants’ Motions To Dismiss

All moving Defendants rely on three common arguments in support of their respective motions to dismiss. First, Defendants argue that this court lacks subject-matter jurisdiction to decide Plaintiffs’ claims. They claim that Section 271(e)(2), the only provision under which Plaintiffs sue, creates a justiciable patent infringement dispute only if an ANDA applicant relies on a Paragraph IV Certification. According to Defendants, if an applicant relies on a section viii statement, Section 271(e)(2) is not triggered and there is no justiciable controversy between the parties.

Second, Defendants argue that there is no justiciable case or controversy between the parties because Plaintiffs’ claims are not ripe. According to Defendants, Plaintiffs cannot create a justiciable claim by alleging that the FDA will, at some point in the future, require them to amend their ANDAs to seek approval for indications claimed by the ’681 and ’152 patents. Defendants argue that, as a matter of law, applicants may carve out patented indications from their ANDA applications.

Third, Defendants argue that even if this Court determines that there is a justiciable controversy, Plaintiffs fail to state a claim because none of the Defendants rely on Paragraph IV Certifications or seek approval for any patented indications.

II. LEGAL STANDARD

Defendants move to dismiss Plaintiffs' complaints based on lack of subject-matter jurisdiction under Rule 12(b)(1) and for failure to state a claim under Rule 12(b)(6). "When a motion under Rule 12 is based on more than one ground, the court should consider the 12(b)(1) challenge first because if it must dismiss the complaint for lack of subject matter jurisdiction, all other defenses and objections become moot." In re Corestates Trust Fee Litig., 837 F. Supp. 104, 105 (E.D. Pa. 1993). Because the Court concludes that there is no jurisdiction in these cases, only the Rule 12(b)(1) standard is relevant.

A district court may treat a party's motion to dismiss for lack of subject-matter jurisdiction under Rule 12(b)(1) as either a facial or factual challenge to the court's jurisdiction. Gould Elecs., Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000). "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." Id. (citing PBGC v. White, 998 F.2d 1192, 1196 (3d Cir. 1993)). "In reviewing a factual attack, the court may consider evidence outside the pleadings." Id. (citing Gotha v. United States, 115 F.3d 176, 178-79 (3d Cir. 1997)); see United States ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 514 (3d Cir. 2007). A district court has "substantial authority" to "weigh the evidence and satisfy itself as to the existence of its power to hear the case." Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977). "[N]o presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Id.

Although courts generally treat a pre-answer motion under Rule 12(b)(1) as a facial challenge, see Cardio-Med. Assoc., Ltd. v. Crozer-Chester Med. Ctr., 721 F.2d 68, 75 (3d Cir.

1983), a "factual challenge under Rule 12(b)(1) may be made prior to service of an answer" if the defendant contests the plaintiff's allegations. Knauss v. United States DOJ, No. 10-26-36, 2010 U.S. Dist. LEXIS 108603, at *6 (E.D. Pa. Oct. 7, 2010) (citing Berardi v. Swanson Mem'l Lodge No. 48 of Fraternal Order of Police, 920 F.2d 198, 200 (3d Cir. 1990)). When a defendant raises a factual challenge to jurisdiction, the plaintiff bears the burden of establishing jurisdiction. Gould Elecs. Inc., 220 F.3d at 176-77.

III. DISCUSSION

A. Whether The Court Should Consider Defendants' ANDA Documentation

As a preliminary matter, Plaintiffs argue that Defendants improperly submit documents from their respective ANDAs and from the Orange Book. Plaintiffs contend that the Court should either reject Defendants' submissions or convert Defendants' motions into motions for summary judgment and give Plaintiffs an opportunity to conduct discovery. The Court disagrees and will consider Defendants' submissions.[11]

First, a court may consider extraneous documents if the complaint references the documents or if the documents are integral to the plaintiff's claims. See In re Burlington Coat Factory Sec. Litig., 114 F.3d at 1426 (holding that court may consider extraneous documents even on a motion to dismiss pursuant to Rule 12(b)(6) if those documents are referenced in the complaint or integral to the plaintiff's claims). Plaintiffs specifically reference each Defendant's ANDA by its assigned FDA record number. It is therefore appropriate for the Court to consider Defendants' Paragraph IV Certifications, section viii statements, and the notice statements sent

[11] Specifically, the Court relies on Defendants' section viii statements and proposed labeling from their ANDAs, Defendants' ANDA documentation showing that the FDA has tentatively approved Defendants' proposed labeling, and documents from the Orange Book showing Plaintiffs' use code narratives for the '618 and '152 patents. The Court also relies on Plaintiffs' FDA-approved labels for CRESTOR, which Plaintiffs submit in opposition to Defendants' motions, and the publicly available approval letter from the FDA regarding Plaintiffs' NDA for rosuvastatin calcium, which lists the drug's FDA-approved indications.

to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(iii). Plaintiffs' complaints also specifically reference each Defendant's proposed ANDA labeling, Plaintiffs' NDA for rosuvastatin calcium and the FDA's approval, and the Orange Book listings for both the '618 and '152 patents. It is therefore appropriate for the Court to consider those documents. See generally Bayer Schera Pharma AG v. Sandoz, Inc., No. 08-3710, 2010 U.S. Dist. LEXIS 102132, at *10-11 n.4 (S.D.N.Y. Sept. 28, 2010) (examining similar documents in a Hatch-Waxman Act infringement case on a motion to dismiss based on the pleadings).

Second, even if Plaintiffs' complaints did not incorporate Defendants' submissions, it would be appropriate for the Court to consider extraneous evidence because Defendants make a factual challenge to the Court's jurisdiction. See Gould Elecs., Inc., 220 F.3d at 176 (holding that a court may consider evidence outside the pleadings when deciding a factual challenge to its jurisdiction). Defendants challenge Plaintiffs' claim that Defendants' ANDAs constitute acts of infringement under Section 271(e)(2). Specifically, Defendants contest Plaintiffs' allegation that the FDA will require Defendants to amend their ANDAs to include all indications for which the FDA has approved rosuvastatin calcium. According to Defendants, none of the ANDAs seek approval for patented indications and the FDA will not require them to seek approval for indications claimed by the '618 and '152 patents. Because those facts have jurisdictional significance, Defendants assert a factual challenge to the Court's jurisdiction, and the Court can properly consider Defendants' submissions. See Novo Nordisk Inc., 2010 U.S. Dist. LEXIS 32569, at *19-20 (analyzing a pre-answer motion to dismiss a claim under the Hatch-Waxman Act and determining that it was a factual challenge to jurisdiction because the defendant challenged the plaintiff's allegation that the FDA would require defendant to submit amended labeling).

Additionally, the Court rejects Plaintiffs' argument that discovery is necessary before deciding Defendants' motions. If documents are referenced in a complaint, the court can consider them without converting a motion based on the pleadings into a motion for summary judgment. See CitiSteel USA, Inc. v. GE, 78 Fed. App'x. 832, 834 (3d Cir. 2003) (upholding the district court's reliance on extraneous documents and its refusal to convert the motion to summary judgment because the documents were referenced in the complaint); Mawhinney v. Francesco, No. 08-62439, 2010 U.S. Dist. LEXIS 62439, at *13-14 (D.N.J. June 22, 2010) (considering documents referenced in the complaint on a motion to dismiss under Rule 12(b)(6) and refusing to convert the motion into a summary judgment motion). The rationale for this rule is that a plaintiff is not permitted to expressly rely upon documents in preparing his claims against a defendant, but then hide behind his complaint's characterization of those documents when the defendant offers the actual documents in his defense. See In re Burlington Coat Factory Sec. Litig., 114 F.3d at 1426 (recognizing this rationale in the context of motion to dismiss under Rule 12(b)(6)). Because the evidence at issue on these motions is incorporated by reference into Plaintiffs' complaints, and because Plaintiffs do not contest the documents' authenticity, there is no basis to deny Defendants' motions as premature in favor of discovery. See CitiSteel USA, Inc., 78 Fed. App'x. at 834 (holding that motion to dismiss under Rule 12(b)(6) need not be converted to summary judgment motion if documents at issue are incorporated into the complaint); Sizova v. Nat'l Inst. of Stds. & Tech., 282 F.3d 1320 (10th Cir. 2002) (holding that jurisdictional discovery and a hearing are necessary before deciding a Rule 12(b)(1) motion only if "pertinent facts bearing on the question of jurisdiction are controverted . . . or where a more satisfactory showing of the facts is necessary."). Plaintiffs expressly rely on

Defendants' ANDAs as the basis for their claims. It is therefore appropriate for the Court to consider Defendants' ANDA documentation.

B. The District Court's Jurisdiction Over Plaintiffs' 35 U.S.C. § 271(e)(2) Infringement Claims

Plaintiffs assert claims for patent infringement under 35 U.S.C. § 271(e)(2)(A), which provides in pertinent part:

> It shall be an act of infringement to submit . . . an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [codified at 21 U.S.C. § 355(j); i.e., an ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent, . . . if the purpose of such submission is to obtain approval under such Act [i.e., Title 21 of the United States Code] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Thus, Section 271(e)(2) "permit[s] patent holders to bring suit against generic companies despite the fact that the generic companies have not yet infringed the patents at issue." Glaxo Grp. Ltd., 376 F.3d at 1351. Section 271(e)(2) "is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts." Id. "The function of [Section 271(e)(2)] is to define a new . . . act of infringement for a very limited and technical purpose that relates only to certain drug applications." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676-77 (1990).

Defendants argue that Section 271(e)(2) creates federal jurisdiction where none would otherwise exist by declaring that the filing of an ANDA constitutes an act of infringement. Defendants further argue that not all ANDAs qualify as an act of infringement under Section 271(e)(2). The core of Defendants' argument is that the filing of an ANDA does not constitute an act of infringement under Section 271(e)(2) if the generic manufacturer includes a section viii statement that it is seeking approval for indications not claimed by relevant method-of-use

patents. According to Defendants, an ANDA triggers Section 271(e)(2) only when it contains a Paragraph IV Certification stating that the applicant is seeking approval for an indication claimed by a relevant method-of-use patent.

Plaintiffs respond that an ANDA triggers Section 271(e)(2) if it seeks approval to market a drug for which there are some patented FDA-approved indications, even if the ANDA seeks approval for only non-patented indications. In other words, Plaintiffs take the position that a generic manufacturer cannot carve out patented indications if those indications are FDA-approved. Plaintiffs argue that this interpretation is most consistent with Section 271(e)(2)'s plain language. Plaintiffs' primary justification for this position is that if the FDA allows Defendants to manufacture rosuvastatin calcium for non-patented indications, doctors will nevertheless prescribe the drug for all approved indications, which will render the '618 and '152 patents effectively worthless. Plaintiffs also argue that Section 271(e)(2) is not a jurisdictional statute because the Court's jurisdiction actually derives from 28 U.S.C. § 1338(a), which grants jurisdiction to hear disputes arising under federal patent law.

The Court first addresses whether Section 271(e)(2) is a jurisdictional statute. The Federal Circuit has described Section 271(e)(2) as a "jurisdictional-conferring statute that establishes a case or controversy." Apotex, 376 F.3d at 1351. Section 271(e)(2) "makes it possible for the district court to exercise its section 1338(a) jurisdiction" in circumstances where there would not otherwise be a justiciable case or controversy. Allergan, Inc. v. Alcon Labs., 324 F.3d 1322, 1330 (Fed. Cir. 2003); see Apotex, 376 F.3d at 1351. Thus, a district court's jurisdiction turns on whether a plaintiff asserts a valid claim under Section 271(e)(2). If a plaintiff does not assert a valid Section 271(e)(2) claim, a court does not have jurisdiction over the matter because, in the absence of a Section 271(e)(2) claim, there is no justiciable case or

controversy between the parties. See Novo Nordisk Inc., 2010 U.S. Dist. LEXIS 32569, at *11 (finding no jurisdiction because plaintiff failed to state a claim under Section 271(e)(2)); Eisai Co. v. Mut. Pharm. Co., No. 06-3613, 2007 U.S. Dist. LEXIS 93585, at *12 (D.N.J. Dec. 20, 2007) (same); see also Apotex, 376 F.3d at 1351 (characterizing Section 271(e)(2) as creating a justiciable case or controversy where one would not otherwise exist).

Thus, the core issue on this motion is whether Plaintiffs may bring an infringement claim under Section 271(e)(2). Specifically, whether Plaintiffs may bring an infringement claim under Section 271(e)(2) based on two FDA-approved method-of-use patents even though Defendants seek approval to manufacture and market rosuvastatin calcium for FDA-approved indications not claimed by Plaintiffs' patents. If Plaintiffs cannot bring such a claim, this Court has no jurisdiction because there is no case or controversy between the parties.

The Federal Circuit's decision in Warner-Lambert v. Apotext Corp., 316 F.3d 1348 (2003), is controlling regarding the elements of a Section 271(e)(2) claim. In Warner-Lambert, the defendant filed an ANDA seeking approval to manufacture a generic drug upon expiration of the pioneering manufacturer's method-of-use patent, which was an FDA-approved indication for the drug. Id. at 1352. However, the pioneering manufacturer also held a second method-of-use patent regarding a separate indication for the drug that the FDA had not yet approved, but which did not expire until long after the FDA-approved method-of-use patent. Id. The generic manufacturer filed a Paragraph IV Certification with its ANDA stating that it would not infringe the pioneering manufacturers' non-FDA approved method-of-use patent because the ANDA sought approval only for the FDA-approved indication claimed by the soon-to-expire method-of-use patent. Id. The pioneering manufacturer nevertheless sued for infringement under Section 271(e)(2) asserting that the defendant's filing of the ANDA was an act of infringement regarding

the patent claiming a non-FDA approved indication because the generic manufacturer could not "carve out" patented indications from its ANDA. Id. at 1353. After the district court entered judgment for the generic manufacturer, the pioneering manufacturer appealed to the Federal Circuit.

The Federal Circuit framed the issue before it as follows:

> The central issue in the present case is whether it is an act of infringement under 35 U.S.C. § 271(e)(2)(A) to submit an ANDA seeking approval to make, use, or sell a drug for an approved use if any other use of the drug is claimed in a patent, or if it is only an act of infringement to submit an ANDA seeking approval to make, use, or sell a drug if the drug or the use for which FDA approval is sought is claimed in a patent.

Id. at 1354. In deciding that issue, the Federal Circuit expressly rejected the argument that "a patent claiming a use of a drug is infringed by the filing of an ANDA irrespective of whether approval is sought to market the drug for the patented use." Id. at 1355. The court held that "it is abundantly clear that the statute does not make the filing of an ANDA prior to patent expiration an act of infringement unless the ANDA seeks approval to manufacture, use, or sell the drug prior to expiration of a patent that would otherwise be infringed by such manufacture, use, or sale . . . ." Id. at 1355-56. The court held that the pioneering manufacturer did not have a claim under Section 271(e)(2) because the generic manufacturer sought approval only for non-patented indications. Id. at 1356, 1362. Thus, Warner-Lambert clearly establishes that a generic manufacturer may carve out patented uses from its ANDA.

Plaintiffs attempt to distinguish Warner-Lambert by noting that the patent at issue there claimed a non-FDA approved indication, but the '618 and '152 patents claim FDA-approved indications. However, the Federal Circuit's reasoning in Warner-Lambert shows that this is a distinction without significance. As support for its conclusion that ANDA applicants can carve

out non-FDA approved indications, the Federal Circuit relied on the following portion of the House Report regarding the Hatch-Waxman Act:

> If there are indications which are claimed by any use patent and for which the applicant is not seeking approval, then an ANDA must state that the applicant is not seeking approval for those indications which are claimed by such use patent. For example, the listed drug may be approved for two indications. If the applicant is seeking approval only for Indication No. 1, and not Indication No. 2 because it is protected by a use patent, then the applicant must make the appropriate certification and a statement explaining that it is not seeking approval for Indication No. 2.

Id. at 1358 (quoting H.R. Rep. No. 98-857(I), at 22, 1984 U.S.C.C.A.N. at 2655) (emphasis added). After further analyzing the House Report and Section 271(e)(2)'s plain language, the Federal Circuit concluded:

> Congress recognized that a single drug could have more than one indication and yet that the ANDA applicant could seek approval for less than all of those indications. Congress clearly contemplated that the FDA could grant approval of an NDA, and hence eventually an ANDA, seeking to market a drug for a single indication even when other indications were known or even approved. Moreover, and perhaps more importantly, Congress made it clear that the ANDA applicant need not certify with respect to every "use" patent that claims an indication for the drug. Rather, the applicant needs only to certify with respect to use patents that claim an indication for which the applicant is seeking approval to market the drug.

Id. at 1360 (emphases added) (citing H.R. Rep. No. 98-857(I), at 22, 1984 U.S.C.C.A.N. at 2655). Thus, according to the Federal Circuit, Congress enacted Section 271(e)(2) with the expectation that ANDA applicants could carve out patented uses from their ANDAs even if those uses were FDA-approved. Id. at 1361 ("Even when a listed drug is approved for more than one indication, Congress contemplated the possibility that there could be indications that are claimed by a use patent but for which the applicant is not seeking approval") (emphasis in original). Plaintiffs' attempt to distinguish Warner-Lambert is therefore unavailing. The Federal Circuit

has interpreted the Hatch-Waxman Act to permit generic manufacturers to carve out patented FDA-approved indications from their ANDAs.

Plaintiffs also argue that allowing Defendants to proceed with their qualified ANDAs will render the '618 and '152 patents effectively worthless. Plaintiffs claim that although Defendants' generic rosuvastatin calcium tablets will not be approved or labeled for the indications claimed by the '618 and '152 patents, doctors will nevertheless prescribe Defendants' cheaper generic tablets for all indications, thus causing infringement and rendering Plaintiffs' patents worthless. Plaintiffs argue that this further distinguishes Warner-Lambert because the patent at issue there was not marketable since it was not FDA-approved. In this case, however, Plaintiffs' patented indications are FDA-approved and there is a possibility that doctors will prescribe Defendants' generic drug for indications claimed by Plaintiffs' patents.

Plaintiffs' argument is misguided. Plaintiffs assert infringement claims under Section 271(e)(2). They do not assert an inducement of infringement claim under Section 271(b).[12] As noted above, Section 271(e)(2) creates an "artificial" act of infringement in circumstances where a patent holder would not otherwise have a claim. It creates "a very limited and technical" infringement claim that applies only if an applicant submits an ANDA seeking approval for an indication claimed by a valid patent. Warner-Lambert, 316 F.3d at 1360-62. Section 271(e)(2) does not extend this artificial cause of action to include an "artificial" inducement of infringement claim based on speculation about how some doctors may prescribe the generic drug. If Plaintiffs believe that Defendants will induce doctors to infringe the '618 and '152 patents upon approval of Defendants' ANDAs, they must assert a "traditional" inducement claim

[12] The Court's original Opinion dated December 15, 2010 incorrectly referred to 35 U.S.C. § 271(d). The correct citation is 35 U.S.C. § 271(b).

under Section 271(b), [13] not a claim under Section 271(e)(2). See id. at 1356 (holding that unless a plaintiff asserts a valid Section 271(e)(2) claim, he must prove infringement "under a traditional infringement analysis"); id. at 1363-66 (discussing the elements of an inducement of infringement claim under Section 271(b) [14]).

Plaintiffs next argue that Section 271(e)(2) will be rendered meaningless if generic manufacturers can evade suit under Section 271(e)(2) by simply filing a conclusory section viii statement that they are not seeking approval for any patented indications. According to Plaintiffs, "[s]uch an approach would improperly and unfairly allow generic companies to define and dictate the circumstances under which the filing of an ANDA would constitute infringement under § 271(e)(2)." (Pl. Opp. Br. at 19).

This argument is also misguided, and the Federal Circuit rejected it in Warner-Lambert. See Warner-Lambert, 316 F.3d at 1360. The formality of submitting a section viii statement does not immunize a generic manufacturer from suit under Section 271(e)(2). See Novo Nordisk, 2010 U.S. Dist. LEXIS 32569, at *11 (holding that jurisdiction exists if an ANDA includes a section viii statement but "should have" included a Paragraph IV Certification); Ben Venue Labs. Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 582 (D.N.J. 2001) (noting same); see also Bristol-Myers Squibb Co. v. Royce Lab., 69 F.3d 1130, 1132 (Fed. Cir. 1995) ("[o]nce it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent-infringement suit"). Nor does filing a Paragraph IV Certification automatically trigger Section 271(e)(2). Indeed, in Warner-Lambert, the generic manufacturer

[13] The Court's original Opinion dated December 15, 2010 incorrectly referred to 35 U.S.C. § 271(d). The correct citation is 35 U.S.C. § 271(b).

[14] The Court's original Opinion dated December 15, 2010 incorrectly referred to 35 U.S.C. § 271(d). The correct citation is 35 U.S.C. § 271(b).

submitted a Paragraph IV Certification, but the Federal Circuit found that "[a]lthough formally labeled as a 'paragraph IV certification,'" the certification "was effectively a statement of non-applicable use pursuant to [section viii]." Warner-Lambert, 316 F.3d at 1360 (emphasis added).

Thus, the district court has jurisdiction under Section 271(e)(2) when, regardless of whether the ANDA contains a Paragraph IV Certification or a section viii statement, the ANDA actually seeks approval for a patented indication.[15] In that event, the filing of an ANDA "constitutes an 'act of infringement' which confers jurisdiction under Section 271(e)(2)(A)." Novo Nordisk Inc., 2010 U.S. Dist. LEXIS 32569, at *11. In order to determine whether an ANDA actually seeks approval for a patented indication, a court need only compare the ANDA's proposed labeling, which provides the basis for FDA approval and defines the indications for which the generic manufacturer can market the drug, to the indications claimed in the patents. See Bayer Schera Pharma AG v. Sandoz, Inc., No. 08-3710, 2010 U.S. Dist. LEXIS 102132, at *26 (S.D.N.Y. Sept. 28, 2010) (conducting this analysis and dismissing a Section 271(e)(2) claim); Novo Nordisk, 601 F.3d at 1361 (describing this analysis in the context of FDA approval of an ANDA). If there is no overlap, then there is no claim under Section 271(e)(2) and no justiciable controversy.

Here, there is no dispute that all Defendants seek approval for indications not claimed by either the '618 or '152 patents. The '618 patent claims the use of rosuvastatin calcium to treat only HeFH. The '152 patent claims the use of rosuvastatin calcium to treat only patients who are nonhypercholesterolemic and who have above-normal levels of C-reactive protein. Defendants

[15] For this reason, Plaintiffs' reliance on Impax Labs., Inc. v. Aventis Pharms., Inc., 468 F.3d 1366, 1372-73 (Fed. Cir. 2006), Bristol-Myers Squibb Co. v. Mylan Pharms, Inc., No. 09-651 (D. Del. Jan. 14, 2010), Glaxo Group Ltd. v. Apotex, Inc., 272 F. Supp. 2d 772, 779 (N.D. Ill. 2003), and Teva Pharms. USA, Inc. v. Abbott Labs., 301 F. Supp. 2d 819 (N.D. Ill. 2004), is misplaced. Each of those cases permitted plaintiffs to pursue Section 271(e)(2) claims even though the ANDAs did not include Paragraph IV Certifications. However, none of those cases refute the proposition that regardless of what statement is included in the ANDA, a plaintiff may only bring a claim under Section 271(e)(2) if the ANDA at issue seeks approval for a patented indication. See Warner-Lambert, 316 F.3d at 1355.

seek approval to market rosuvastatin calcium to treat only nonfamilial hypercholesterolemia, hypertriglyceridemia, or HoFH. Plaintiffs do not allege or present any evidence that the '618 or '152 patents claim any of those indications. Thus, Plaintiffs do not have a claim under Section 271(e)(2) and this Court does not have jurisdiction over this matter.

C. Plaintiffs' Infringement Claims Based On "Amended" Labeling

Perhaps aware of the above deficiencies in their claims, Plaintiffs allege in their complaints that the FDA will require Defendants to amend their proposed labeling to include all FDA-approved indications. Plaintiffs argue that Defendants' amended labeling will trigger Section 271(e)(2) because the new labeling will include indications claimed by the '618 and '152 patents. Defendants respond that this theory of infringement under Section 271(e)(2) is not ripe because it is predicated on contingent future events that are unlikely to occur. The Court agrees.

"A claim is not ripe for adjudication if it rests on contingent future events that may not occur as anticipated, or indeed may not occur at all." Texas v. United States, 523 U.S. 296, 300 (1998). An action must be ripe to present a case or controversy that is justiciable under Article III. Caraco Pharm. Labs., Ltd v. Forest Labs., Inc., 527 F.3d 1278, 1291 (Fed. Cir. 2008).

Plaintiffs' claims are not ripe because, as discussed above, Defendants are not required to include all FDA-approved indications on their proposed labeling. The Federal Circuit made clear in Warner-Lambert that "even when a listed drug is approved for more than one indication, Congress contemplated the possibility that there could be indications that are claimed by a use patent but for which the [ANDA] applicant is not seeking approval." Warner-Lambert, 316 F.3d at 1361. More importantly, the Federal Circuit rejected Plaintiffs' argument that the Hatch-Waxman Act requires ANDA proposed labeling to include all FDA-approved indications: "Congress clearly contemplated that the FDA could grant approval of . . . an ANDA . . . seeking

to market a drug for a single indication even when other indications were known or even approved." Id. at 1360; see also Novo Nordisk, 601 F.3d at 1362-63 (describing FDA approval of ANDA proposed labeling that carved out one of three FDA-approved indication because that indication was claimed by a valid patent).

Because the Hatch-Waxman Act allows ANDAs to carve out FDA-approved indications, and because there is no reason to believe that the FDA will not continue to approve qualified ANDAs, Plaintiffs' claims are based on contingent future events that are unlikely to occur. The FDA is not likely to require Defendants to amend their ANDAs to include proposed labeling claiming all FDA-approved indications for rosuvastatin calcium. Consequently, Plaintiffs claims are not ripe.

D. Plaintiffs Must Show Cause Why The Court Should Not Dismiss Their Claims Against Sandoz For Lack Of Subject-Matter Jurisdiction

If there is no subject-matter jurisdiction over a claim, the Court lacks authority to consider the merits of the case. Ruhrgas AG v. Marathon Oil Co., 526 U.S. 574, 583 (1999). This Court has an independent obligation to ensure that it has subject-matter jurisdiction over every action, even if the issue is not raised by a party. See Fed. R. Civ. P. 12(h)(3) ("If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action."); Arbaugh v. Y&H Corp., 546 U.S. 500, 514 (2006). Thus, if subject-matter jurisdiction is uncertain, the Court may sua sponte order the parties to show cause as to why the matter should not be dismissed for lack of jurisdiction. See Butz v. Schleig, No. 09-761, 2009 U.S. Dist. LEXIS 29809, at *10-12 n. 3 (D.N.J. Apr. 7, 2009) (explaining the court's authority to order parties to show cause why the matter should not be dismiss for lack of subject-matter jurisdiction); Sullivan v. Novartis Pharms. Corp., 602 F. Supp. 2d 527, 529 (D.N.J. 2009) (issuing order to show cause regarding subject-matter jurisdiction); Scott v. Sysco Food Serv. of

Metro N.Y., L.L.C., No. 07-3656, 2007 U.S. Dist. LEXIS 79519, *1 (D.N.J. Oct. 26, 2007) (issuing order to show cause regarding subject-matter jurisdiction).

As discussed above, the Court's jurisdiction over this matter turns on whether Sandoz actually seeks FDA-approval to manufacture rosuvastatin calcium for indications claimed by the '618 and '152 patents. Plaintiffs do not[16] specifically allege that Sandoz seeks approval for indications claimed by either the '618 or '152 patents. They allege only that Sandoz filed a Paragraph IV Certification declaring "that the claims of the '618 patent are invalid, unenforceable, or not infringed." (Sandoz Am. Compl. ¶ 20). Unlike the nine related cases discussed above, Sandoz did not move to dismiss Plaintiffs' claims based on the fact that they do not seek approval for indications claimed by Plaintiffs' patents. Thus, although the Court's subject-matter jurisdiction turns on whether Sandoz actually seeks FDA approval for an indication claimed by the '618 or '152 patents, that fact is unclear on the face of the Amended Complaint and Sandoz has not provided the determinative documentation referenced in the Amended Complaint. Because the Court has an independent obligation to ensure that it has jurisdiction over this matter, and because Plaintiffs bear the burden of establishing that subject-matter jurisdiction is proper, it is appropriate for the Court to order Plaintiffs to show cause as to why this matter should not be dismissed for lack of jurisdiction.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' complaints are dismissed for lack of jurisdiction in the nine matters where the Defendants moved for dismissal (Civ. Nos. 10-338, 10-339, 10-340, 10-341, 10-342, 10-343, 10-345, 10-346, 10-584). Because the Court does not have jurisdiction over those matters, it does not address additional arguments made by some of those Defendants. An appropriate order shall issue in those cases. Because the Court's subject-matter jurisdiction

[16] The Court's original Opinion dated December 15, 2010 inadvertently omitted the word "not."

is unclear in Astra Zeneca Pharm. LP, et al. v. Sandoz Inc. (No. 10-344), the Court shall issue an Order to Show Cause as to why that matter should not be dismissed for lack of subject-matter jurisdiction.

Dated: 12/22/10

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge