IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|---|---|---|
| TAKEDA PHARMACEUTICALS U.S.A., INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | C. A. No.: 14-268-SLR |
| v. | ) | |
| | ) | |
| WATSON LABORATORIES, INC. | ) | |
| | ) | |
| Defendant. | ) | |

**WATSON LABORATORIES, INC.'S OPPOSITION TO**
**PLAINTIFF'S MOTION FOR LEAVE TO FILE AN AMENDED COMPLAINT**

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## PRELIMINARY STATEMENT

Plaintiff Takeda has moved under Fed. R. Civ. P. 15(a)(2) to amend its complaint to add new allegations in Counts IV to XVII seeking a declaratory judgment of contributory infringement under 35 U.S.C. § 271(c). The Court should deny Takeda's motion as futile for two reasons. First, this Court lacks subject matter jurisdiction over the new counts because they improperly seek an advisory opinion of "future contributory infringement" based solely on a Watson ANDA that Takeda concedes cannot properly be litigated under 35 U.S.C. § 271(e). In the absence of a legitimate § 271(e) claim, Watson's ANDA filing alone does not create a case or controversy for these declaratory judgment claims. Second, the new counts fail to state a claim for contributory infringement under Fed. R. Civ. P. 12(b)(6) because the facts alleged by Takeda, assumed to be true, establish as a matter of law that Watson's ANDA product is a "staple article of commerce that is suitable for substantial non-infringing use." The sale of such products cannot constitute contributory infringement under 35 U.S.C. § 271(c).

## NATURE AND STAGE OF THE PROCEEDING

This is a patent infringement lawsuit involving several Takeda patents that purport to cover uses of the drug colchicine. On February 27, 2014, Takeda filed its original complaint against Watson alleging that Watson had infringed fourteen Takeda patents under 35 U.S.C. § 271(e) by filing an ANDA seeking approval to sell colchicine for use in treating gout. Watson subsequently amended its ANDA to "carve out," or disavow, gout as a treatment indication and instead request approval to sell colchicine to treat Familial Mediterranean Fever ("FMF"). On May 28, 2014, Takeda filed the instant motion to amend its complaint, requesting permission to add five counts of infringement under § 271(e), asserting patents on FMF treatment methods, and fourteen counts seeking a declaratory judgment that Watson will contributorily infringe Takeda's patents on gout treatment methods if its ANDA for FMF treatment is approved and colchicine is

eventually sold by Watson. The Court has not entered a scheduling order, and discovery has not yet begun.

## SUMMARY OF ARGUMENT

1. Takeda has moved to amend its complaint to allege Counts IV to XVII seeking a declaratory judgment of "future contributory infringement" under 35 U.S.C. § 271(c). A motion to amend under Fed. R. Civ. P. 15(a)(2) should be denied if the amendment would be futile or result in undue prejudice to the nonmoving party. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). Takeda's new allegations are futile because the court lacks subject matter jurisdiction over them and they fail to state a claim upon which relief can be granted. *Id.*, *Harrison v. Henry*, 2009 U.S. Dist. LEXIS 13746, at *31 (D. Del. Feb. 24, 2009).

2. Under § 271(e) a patentee who owns a New Drug Application ("NDA") granting it the right to sell a drug for a specific use may sue the filer of an Abbreviated New Drug Application ("ANDA") for infringement only if the ANDA seeks approval from the FDA to sell the drug for a use claimed in a patent that the owner has listed with the FDA. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-55 (Fed. Cir. 2003).

3. Takeda is the owner of three NDAs that authorize it to sell the drug colchicine for treatment of gout and Familial Mediterranean Fever ("FMF"). In Takeda's original complaint in this case, it alleged that Watson had infringed under § 271(e) fourteen patents covering treatment of gout based on Watson's filing of an ANDA seeking approval to sell generic colchicine for gout treatment.

4. In May of this year, however, Watson amended its ANDA to "carve out" gout treatment by filing a section viii statement under 21 U.S.C. § 355(j)(2)(A)(viii) averring that the ANDA excludes all gout treatment uses. Watson instead limited its ANDA to a request for approval to treat FMF. Because Watson is no longer seeking approval for gout treatment, the

fourteen counts in Takeda's original complaint—all asserting gout treatment patents—are mooted, and should be withdrawn by Takeda. The Federal Circuit has held that a § 271(e) claim may not be based on an ANDA that does not seek approval of a drug for use in a method covered by the patent that plaintiff seeks to assert. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354, 1356 (Fed. Cir. 2003).

5. Rather than dismiss its gout treatment counts in view of Watson's ANDA amendment, Takeda filed the instant motion seeking to recast its § 271(e) claims for the gout patents as claims under § 271(c) for a declaratory judgment of future contributory infringement of those same patents.

6. This approach is fatally flawed because, in the absence of a legitimate § 271(e) claim, Takeda must show an independent basis for subject matter jurisdiction over its declaratory judgment claims. *Intermedics, Inc. v. Ventritex Co.*, 1993 U.S. App. LEXIS 3620 (Fed. Cir. Feb. 22, 1993). Takeda cannot establish a case or controversy here because its claims are based solely on Watson's ANDA filing and rank speculation about the future.

7. Takeda has not alleged any facts that show there is an immediate controversy concerning "future contributory infringement" by Watson that is ripe for decision. This is because none of the facts necessary to prove such a claim have occurred or will occur with certainty. Contributory infringement requires proof that a contributory infringer sold a product, especially designed for infringement, to another who actually used the product to directly infringe a patented process. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010).

8. In this case, Takeda has not alleged either the sale of colchicine or the direct infringement of the gout patents. Watson's ANDA has not been approved and may never be approved by the FDA, meaning Watson may never be free to sell colchicine. Watson has not

offered for sale or sold any colchicine to customers, so that there are no direct infringers who have directly infringed Takeda's gout treatment patents, or will do so in the foreseeable future. Moreover, Takeda has been granted Orphan Drug Exclusivity for colchicine treatment of FMF that precludes Watson from selling colchicine until July 29, 2016, regardless of the outcome of this lawsuit.

9. Takeda's declaratory judgment counts must also be rejected because they fail to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6). Under § 271(c), there can be no contributory infringement based on the sale of a "staple article of commerce" that is "suitable for substantial noninfringing use." 35 U.S.C. § 271(c). According to the Supreme Court, a "substantial noninfringing use" is *any* use that does not infringe the asserted patent. *Sony Corp. v. Universal City Studios*, Inc., 464 U.S. 417, 440-441 (1984).

10. Takeda concedes in its amended complaint that colchicine is used for purposes other than treating gout according to its patent. (D.I. 19-1 at 7-9, ¶¶ 18-20 and 23; at 13-19, Counts I-V). In particular, Takeda admits that (a) colchicine was used to treat gout in the prior art according to methods not covered by Takeda's gout patents; (b) colchicine was used to treat FMF in the prior art according to methods not covered by Takeda's gout patents; and (c) colchicine is currently being used to treat FMF according to methods not covered by Takeda's gout patents. *Id.* Thus, the facts alleged by Takeda establish as a matter of law, not fact, that there are at least three substantial uses of colchicine that do not infringe Takeda's gout patents. Takeda has therefore failed to state a claim upon which relief can be granted for contributory infringement.

## CONCISE STATEMENT OF THE FACTS

### A. Colchicine treatment of gout and FMF

The drug colchicine is a derivative of the autumn crocus plant, which was widely used to treat gout in Europe at least as early as the 1700s. (Goggin Ex. 1[1] at 674.) It is believed that Benjamin Franklin brought autumn crocus back from Europe and popularized its use in America as a treatment for gout. (*Id.*) Colchicine was first chemically purified from its plant source in 1820, and has been continuously used ever since for treatment of gout. (*Id.*; Goggin Ex. 2 at 60768.) In addition, the use of colchicine to treat FMF has been documented in the medical literature for several decades. (Goggin Ex. 1 at 676; Goggin Ex. 2 at 60768.)

Because the medical use of colchicine was well established when the FDA was created in 1938, colchicine was not a "new drug" that was required to go through the FDA approval process. (Goggin Ex. 3.) As a consequence, colchicine was for many decades prescribed by physicians to treat gout and FMF even though there was no FDA approved supplier of the drug. (*Id.*) Throughout that time, colchicine was available at very low cost from a large number of manufacturers operating in a competitive market.

In 2006, the FDA announced its Unapproved Drugs Initiative whereby it offered short-term exclusivity to manufacturers who would perform on established drugs that were not FDA approved, such as colchicine, the testing that the FDA requires for new drugs. (Goggin Ex. 4.) Pursuant to this program, Takeda's predecessor Mutual Pharmaceuticals filed an NDA covering the use of Colcrys® brand colchicine to treat gout.[2] (*Id.*) In 2009, the FDA granted Mutual a 3-year period of exclusivity during which all other sellers of colchicine were driven from the market. (Goggin Ex. 5; Goggin Ex. 6 at ¶ 9.) Mutual was also granted a 7-year period of

[1] Exhibit to the Declaration of Matthew J. Goggin, filed herewith.
[2] Takeda is now the owner of the Mutual NDAs covering the use of colchicine to treat gout and FMF.

exclusivity under the Orphan Drug Act for the sale of colchicine for treatment of FMF. (Goggin Ex. 2 at 60768-69; Goggin Ex. 6 at ¶ 10.) Takeda's Orphan Drug Exclusivity expires in July 2016. (Goggin Ex. 6 at ¶ 10.)

These FDA programs have been a bonanza for Takeda. After the FDA granted it market exclusivity, Takeda raised the price of colchicine from $0.09 per pill to $4.85 per pill. (Goggin Ex. 3). In addition, on the basis of the specific research requested by the FDA on old treatment methods for FMF and gout, Takeda filed numerous patent applications covering methods of treating gout and FMF with colchicine. (*See, e.g.*, Goggin Ex. 7.) These patent applications ultimately matured into the 17 patents that Takeda seeks to assert against Watson in its amended complaint here. Of these, twelve include claims directed to treatment of gout alone; two have claims that cover treatment of both gout and FMF, and three have claims to FMF treatment alone. Takeda has listed all these patents in the FDA Orange Book in association with its NDAs.

| **Takeda Patent** | **Claimed Methods** | **Proposed Amended Complaint** |
|---|---|---|
| U.S. Patent 7,906,519 | Treatment of FMF | Count I |
| U.S. Patent 7,935,731 | Treatment of FMF | Count II |
| U.S. Patent 8,093,298 | Treatment of FMF | Count III |
| U.S. Patent 7,964,648 | Treatment of FMF & Gout | Count IV |
| U.S. Patent 8,093,297 | Treatment of FMF & Gout | Count V |
| U.S. Patent 7,619,004 | Treatment of Gout | Count VI |
| U.S. Patent 7,601,758 | Treatment of Gout | Count VII |
| U.S. Patent 7,820,681 | Treatment of Gout | Count VIII |
| U.S. Patent 7,915,269 | Treatment of Gout | Count IX |
| U.S. Patent 7,964,647 | Treatment of Gout | Count X |
| U.S. Patent 7,981,938 | Treatment of Gout | Count XI |
| U.S. Patent 8,093,296 | Treatment of Gout | Count XII |
| U.S. Patent 8,097,655 | Treatment of Gout | Count XIII |
| U.S. Patent 8,415,395 | Treatment of Gout | Count XIV |
| U.S. Patent 8,415,396 | Treatment of Gout | Count XV |
| U.S. Patent 8,440,721 | Treatment of Gout | Count XVI |
| U.S. Patent 8,440,722 | Treatment of Gout | Count XVII |

## B. Takeda's infringement allegations

### 1. The original complaint was limited to the gout patents

In January 2014, Watson sent a Notice Letter to Takeda informing it that Watson had filed an ANDA seeking approval to market generic colchicine for prophylaxis and treatment of gout flares in adults. (D.I. 19-1 at ¶¶ 25-26.) The Notice Letter included a Paragraph IV[3] certification directed at the 14 Takeda patents listed in the Orange Book (and in the table above) that include claims directed to treatment of gout, certifying that the patents were invalid or not infringed. (*Id.* at ¶ 25.)

Takeda filed its original complaint in this suit on February 27, 2014, alleging 14 counts of infringement under 35 U.S.C. § 271(e) based on Watson's ANDA filing. The original counts each asserted that, if the ANDA were approved, Takeda's gout patents would be directly infringed by doctors and patients using colchicine to treat gout in accordance with approved product label, and that Watson would be liable under § 271(e) for contributory infringement. (D.I.1 at 7-30.)

On May 12, 2014, Watson sent a new Notice Letter that informed Takeda that Watson had amended its ANDA to seek approval for treatment of FMF and to withdraw its request for approval for treatment of gout. (D.I. 19-1 at 10-11, ¶¶ 28-29.) The Paragraph IV certification in the second letter was limited to the five Takeda patents that included claims covering methods of treating FMF with colchicine. (*Id.* at 11, ¶ 28.)

### 2. The amended complaint alleges "future contributory infringement"

Although Watson is not seeking approval to sell colchicine for gout treatment, Takeda nevertheless seeks to assert in its amended complaint 14 declaratory judgment counts requesting

[3] 21 U.S.C. § 355(j)(2)(B)(iv).

preemptive relief to prevent *future* contributory infringement of the gout treatment patents.[4] (D.I. 19-1, Counts IV – XVIII.) Each count contends that upon approval of Watson's ANDA, Watson, in violation of 35 U.S.C. § 271(c), will contribute to the infringement of the patents by selling its product "for the prevention and treatment of gout flares." *Id.*

Takeda does not allege that Watson's proposed drug label—which recommends colchicine only for treatment of FMF—supports a contributory infringement claim. Takeda instead alleges that the ANDA drug label is irrelevant to contributory infringement. (D.I. 19-1 at 8-9, ¶¶ 21-23.) The complaint suggests that the FDA approval process is a sham because physicians will prescribe a drug for infringing "off label" uses of colchicine "whether or not that indication appears on the generic label." *Id.* at ¶ 21. It further contends that pharmacists will substitute Watson's generic colchicine for Takeda's branded drug "irrespective of whether the generic drug is FDA-approved for the indication for which the brand drug is prescribed." *Id.* at ¶ 22. According to the complaint, Watson knows about these alleged weaknesses in the system, and therefore, intends that physicians will improperly prescribe generic colchicine and pharmacists will improperly fill prescriptions with it. (*Id.;* D.I. 20 at 1, 6.) These allegations—not any conduct by Watson—are the basis of Takeda's declaratory judgment counts.

Also pertinent to the contributory infringement allegations, the amended complaint describes three commercial uses of colchicine that do not infringe its gout treatment patents. The

[4] In Takeda's proposed Amended Complaint, in addition to the 14 counts seeking a declaratory judgment of future contributory infringement in relation to the gout patents, Takeda has also asserted five counts of infringement under § 271(e) of its FMF treatment patents based on the ANDA amendment seeking approval for FMF treatment. (D.I. 19-1, Counts I – V.) Two of the § 271(e) allegations are included in Counts IV and V, which also include declaratory judgment requests based on the gout patents. Watson does not oppose Takeda's proposed amendment to Counts I-III, and opposes new Counts IV and V only to the extent they seek a declaratory judgment based on the gout patents.

complaint admits that colchicine was used to treat gout and FMF according to prior art methods long before Takeda filed any of its seventeen patent applications,[5] citing prescribing data for both uses going back to 2004. (D.I. 19-1 at 7, ¶ 19.) As a result, Takeda asserts, "physicians regularly use the phrase 'colchicine' instead of Colcrys® when writing prescription for patients suffering from gout flares." *Id.* at 9, ¶ 23. *Id.* In addition, the FMF treatment methods described in Counts I to V of the complaint do not infringe the gout treatment patents. *Id.* at 13-19.

## ARGUMENT

Federal Rule of Civil Procedure 15(a)(2) provides that a party may amend its pleading with leave of the court. Fed. R. Civ. P. 15(a)(2). It is a matter of the court's discretion whether to grant a motion to amend under Rule 15(a)(2). *Foman v. Davis*, 371 U.S. 178, 182 (1962). While leave to amend should be given when justice so requires, a court may deny a motion under Rule 15(a)(2) on the basis of undue delay, bad faith, dilatory motive, prejudice, or futility. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). "Futility means that the complaint, as amended, would fail to state a claim upon which relief could be granted." *Id.* An amendment is futile if the court lacks subject matter jurisdiction over the claims as amended. *Harrison v. Henry*, 2009 U.S. Dist. LEXIS 13746, at*31 (D. Del. Feb. 24, 2009) (citing *Miklavic v. USAir, Inc.*, 21 F.3d 551, 557-58 (3rd Cir. 1994)). The court here should deny Takeda's motion to amend as futile because (1) the Court lacks subject matter jurisdiction over the new declaratory judgment allegations, and (2) Takeda has failed to state a claim for contributory infringement for which relief can be granted.

[5] Takeda's earliest patent application for a colchicine treatment method was filed in 2008, resulting in U.S. Patent No. 7,619,004.

## A. Takeda's motion should be denied as futile under Rule 15(a)(2) because there is no subject matter jurisdiction over its declaratory judgment claims

### 1. The Hatch-Waxman Act does not provide subject matter jurisdiction over Takeda's claims based on Watson's possible future acts

Takeda's declaratory judgment counts are based entirely on Watson's ANDA for colchicine, and could not have been brought under § 271(e) because the ANDA does not seek permission to sell colchicine for a use covered by the gout patents listed in the Orange Book that Takeda seeks to assert in its proposed counts. The ANDA instead seeks permission to sell colchicine for treatment of FMF. The Federal Circuit has held that "a patented method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval to market the drug for that use." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358-59 (Fed. Cir. 2003). Under these cases, Takeda could not bring a § 271(e) claim for infringement of its gout treatment patents based on an ANDA that only sought approval for FMF treatment.

Section 271(e) was created as part of the Hatch-Waxman Act to allow branded pharmaceutical companies such as Takeda, in limited circumstances, to litigate patent disputes based entirely on an ANDA filing before any infringing product had been made or sold by a generic company. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). The Federal Circuit has acknowledged that a § 271(e) claim "is, by its very nature, speculative to a certain degree." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331 (Fed. Cir. 2003). And the Supreme Court has described § 271(e) as defining "a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications." *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

Section 271(e) provided a basis for subject matter jurisdiction in certain cases that otherwise would have failed to meet the standard for lack of case or controversy. *Allergan*, 324 F.3d at 1332. The Federal Circuit has explained that "section 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity." *Id.*; *Glaxo*, 110 F.3d at 1569. The "defined act" that creates a case or controversy is the filing of an ANDA that seeks approval to sell a drug for a use covered by a listed patent that the plaintiff seeks to assert. *AstraZeneca Pharm. LP*, 669 F.3d at 1379; *Warner-Lambert Co.*, 316 F.3d at 1358-59.

Litigation of ANDA claims under § 271(e) is by its nature based on speculation about future events. *Glaxo, Inc.*, 110 F.3d at 1569. In a typical § 271(e) case, the accused drug has not yet been "made, used, sold, and is thus not necessarily available for the court to compare to the claims." *Id.* Thus, "[s]ection 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." *Id.*

**(a) Takeda's declaratory judgment claims are precluded under § 271(e) because Watson's ANDA does not seek approval to use colchicine for treatment of gout**

"[I]t is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-55 (Fed. Cir. 2003). The Federal Circuit has unequivocally held that "a patented method of using a drug can only be infringed under § 271(e)(2) by filing an ANDA that seeks approval to market the drug for that use." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012). The statute even provides a carve-out process—known as a "section viii

statement"—by which an ANDA applicant can expressly exclude NDA-approved uses from their ANDA product label. *Id.* at 1374. If an ANDA applicant files a section viii statement carving out specific indications, patents claiming uses for those indications are beyond the scope of § 271(e)(2). *Id.*; *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1334 (Fed. Cir. 2003) (precluding suit under 271(e)(2) where the uses claimed in the patent were not FDA-approved). To allow a patentee to assert claims for off-label methods of use patents under § 271(e)(2) would "confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." *Allergan*, 324 F.3d at 1333 (quoting *Warner-Lambert*, 316 F.3d at 1359).

Applying these principles here, Takeda cannot sue Watson for infringing its gout patents under § 271(e) because Watson's ANDA does not seek approval to sell colchicine for treatment of gout. Watson's ANDA instead seeks approval for treatment of FMF. Watson's ANDA filing is not an "act of infringement" under § 271(e) with respect to the gout patents, and therefore, Takeda cannot claim subject matter for these infringement claims from § 271(e). Shorn of § 271(e) support for jurisdiction, Takeda's declaratory judgment claims are merely speculative claims based on unknown future events. *Glaxo*, 110 F.3d at 1569.

**(b) Congress did not intend for Hatch-Waxman to create jurisdiction for Takeda's claims other than those under § 271(e)**

Takeda is attempting to thwart the intended limitations on ANDA litigation by recasting ANDA claims that could not be litigated under § 271(e) as declaratory judgment counts based solely on Watson's ANDA filing. Section 271(e)(2) causes of action are limited to treatment indications that are expressly included in the ANDA. *Id.* at 1359; *AstraZeneca*, 669 F.3d at 1379. Thus, claims for infringement based on indications that are not in the ANDA cannot be

premised on the filing of the ANDA. *Id.* Rather, like any other case outside of the Hatch-Waxman framework, they can be determined only upon actual infringement. In such cases, the infringement analysis focuses on the product that is made, used, sold or offered for sale, and not simply what is described in the ANDA. 35 U.S.C. §§ 271(a)-(c). This is the difference between the "artificial" act of infringement that is the foundation of § 271(e)(2) and actual infringement.

Here, Takeda seeks to utilize the benefits of § 271(e)(2) in a situation where Congress did not intend for it to apply. This lawsuit, based solely on Watson's filing of its ANDA, creates jurisdiction under § 271(e)(2) for *only* those patents claiming uses that are covered in Watson's ANDA. Watson's proposed ANDA product is indicated only for the treatment of FMF; there is no longer any reference to gout in Watson's ANDA label. In fact, Watson has filed a section viii carve-out for gout, meaning that Watson has told the FDA that it will not market its proposed ANDA product for the treatment of gout. Therefore, Watsons's alleged infringement of the gout patents can only be determined once Watson has *actually* marketed its proposed product. To allow a determination at this stage would thwart Congress's intent, ignore past precedent, and circumvent the limits of § 271(e)(2). What is certain, however, is that Takeda cannot rely on § 271(e) to provide subject matter jurisdiction over its proposed declaratory judgment counts.

**2. There is no basis for subject matter jurisdiction for Takeda's claims that is independent of § 271(e)**

In the absence of a qualifying ANDA, Takeda cannot claim the benefit of subject matter jurisdiction under § 271(e). Rather, the plaintiff must establish the existence of a case or controversy independent of § 271(e) based on traditional constitutional standards, including the requirement that the dispute have immediacy and be ripe for resolution. *Intermedics, Inc. v. Ventritex Co.*, 1993 U.S. App. LEXIS 3620, at *13-15 (Fed. Cir. 1993) (unpublished); *Eisai Co., Ltd. v. Mutual Pharm. Co.,* 2007 U.S. Dist. LEXIS 93585, at *51-58 (D.N.J. Dec. 20, 2007).

**(a) Takeda's § 271(c) claims are not based on a controversy of sufficient immediacy and reality**

The burden is on the plaintiff to prove, by a preponderance of the evidence, that an actual controversy exists. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed. Cir. 1992). "A claim is not ripe for adjudication if it rests upon 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) (internal quotations omitted). Takeda's new counts are not ripe under this standard because they are based on events that may never occur.

Takeda has only alleged that Watson filed an ANDA, and that Watson may in the future contributorily infringe the gout patents if a future patient practices the methods of those patents. These allegations are grounded in pure speculation. Watson's ANDA has not been approved and may never be approved. Watson has not sold or offered to sell its ANDA product to any customers. Takeda identifies not even a single direct infringer of any of its gout patents. Even if Watson's ANDA is approved by the FDA, it will not be able to sell generic colchicine until after Takeda's Orphan Drug Exclusivity expires in July 2016, and Watson may then decide for business reasons not to market a colchicine product.

This court does not have jurisdiction over Takeda's declaratory judgment claims under § 271(c). Contributory infringement under § 271(c) requires an initial finding of direct infringement, and there can be no direct infringement until Watson enters the market. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 2014 U.S. LEXIS 3817, at *9 (U.S. June 2, 2014); *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010). The alleged contributory infringement by Watson is not immediate, and is not even certain, because Watson is prohibited from entering the market until it gains FDA approval. As of today, Watson's proposed colchicine product has not been approved by the FDA and cannot be approved by the FDA. No

one can be sure if it will ever be approved by the FDA. Moreover, Watson has not made, offered for sale or sold its ANDA product. Thus, this controversy is neither immediate nor certain.

In *Intermedics, Inc. v. Ventritex Co., Inc.*, the Federal Circuit affirmed a court's dismissal of declaratory judgment claims where the defendant did not yet have FDA approval of its device. 1993 U.S. App. LEXIS 3620 (Fed. Cir. Feb. 22, 1993). In that case, the defendant Ventritex was in the process of seeking FDA approval for its implantable defibrillators. Ventritex had not sold any defibrillators, but was only in the beginning stages of clinical trials. *Id.* at *2. The district court held that Ventritex's activities were protected from suit under 35 U.S.C. § 271(e)(1), and further that it had no jurisdiction over Intermedics' declaratory judgment claims. The Federal Circuit agreed with the district court that there was no controversy of sufficient "immediacy and reality" where: (1) Ventritex was prohibited from selling its defibrillators before it obtained FDA approval; (2) it was impossible to know when and if the FDA might grant approval; and (3) the FDA could require Ventritex to make changes to the device before granting approval. *Id.* at *14-15.

This case is very similar to *Ventritex*. Here, it is entirely speculative as to when or even if the FDA will grant approval for Watson's proposed colchicine product. Takeda's exclusivity under the Orphan Drug Act does not expire until July 29, 2016. Moreover, Watson's 30-month stay prevents the FDA from approving Watson's ANDA until at least November 13, 2016. Thus, November of 2016 is the earliest that the FDA could possibly approve Watson's drug product for sale unless Watson first prevails in this litigation, another speculative fact.

Even then, however, there are several other contingencies that may prevent Watson from entering the market. First, the FDA may not approve Watson's ANDA if the tests and data in Watson's ANDA do not satisfy the FDA's requirements. Second, the FDA cannot approve

Watson's ANDA unless Watson wins this patent litigation with respect to the FMF patents. If the Orange Book patents for Watson's FMF indication are found valid and infringed in this lawsuit, then the FDA cannot grant approval until expiration of those patents in 2029. Finally, Watson may decide not to market colchicine. For any and all of the above reasons, this case is not of sufficient immediacy and reality to warrant declaratory judgment jurisdiction.

Other courts have reached the same conclusion in similar circumstances. For example, in *Eisai Co. v. Mutual Pharm. Co.*, the District of New Jersey found there was no case or controversy because

> [t]he alleged future infringement depends on two contingent future events: FDA approval of Mutual's ANDA, and Mutual's decision to market a generic version of [the ANDA drug] pursuant to the NDA. At least until the ANDA is approved, however, the controversy is not sufficiently immediate.

2007 U.S. Dist. LEXIS 93585, at *62 (D.N.J. Dec. 20, 2007). Similarly, in a recent case before the Eastern District of North Carolina, *Reckitt Benckiser Pharmaceuticals v. Biodelivery Sciences International*, the court concluded that it lacked subject matter jurisdiction because the alleged future infringement depended on approval of the NDA and defendant's decision to market the drug. 2014 U.S. Dist. LEXIS 69805, *5-7 (E.D.N.C. May 21, 2014); *see also AstraZeneca Pharms. LP v. Mylan Pharm, Inc.*, 2008 U.S. Dist. LEXIS 96289, at *46-47 (finding no controversy of "sufficient immediacy" where the defendants had not and could not immediately obtain FDA approval); *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992) (concluding that the district court correctly found lack of declaratory judgment jurisdiction where defendant lacked FDA approval).

The *Intermedics* court explained that it would be nonsensical to permit the defendant to be protected from direct suit for infringement under § 271(e) and yet allow the same activities to

be subject to suit in a declaratory judgment action. 1993 U.S. App. LEXIS 3620 at *15. The same analysis applies here where Takeda is attempting to disguise its ANDA claim as a declaratory judgment because it is forbidden from litigating it under § 271(e).

**(b) Takeda's off label use contentions do not create a real case or controversy**

Although Watson's ANDA is expressly limited to treatment of FMF, Takeda argues that its gout patents will be infringed in the future because of off label uses by prescribing physicians and pharmacists. (D.I. at 20 at 6; D.I. 19-1 at 8-9.)

Takeda identifies nothing that Watson has said or done that is inconsistent with the statements in its ANDA. Instead, it alleges that because off label uses are supposedly common knowledge, Watson must know about them and intend that doctors and pharmacists use colchicine for unapproved uses not on the ANDA label. (D.I. 19-1 at 13, ¶¶ 39-40.) The thrust of Takeda's argument is that FDA approval of drug labels is an ineffective sham and that the label should be ignored.

The Federal Circuit rejected the argument that alleged "off label" uses could establish jurisdiction over an ANDA claim that did not qualify under § 271(e) in *AstraZeneca*, 669 F.3d 1370, 1380 (Fed. Cir. 2012). As in this case, the ANDA at issue had carved out the patented uses of the approved drug. *Id.* at 1379. The appellant urged the court to assert jurisdiction because the carve-out ignored "market realities because even if a generic drug is formally approved only for unpatented uses, pharmacists and doctors will nonetheless substitute the generic for all indications once is becomes available." *Id.* at 1380. The court refused, rejecting the very argument Takeda asserts here, because it would improperly enable § 271(e) infringement claims "despite the fact that Appellees' section viii statements and corresponding

proposed labeling explicitly and undisputedly carve out all patented indications for [the drug]."[6] *Id.*

Takeda's "off label" contentions should be rejected here for the same reason. As in *AstraZeneca*, Watson has filed a section viii statement in its ANDA that explicitly and undisputedly carves out indications for treatment of gout. The FDA drug approval process is based on the premise that drug makers will tell the truth in their filings and follow the law if granted approval. Takeda has presented no allegations that would support an allegation that Watson intends anything other than to sell colchicine for treatment of FMF.

### B. Takeda fails to state a claim for Contributory Infringement because the complaint establishes substantial noninfringing uses for colchicine

As discussed above, an amendment to a complaint is futile if it fails to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6). *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). A complaint fails to state a claim if, assuming the truth of the plaintiff's factual allegations, the complaint has not pled facts that would entitle it to relief under the law. *Doug Grant v. Greate Bay Casino Corp.*, 232 F.3d 173, 183 (3d Cir. 2000).

Takeda's contributory infringement allegations fail under this standard because the facts alleged in the complaint establish that colchicine is a staple article of commerce that is suitable for substantial noninfringing uses. The text of § 271(c) provides that a contributory infringement claim cannot be brought if the accused product is a "staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c).

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[6] The court reached the same conclusion in the case that is the centerpiece of Takeda's brief, *Novartis Pharm. Corp. v. Wockhardt USA LLC.*, 2013 U.S. Dist. LEXIS 152141 (D.N.J. Oct. 23, 2013). The plaintiff there alleged that defendant's section viii carve out was "knowingly incorrect" because of statistical data showing most patients used the drug for a patent method. *Id.* at *10-11.

The allegations in the amended complaint, accepted as true for purposes of this motion, establish that colchicine has at least three substantial non-infringing uses in relation to Takeda's gout-treatment patents: (1) treatment of gout according to prior-art methods not covered by Takeda's patents; (2) treatment of FMF according to prior-art methods; and (3) treatment of FMF according to the methods covered by Takeda's FMF-treatment patents. (D.I. 19-1 at 7-9, ¶¶ 18-20 and 23; at 13-19, Counts I-V). Takeda expressly asserts in the amended complaint that before 2009, when it filed its NDA, "non-FDA approved colchicine was prescribed in the United States" for treatment of gout flares. *Id.* at 9, ¶ 23. Takeda asserts throughout its complaint that physicians remain free to use colchicine for these non-infringing treatment methods.

These alleged facts establish the substantial noninfringing uses of colchicine as a matter of law. The Supreme Court in *Sony Corp. v. Universal City Studios* reviewed the law of contributory patent infringement and said that a patentee has no right "to control the distribution of unpatented articles unless they are unsuited for any commercial noninfringing use." 464 U.S. 417, 441 (1984), *citing Dawson Chemical Co. v. Rohm & Hass Co.,* 448 U.S. 176, 198 (1980). The court explained that "unless a commodity has no use except through practice of the patented method, the patentee has no right to claim that its distribution constitutes contributory infringement." *Sony*, 464 US at 441. Thus, "a sale of an article which though adapted to an infringing use is also adapted to other and lawful uses, is not enough to make the seller a contributory infringer." *Id.*

Since Takeda itself has identified three uses of colchicine that do not infringe its gout-treatment patents, its amended complaint fails to state a claim for contributory infringement upon which relief can be granted.

## CONCLUSION

For the foregoing reasons, Takeda's motion to amend should be denied to the extent it seeks declaratory judgments in Counts IV – XVII that Watson's ANDA will in the future contributorily infringe Takeda's patents covering colchicine treatment of gout.

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