IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMARIN PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. OMTHERA PHARMACEUTICALS, INC. and ASTRAZENECA PHARMACEUTICALS LP, Defendants.	)	C.A. No. 14-279-GMS

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT

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I. NATURE AND STAGE OF THE PROCEEDINGS

Defendants Omthera Pharmaceuticals, Inc. and AstraZeneca Pharmaceuticals LP (collectively, "Defendants" or "AstraZeneca") respectfully move under Fed. R. Civ. P. 12(b)(1) and 12(b)(6) to dismiss the Complaint of Plaintiff Amarin Pharmaceuticals Ireland Limited ("Amarin"). The Complaint seeks declaratory judgment of induced and contributory infringement of U.S. Patent No. 8,663,662 ("the '662 patent") based on the alleged future commercialization and use of AstraZeneca's Epanova™ pharmaceutical product.

The asserted patent claims a method of administering a drug to a patient to obtain a specific result, namely, reducing triglycerides without increasing low-density lipoprotein cholesterol ("LDL-C") by more than 20%. Allegations of induced and contributory infringement of the sort advanced here critically depend on the contents of the label and instructions for use accompanying U.S. Food and Drug Administration ("FDA") -approved drugs. Yet, FDA has not finally approved a label or any instructions for the use of any Epanova™ product that may be marketed in the future. The absence of FDA-approved labeling leaves Amarin unable to plead specific facts that plausibly support an allegation that Defendants will induce or contribute to the practice of methods that obtain the specific result required by the patent claims. Accordingly, Amarin's conclusory Complaint fails to state an indirect infringement claim upon which relief can be granted. The absence of approved labeling also requires that the Complaint be dismissed for lack of subject matter jurisdiction due to the absence of a real and immediate case or controversy.

II. SUMMARY OF ARGUMENT

1. Amarin does not plead facts plausibly showing that Defendants (1) will take affirmative steps with the specific intent to induce others to infringe the '662 patent and (2) will

know that the acts of others constitute infringement. Therefore, the claim for induced infringement should be dismissed under Fed. R. Civ. P. 12(b)(6).

2. Amarin does not plead facts plausibly showing that AstraZeneca's Epanova™ product (1) will have no substantial non-infringing uses and (2) is known by Defendants to be especially made or especially adapted for use in infringing the patent. Therefore, the claim for contributory infringement should be dismissed under Fed. R. Civ. P. 12(b)(6).

3. The Complaint does not allege facts showing that at the time it was filed, there was a substantial controversy of sufficient immediacy and reality regarding the as-yet unapproved Epanova™ product to warrant the issuance of a declaratory judgment. Therefore, the Complaint should be dismissed under Fed. R. Civ. P. 12(b)(1).

III. STATEMENT OF FACTS

The sole independent claim of the asserted '662 patent is directed to "[a] method of lowering triglycerides in a subject" that comprises administering a pharmaceutical composition to obtain a specific result, that is, "for a period effective to reduce triglycerides in the subject *without increasing LDL-C by more than 20%*." (D.I. 1, Ex. A at col. 25, ll. 34-43, claim 1 (emphasis added).) The Complaint does not allege that there has been any direct infringement to date, such as by use of a product to obtain the specified result. Nor does the Complaint allege that there has been any actual induced or contributory infringement to date, such as by marketing or selling a product with instructions to obtain the specified result. The Complaint is instead premised on alleged future acts by AstraZeneca related to the commercialization of its as-yet unapproved Epanova™ pharmaceutical product. (D.I. 1 ¶¶ 16, 19-21.)

More specifically, the Complaint alleges that AstraZeneca is seeking FDA approval to market and sell its Epanova™ product (*id.* ¶ 16) and contends generally that AstraZeneca will, at some unspecified future time, be liable for induced and contributory infringement of the '662

patent based on sales of the Epanova™ product (*id.* ¶¶ 23-33). The Complaint relies on its Exhibit B for a description of the Epanova™ product as "a coated soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids derived from fish oils, including multiple long-chain omega-3 and omega-6 fatty acids, with EPA [eicosapentaenoic acid], DHA [docosahexaenoic acid], and docosapentaenoic acid [DPA] being the most abundant forms of omega-3 fatty acids." (D.I. 1, Ex. B at 1.) The Complaint, however, does not cite any instructions for how Epanova™ is to be used, and acknowledges instead that the Epanova™ product, and implicitly its instruction and indication label, has not been approved by the FDA. (D.I. 1 ¶ 20.)

IV. ARGUMENT

A. Amarin's Complaint Fails to State a Claim Upon Which Relief Can Be Granted

Amarin's Complaint for alleged future inducement and contributory infringement should be dismissed under Fed. R. Civ. P. 12(b)(6) because it does not "plead 'enough factual matter' that, when taken as true, 'state[s] a claim to relief that is plausible on its face.'" *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1331 (Fed. Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); citing *Fabian v. Fulmer Helmets, Inc.*, 628 F.3d 278, 280 (6th Cir. 2010)). The Federal Circuit has specifically applied the principles of *Twombly* and *Iqbal* to claims for induced and contributory infringement, such that Amarin's Complaint was required to plead ***facts*** plausibly establishing each element of induced and contributory infringement. *See id.* at 1334-46 (citing *Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Twombly*, 550 U.S. 544).

Induced infringement would require that Defendants (1) will take affirmative steps to induce infringement by others, (2) will specifically intend for others to infringe the '662 patent,

and (3) will know that the acts of others constitute infringement. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2068 (2011); *In re Bill of Lading*, 681 F.3d at 1339; *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). Contributory infringement would require that AstraZeneca's Epanova™ product (1) will have no substantial non-infringing uses and (2) is known by Defendants "to be especially made or especially adapted for use in an infringement of such patent.'" *In re Bill of Lading*, 681 F.3d at 1337 (quoting 35 U.S.C. § 271(c)).

Instead, Amarin's Complaint does no more than improperly parrot the elements of induced and contributory infringement without factual basis. (D.I. 1 ¶¶ 23-33.) This is not sufficient. *See Iqbal*, 556 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." (citing *Twombly*, 550 U.S. at 555)). Such formulaic recitation of the elements of induced and contributory infringement is "not entitled to be assumed true" and carries no weight in a Rule 12(b)(6) analysis. *Id.* at 681.

1. Amarin's Claim for Induced Infringement Should Be Dismissed

Amarin's claim for induced infringement is based on the following unsupported and conclusory allegations, which merely recite the elements of inducement:

> 23. The commercial manufacture, sale, offer for sale, and/or importation of Defendants' Epanova™ product will induce the direct infringement of at least claim 1 of the '662 patent under 35 U.S.C. § 271(b).
>
> 24. Defendants have actual knowledge of the '662 patent no later than the date of filing this Complaint.
>
> 25. The use of Epanova™ by patients and/or doctors directly infringes at least claim 1 of the '662 patent.
>
> 26. Defendants will encourage the direct infringement of at least claim 1 of the '662 patent by and through the commercial manufacture, sale, offer for sale, and/or importation of Epanova™.

> 27. On information and belief, Defendants know or should know that their commercial manufacture, sale, offer for sale, and/or importation of Epanova™ will actively induce direct infringement of at least claim 1 of the '662 patent[.]
>
> 28. Defendants' acts described in paragraphs 26 and 27 will be done with knowledge of the '662 patent and with the intent to encourage infringement.

(D.I. 1 ¶¶ 23-28.) Knowledge of the patent, which is undisputed for purposes of the present motion, is not sufficient for plausibly establishing an inducement claim. *See DSU Med.*, 471 F.3d at 1305. Amarin does not plead facts plausibly showing that Defendants (1) will take affirmative steps with the specific intent to induce others to infringe the '662 patent and (2) will know that the acts of others constitute infringement.

The reason for Amarin's pleading failure is self-evident. The labeling for AstraZeneca's Epanova™ product has not been finally approved by the FDA, and the Complaint contains no reference to any instructions for use that will accompany sale of the product in the future. But inducement allegations in the context of pharmaceutical products are based on such instructions. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("The pertinent question is whether the proposed label instructs users to perform the patented method."). Indeed, for a pharmaceutical that can only be marketed for limited purposes, the label is the affirmative act upon which inducement is evaluated. *See* 21 C.F.R. § 201.57 (setting forth the labeling requirements for prescription drugs).

As previously noted, Amarin's Complaint contains no allegations about a label or instructions for use that will be provided with AstraZeneca's Epanova™ product, let alone that such label or instructions will encourage use of the product in an infringing manner. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1324 (Fed. Cir. 2012) ("[T]he point is that the label, taken in its entirety, fails to recommend or suggest to a physician that Yasmin is safe

and effective for inducing the claimed combination of effects in patients in need thereof."). Given the absence of factual averments linking a labeled indication for Epanova™ to the elements of Amarin's patent claims, Amarin has not plausibly pled inducement. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1381 (Fed. Cir. 2012) (dismissing claim where patented use was not the use for which Apotex was seeking FDA approval); *Warner-Lambert v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003) (affirming summary judgment of non-infringement where patented use was not an FDA-approved use); *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1334 (Fed. Cir. 2003) (same).

Amarin does not overcome its failure to rely upon a labeled indication or instruction with any other facts linking the future use of AstraZeneca's Epanova™ product to the method claimed in the '662 patent. Specifically, Amarin does not plead facts plausibly establishing that AstraZeneca's Epanova™ product will be indicated for reducing triglycerides "without increasing LDL-C by more than 20%," as required by the '662 patent claims. (*See* D.I. 1, Ex. A at col. 25, ll. 34-43.) There is no allegation, for example, that the label will instruct physicians (1) to adjust the treatment to limit the increase in LDL-C levels to 20%, or (2) to discontinue treatment if LDL-C levels rise more than 20%.

Consistent with cases previously considered by this Court, without facts plausibly establishing a link between sale of the product and the specifically claimed method of treatment, Amarin's inducement claim cannot survive. *See, e.g., Trans Video Elecs., Ltd. v. Netflix, Inc.*, No. 12-1743-LPS-CJB, 2014 WL 900929, at *3 (D. Del. Mar. 4, 2014) (finding inducement claim insufficient where it "merely parrot[ed] [a portion] of the preamble of [the patent claim]" and "[did] not give any hint as to how the customers' actions [were] said to relate to the content of the method-at-issue"); *Pragmatus AV, LLC v. TangoMe, Inc.*, No. 11-1092-LPS-CJB, 2013

WL 571798, at *12 (D. Del. Feb. 13, 2013) (finding inducement claim insufficient where it did not include "factual allegations . . . about how the use of [the defendant's product] relates to the patented methods"); *E.I. Du Pont de Nemours & Co. v. Heraeus Holding GmbH*, No. 11-0773-SLR-CJB, 2012 WL 4511258, at *8 (D. Del. Sept. 28, 2012) (same). *See also Bascom Research LLC v. Facebook, Inc.*, Nos. 12-6293 to -97, 2013 WL 968210, at *5 (N.D. Cal. Mar. 12, 2013) (dismissing inducement claim that did not specifically allege "how defendants [had] advertised an infringing use or instructed customers or third parties regarding how to engage in an infringing use").

In addition, the Complaint does not plead any basis, in fact or theory, as to how AstraZeneca could know whether a given patient is treated for a period that does not "increas[e] LDL-C by more than 20%," as required by the patent claims, especially when there are no averments that AstraZeneca will instruct or direct such use of Epanova™. Amarin's Complaint thus also fails to plead facts plausibly establishing that AstraZeneca had knowledge, or will have knowledge, that use of Epanova™ will infringe the '662 patent. This is a fatal flaw, as there can be no inducement absent knowledge of actual infringement caused by Defendants' specific encouragement. *See In re Bill of Lading*, 681 F.3d at 1339 ("Liability under § 271(b) 'requires knowledge that the induced acts constitute patent infringement.'" (quoting *Global-Tech Appliances*, 131 S. Ct. at 2068; citing *DSU Med.*, 471 F.3d at 1306)).)

This Court addressed a plaintiff's failure to plead knowledge of direct infringement in *Bonutti Skeletal Innovations LLC v. Smith & Nephew, Inc.*, where the inducement claim was dismissed under Fed. R. Civ. P. 12(b)(6). No. 12-1111-GMS, 2013 WL 6058472 (D. Del. Nov. 18, 2013). The complaint in *Bonutti* alleged that "[the defendant] knew of [the] patents and of its customers' use of [the defendant's] products." *Id.* at *2 n.5. In dismissing the inducement

claim, this Court stated that "[a]llegations that [the defendant] knew of [the] patents and of its customers' use of [the defendant's] products [did] not suffice to establish that [the defendant] also knew that its customers' use of [its] own products would amount to infringement of [the] patents." *Id.* (citing *Bill of Lading*, 681 F.3d at 1323). Amarin's conclusory allegations of knowledge of infringement are likewise deficient.

Because Amarin does not plead facts plausibly showing that Defendants (1) will take affirmative steps with the specific intent to induce others to infringe the '662 patent and (2) will know that the acts of others constitute infringement, Defendants respectfully request that the claim for induced infringement be dismissed.

2. Amarin's Claim for Contributory Infringement Should Be Dismissed

Like its claim for inducement, Amarin's claim for contributory infringement does no more than improperly parrot the elements of contributory infringement. More specifically, Amarin's claim for contributory infringement is based on the following conclusory, unsupported allegations:

> 29. The commercial manufacture, sale, offer for sale, and/or importation of Epanova™ will contribute to the direct infringement of at least claim 1 of the '662 patent under 35 U.S.C § 271(c).
>
> 30. On information and belief, Defendants know or should know Epanova™ will be especially made or especially adapted for use in an infringement of the '662 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.
>
> 31. On information and belief, Defendants know or should know that their offer for sale, sale and/or importation of Epanova™ will contribute to the direct infringement of the '662 patent.
>
> 32. Defendants' acts described in paragraphs 29 through 31 will be done with knowledge of the '662 patent and with the intent to encourage infringement.

(D.I. 1 ¶¶ 29-32.) Amarin does not plead facts plausibly supporting these conclusory and formulaic recitations.

This Court dismissed a claim for contributory infringement under similar circumstances in *Bonutti*. Unlike Amarin's Complaint, which is purportedly premised on future potential commercial acts by AstraZeneca, the plaintiff's claim for contributory infringement in *Bonutti* "properly plead[ed] facts establishing that [the defendant] sold or offered for sale products that infringe[d] the patents-in-suit, and possessed and continued to possess knowledge of the patents-in-suit." 2013 WL 6058472, at *2 n.5. Even still, this Court dismissed the contributory infringement claim in *Bonutti* because it did not adequately plead "that [the defendant's] products [had] no other substantial non-infringing uses." *Id.* (citing *Stephenson v. Game Show Network, LLC*, 933 F. Supp. 2d 674, 681 (D. Del. 2013)).

Amarin's conclusory allegations suffer from the same defect. Specifically, the Complaint does not include facts from which it may be inferred that Epanova™ has no substantial non-infringing use, such as a use where LDL-C is increased by more than 20%. Merely using the words "no substantial non-infringing use" is insufficient. *In re Bill of Lading*, 681 F.3d at 1337. *See also CAO Group, Inc. v. Sybron Dental Specialties, Inc.*, No. 12-1062, 2014 WL 119134, at *2-3 (D. Utah Jan. 10, 2014) (dismissing contributory infringement claim where it alleged generally that the products had no substantial non-infringing use); *Palmetto Pharms. LLC v. AstraZeneca Pharms. LP*, No. 11-0807, 2012 WL 484907, at *7 (D.S.C. Jan. 4, 2012) (finding contributory infringement claim inadequate where it did not plead facts plausibly establishing no substantial non-infringing uses); *Shearing v. Optical Radiation Corp.*, No. 93-850, 1994 WL 382444, at *2 (D. Nev. Mar. 25, 1994) (dismissing contributory infringement claim where it did not provide facts alleging that the product was not suitable for substantial non-infringing use).

Amarin's Complaint also fails to adequately plead that AstraZeneca knows, or will in the future know, that the Epanova™ product is "especially made or especially adapted for use in an infringement of" the '662 patent. *See* 35 U.S.C. §271(c). Indeed, for the same reasons that Amarin failed to plead facts supportive of the requisite knowledge for inducement, it also failed to plead facts supportive of such knowledge for its contributory infringement claim. As noted in *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330 (Fed. Cir. 2010) (quoting *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004)):

> [W]e disagree with Philips' claim that it need only show that Netgear knew of the patent and of the relevant acts, not whether these acts constituted infringement. Our case law is clear that Philips must show that Netgear "knew that the combination for which its components were especially made was both patented and infringing."

Because Amarin does not plead facts plausibly showing that AstraZeneca's Epanova™ product (1) will have no substantial non-infringing uses and (2) is known by Defendants to be especially made or especially adapted for use in infringing the patent, Defendants respectfully request that the claim for contributory infringement be dismissed.

B. This Court Lacks Subject Matter Jurisdiction Over Amarin's Claims

Even if Amarin met the pleading standards for its indirect infringement claims, the Complaint should be dismissed under Fed. R. Civ. P. 12(b)(1) for failing to "satisfy the case-or-controversy requirement." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007). Specifically, the Complaint does not allege facts showing that at the time it was filed "there [was] a substantial controversy . . . of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Casualty Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)); *see also Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 05-0590-GMS, 2006 WL 2375035, at *2-3 (D. Del. Aug. 16, 2006) (stating that "the court must test the existence of

jurisdiction as of the time the complaint was filed," and that "the declaratory judgment plaintiff bears the burden of proving the existence of facts underlying its allegations of the existence of an actual controversy" (citations omitted)).

First, the Complaint does not meet the immediacy requirement. At the time Amarin filed the Complaint, the FDA had not approved AstraZeneca's Epanova™ product and Defendants could not predict when, or if, the FDA would approve the product. *See Eisai Co. v. Mut. Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *18 (D.N.J. Dec. 20, 2007); *Abbott*, 2006 WL 2375035 at *3 n.3 ("[T]he court finds that the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate."). Much like the facially insufficient allegation of an ***expected*** approval date in *Abbott*, Amarin's reference to "the Prescription Drug User Fee Act ('PDUFA') ***goal*** date for the FDA to approve the marketing and sale of Epanova™" (D.I. 1 ¶ 20 (emphasis added)) does not plead the immediacy required for declaratory judgment jurisdiction. *See Abbott*, 2006 WL 2375035, at *3. Also like the complaint in *Abbott*, Amarin's Complaint is additionally insufficient because it does not allege that Defendants have "distributed sales literature, prepared to solicit orders, or engaged in any sales or marketing activity" for its Epanova™ product. *Id.* (citations omitted).

Second, the Complaint does not meet the reality requirement for declaratory judgment jurisdiction. As an initial matter, all Defendants have done thus far is to seek FDA approval to sell a drug. Such activity related to ***obtaining*** FDA approval is protected from claims of infringement by the safe harbor provision of 35 U.S.C. § 271(e)(1) and cannot serve as the basis of a declaratory judgment action for future infringement. *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1523-26 (Fed. Cir. 1992); *Intermedics, Inc. v. Ventritex Co.*, 991 F.2d 808, at *4 (Fed. Cir. 1993) (unpublished) ("To permit [the defendant] to be protected from

direct suit for infringement [under § 271(e)(1)] and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical."); *Eisai Co.*, 2007 WL 4556958, at *17.

Moreover, the Complaint does not allege that the FDA has finally approved a label for AstraZeneca's Epanova™ product or contain any other allegations about such a label. Thus, Amarin cannot make the requisite "reality" showing, because induced and contributory infringement claims for a pharmaceutical product depend on the product's label. *See Bayer*, 676 F.3d at 1324; *AstraZeneca*, 669 F.3d at 1381; *Warner-Lambert*, 316 F.3d at 1366; *Allergan*, 324 F.3d at 1334. For the intent element of induced infringement, for example, "[t]he pertinent question is whether the proposed label instructs users to perform the patented method." *AstraZeneca*, 633 F.3d at 1060.

Here, because there is no FDA approved label (and moreover, no allegations about a label), the question of induced and contributory infringement is presently unanswerable. Indeed, even if the Complaint were based on a draft or proposed product and label, both may change during the approval process. *See, e.g.*, *Abbott*, 2006 WL 2375035, at *3 ("Abbott did not, and could not, allege with any certainty that 'the device when approved would be the same device that began clinical trials . . . ." (quoting *Telectronics*, 982 F.2d at 1527)); *Intermedics*, 991 F.2d 808, at *4 (unpublished) ("At that time [when the complaint was filed prior to FDA approval] it was impossible to know when the FDA might make such a determination in response to Ventritex's application. Moreover, [the] FDA could require Ventritex to make further changes to its device before approval is given."). Thus, the Complaint does not—and cannot—meet the reality requirement for declaratory judgment jurisdiction.

Because the Complaint does not allege facts showing that at the time it was filed, there was a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment, Defendants respectfully request that this action be dismissed.

V. CONCLUSION

For the reasons stated herein, Defendants respectfully request that the Court dismiss Amarin's Complaint under Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

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