UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, et al. ,	Civil No. 14-7992 (NLH/AMD)
Plaintiffs,	
v.	**OPINION** **FILED UNDER SEAL**
ACTAVIS LABORATORIES, UT, INC. , et al .,	
Defendants.	

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HILLMAN, District Judge

This is a Hatch-Waxman Act[1] action that concerns the Abbreviated New Drug Application No. 207238 ("ANDA") filed by Defendant, Actavis Laboratories UT, Inc., for its generic copy of PENNSAID® 2%. Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.) is the

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[1] Prior to 1984, both name-brand and generic drug manufacturers were required to go through the same NDA process. That year, Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. The Act loosened the approval rules for generics by creating an Abbreviated New Drug Application ("ANDA") process. The ANDA process permits generic drug companies to rely on a name-brand drug company's original NDA approval for a particular drug in order to gain quicker, less costly FDA approval of a generic version of the drug. By enabling generic manufacturers to piggy-back on a brand drug's scientific studies and the significant costs associated with their NDA, Hatch-Waxman speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition.

Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Limited Company, 838 F.3d 421, 427 (3d Cir. 2016) (internal quotations and citations omitted).

current owner and assignee of the patents-in-issue,[2] and of the PENNSAID® 2% New Drug Application ("NDA"). PENNSAID® 2% (hereinafter "PENNSAID") is the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis ("OA") of the knees.

The patents-in-suit fall into two patent families: the '838 formulation patent family and '450 method of treatment patent family. The current matter before the Court is Actavis's motion for summary judgment [245] on Horizon's claims that Actavis's ANDA product, through its package labeling, will, if placed into the market, infringe on three patents in the '450 method of treatment patent family.[3] For the reasons expressed below,

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[2] U.S. Patent Nos. 8,252,838 ("the '838 patent"), 8,563,613 ("the '613 patent"), 8,871,809 ("the '809 patent"), 9,066,913 ("the '913 patent"), 9,101,591 ("the '591 patent"), 8,546,450 ("the '450 patent"), 8,217,078 ("the '078 patent"), 8,618,164 ("the '164 patent") and 9,132,110 ("the '110 patent").

[3] The FDA will not give final approval to produce a generic version of a drug that is entitled to non-patent exclusivity under the Hatch-Waxman Act, and it "cannot authorize a generic drug that would infringe a patent." In re Modafinil Antitrust Litigation, 837 F.3d 238, 243 (3d Cir. 2016) (citation omitted). Brand manufacturers are required to include the patent number and expiration date of the patent that covers the drug or that covers a method of using that drug in their NDAs, which are then published by the FDA in the Orange Book, more formally known as the Approved Drug Products with Therapeutic Equivalence Evaluations. Id. (citations omitted). Once a patent has been listed in the Orange Book, the generic manufacturer is free to file an ANDA if it can certify that its proposed generic drug will not actually violate the brand manufacturer's patents. Id. (citation omitted). Under 21 U.S.C. § 355 (j) (2) (A) (vii), there are four ways in which a generic manufacturer can make this

Actavis's motion will be granted.

DISCUSSION

A. Subject matter jurisdiction

This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271.

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certification: (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. An ANDA with a paragraph IV certification may only be filed after the expiration of the fourth year of the New Chemical Entity ("NCE") five-year exclusivity period. Id. (citing 21 U.S.C. § 355(j) (5) (E) (ii)). The paragraph IV route automatically counts as patent infringement. Id. (citing 35 U.S.C. § 271(e) (2) (A)) (quotations and other citations omitted). As a result, this often "means provoking litigation" instituted by the brand manufacturer. Id. (citation omitted). If the brand manufacturer initiates a patent infringement suit, the FDA must withhold approval of the generic for at least 30 months while the parties litigate the validity or infringement of the patent; if the suit has concluded at the end of this 30-month period, then the FDA will follow the outcome of the litigation. Id. (citations omitted). In response, an ANDA applicant sued for patent infringement may "assert a counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or (c) [of§ 355] on the ground that the patent does not claim either- "(aa) the drug for which the [brand's NDA] was approved; or "(bb) an approved method of using the drug." 21 U.S.C. § 355(j) (5) (C) (ii) (I). The counterclaim thus enables a generic competitor to obtain a judgment directing a brand to "correct or delete" certain patent information that is blocking the FDA's approval of a generic product. Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 408-09 (2012)

This action is a "paragraph IV" case, Actavis has asserted counterclaims, and the 30-month period expires on May 14, 2017.

B. Summary judgment standard

Summary judgment is appropriate where the Court is satisfied that the materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations, admissions, or interrogatory answers, demonstrate that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986); Fed. R. Civ. P. 56(a).

C. Analysis

The '450, '078, and '110 patents-in-suit are all from the same method patent family and share substantially similar specifications. The particular claims at issue are: '450 patent, claims 10, 11, 15, 17; '078 patent, claim 14; '110 patent, claims 3, 11, 13.

Horizon alleges that Actavis's ANDA product would improperly induce infringement of its patents in violation of 35 U.S.C. § 271(b), which states, "Whoever actively induces infringement of a patent shall be liable as an infringer." Specifically, Horizon alleges that the FDA-approved use of PENNSAID and the use sought by Actavis is the same use that is claimed in Horizon's '450, '078, and '110 patents. Horizon further claims that Actavis's proposed labeling for its generic version of PENNSAID constitutes an instruction, encouragement,

or recommendation to practice the methods of Horizon's '450, '078, and '110 patents, and the labeling therefore constitutes induced infringement. Actavis argues that it is entitled to summary judgment on these allegations because Horizon cannot demonstrate Actavis's specific intent to induce infringement. Actavis also contends that Horizon cannot refute that its labeling does not induce infringement because its claimed method is different from the methods claimed in Horizon's patents.

In order to determine whether Actavis's labeling induces a use of its product that infringes on Horizon's method patents, the Court must first look to the relevant claims in the method patents.

'450 patent

> 10. A method for applying topical agents to a knee of a patient with pain, said method comprising:
>
> applying a first medication consisting of a topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical diclofenac preparation comprises a therapeutically effective amount of a diclofenac salt and 40- 50% w/w dimethyl sulfoxide;
>
> waiting for the treated area to dry;
>
> subsequently applying a sunscreen, or an insect repellant to said treated area after said treated area is dry, wherein said step of applying a first medication does not enhance the systemic absorption of the subsequently applied sunscreen, or insect repellant;
>
> and wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation.

'078 patent

> 14. A method for applying topical agents to a knee of a patient with pain, said method comprising:
>
> applying a first medication consisting of a topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical

diclofenac preparation comprises a therapeutically effective amount of diclofenac and 40-50% w/w dimethyl sulfoxide;

waiting for the treated area to dry; and

subsequently applying a second medication consisting of a topical medication, which is other than said first medication and comprises a corticosteroid, to said treated area after said treated area is dry, wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation.

'110 patent

1. A method for applying topical agents to a knee of a patient with pain, the method comprising:

(a) a patient obtaining a topical diclofenac preparation;

(b) the patient being informed to:

i) apply a first medication consisting of the topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical diclofenac preparation comprises a therapeutically effective amount of diclofenac, or a pharmaceutically acceptable salt thereof, and 40-50% w/w dimethyl sulfoxide;

ii) wait for the treated area to dry;

iii) subsequently apply a sunscreen, an insect repellant or a second medication consisting of a topical medication, which is other than said first medication, to said treated area after said treated area is dry, wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation, and then

(c) the patient carrying-out steps i-iii as informed.

3. The method according to claim 1, wherein said therapeutically effective amount of diclofenac, or a pharmaceutically acceptable salt thereof, is 2% w/w diclofenac sodium.

10. A method for applying topical agents to a knee of a patient with pain, said method comprising:

(a) providing a topical diclofenac preparation;

(b) providing information to:

i) apply a first medication consisting of the topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical diclofenac preparation comprises a therapeutically effective amount of diclofenac, or a pharmaceutically acceptable salt thereof, and 40-50% w/w dimethyl sulfoxide;

ii) wait for the treated area to dry;

iii) subsequently apply a sunscreen, an insect repellant or a second medication consisting of a topical medication, which is other than said first medication, to said treated area after said treated area is dry, wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation, and then

(c) the patient conducting steps i-iii in accordance with published material.

11. The method according to claim 10, wherein said therapeutically effective amount of diclofenac is 2% w/w diclofenac sodium.

12. A method for applying topical agents to a knee of a patient with pain, said method comprising:

(a) providing a topical diclofenac preparation to the patient;

(b) informing the patient to:

i) apply a first medication consisting of the topical diclofenac preparation to an area of the knee of said patient to treat osteoarthritis of the knee of said patient, wherein the topical diclofenac preparation comprises a therapeutically effective amount of diclofenac, or a pharmaceutically acceptable salt thereof, and 40-50% w/w dimethyl sulfoxide;

ii) wait for the treated area to dry;

iii) subsequently apply a sunscreen, an insect repellant or a second medication consisting of a topical medication, which is other than said first medication, to said treated area after said treated area is dry, wherein said subsequent application occurs during a course of treatment of said patient with said topical diclofenac preparation, and then

(c) administering the first medication to the knee conducting steps i-iii in accordance with a medium providing information.

13. The method according to claim 12, wherein said therapeutically effective amount of diclofenac is 2% w/w diclofenac sodium.

(Docket No. 246 at 11.)

Next, the Court must consider the package labeling. The relevant portions of Horizon's label provides:

----------INDICATIONS AND USAGE ----------

PENNSAID is a r1onsteroidal anti-intlanunatory drug indicated for the treatment ofthe pain ofost oarthritis ()fthe knee(s). (1)

---------- -------- DOS.AG : AND Alli\HNISTRATION -----··----------

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goats.

l11e recommended dose is 2 pump actuations on each paittful knee, 2 times a day. (2)

- Apply PENNSAID, to clean, dry skin. (2.1)
- Dispense 40 mg (2 pump actuations) directly onto the knee or first into the hand and then onto the knee. Spread evenly around front, back and sides ofthe knee. (2.1)
- \Vash hands completely after administering the product. (2.2)
- \Vait until the art!a ls compldddy dry before covering with clothing or applying sunscreen, insect repellent cosmetics, topical rnedications, or other substances. (2.2)
- Until the treated k:nee(s) is completely dry, avoid skin-to-skin contact between other people and the treated kncc(). (2.2)
- Do not get PENNSAID in your eyes nose, or mouth (2.2),

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Instructions

Use the lowest ellcctivc dosage for the shortest duration consistent" ith indi\idual patient lrcatmcnl goals lsc,t Warnings and Precawions (S1)J.

For relief o f the pain o f 1stcoarthritis (OA) o f the kncc(s}, the rccommcndcd dose is 40 mg o f diclofonac sodium (2 pump actuations) on each painful knee. 2 times a day.

Apply PENNSA!D to clean, dry skin.

The pump must be primed before first use. Instruct patients to fully depress the pump mechanism (actuation) 4 times while holding the bottle in an upright position. This portion should be discarded to ensure proper priming o f the pump, No further priming o f the bottle should be required.

A ller 1he priming procedure, PEN NSA!D is properly dispensed by completely depressing the pump 2 times to achieve the prescribed dosage for one knee. Dclh er the product directly into the palm o f the hand and then apply erenly around front, back, and sides or the knee.

Application o f PENN SAID in an amount exceeding or less tlum the recommended dose has not been studied and is therefore not recommended.

2.2 S1>ecial Prec.autions

- Avoid showering/bathing for at least :m minutes alter !he application o f PEN NSA!D to the treated knee,
- Wash and dry hands aller use.
- Do not apply PENN SAID to open wounds.
- Avoid contact o f PENNSAID with c,cs and mucIJus membranes.
- Do not apply external heal andlor occlusive dressings to treated knees.
- A rnid wearing clothing O\er the PENN SA ID-treated knee{s) until the treated knee is dry.
- Protect tlle treated knec{s) from natural and artificial sunlight
- Wait until the treated area is dry before applying sunscreen. insect rcpellant, lotion, moisturizer, cosmetics, or other topical medication to the same knee you Im e just treated with PENNSAID.
- Until the treated lmec(s) is completely dry. a\oid skin-lo-skin contact between other people and the treated knec(s),
- Do not use combination therapy with PENNSAID and an oral NSAID unless the benefit outweighs the risk and conduct periodic laboratory e\aluatlons,

(Docket No. 255 at 11-12.)

The primary language in dispute is, "Wait until the area is completely dry before covering with clothin or applying sunscreen, insect repellant, cosmetics, topical medications, or other substances" and "Wait until the treated area is dry before applying sunscreen, insect repellant, lotion, moisturizer, cosmetics, or other topical medication to the same knee you have just treated with PENNSAID."

Federal law prevents generic drug manufacturers from

changing their labels. Mutual Pharmaceutical Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2476 (U.S. 2013) (21 U.S.C. § 355 (j) (2) (A) (v) ("[T]he labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug.") (other citations omitted). [redacted]

With the patent claims and the product labeling in mind, the Court must now determine whether Actavis's proposed labeling would induce a patient[4] to infringe on Horizon's patents.[5] The

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[4] A party being induced to infringe a patent may be, among others, the patient using the drug, a doctor prescribing the drug, or a pharmacist who advises a customer on how to use the drug. For simplicity, the Court will refer to "the patient" as the alleged induced party.

[5] Actavis argues that judgment should be entered in its favor because Horizon has not shown that any acts of infringement have actually occurred as a result of Actavis's label. Such evidence would be an impossibility at this time because Actavis's ANDA product has not yet been approved for the public. The Federal Circuit has explained that 35 U.S.C. § 271(e) (2) (A)

> provides an "artificial" act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product. Once jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context,

Federal Circuit has set forth the analysis of a § 271(b) induced infringement claim in the context of ANDA proposed package labeling:

> The sale of a lawful product by lawful means, with the knowledge that an unaffiliated, third party may infringe, cannot, in and of itself, constitute inducement of infringement. The accused infringer must have knowingly aided and abetted direct infringement . . . . [T]here is no indirect infringement when a defendant merely sells a commercial product suitable for some lawful use. Infringement only exists where there is evidence that goes beyond a product's characteristics or the knowledge that it may be put to infringing uses. Inducement can be found where there is evidence of active steps taken to encourage direct infringement, which can in turn be found in advertising an infringing use or instructing how to engage in an infringing use. But such instructions need to evidence intent to encourage infringement. The question is not just whether instructions describe the infringing mode, but whether the instructions teach an infringing use of the device such that we are willing to infer from those instructions an affirmative intent to infringe the patent. Merely describing an infringing mode is not the same as recommending, encouraging, or promoting an infringing use, or suggesting that an infringing use should be performed.

Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp., 785 F.3d 625, 630-31 (Fed. Cir. 2015) (internal quotations, alterations, and citations omitted). With regard to

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> the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed. The plain language of 35 U.S.C. § 271(e)(2)(A) does not alter a patentee's burden of proving infringement. The proper inquiry under § 271(e)(2)(A) is whether, if a particular drug were put on the market, it would infringe the relevant patent.

Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365-66 (Fed. Cir. 2003) (internal citations omitted).

finding specific intent, the question is not whether a patient following the instructions on the packaging may end up using the medication in an infringing way, but rather whether the proposed label instructs the patient to perform the patented method. AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1060 (Fed. Cir. 2010) (citing Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009)); Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003) ("[W]here a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the [alleged inducer] has actual knowledge that some users of its product may be infringing the patent."). Thus, Horizon has the burden of proving that Actavis's instructions in its proposed package labeling teach an infringing method of applying its ANDA product such that those instructions infer Actavis's affirmative intent to infringe Horizons' patents.

Actavis argues that its labeling does not compel infringement because Horizon's patents present three methods by which PENNSAID must be applied, and those methods are different from its method.

Horizon's methods instruct:

(1) apply medication to the knee;

(2) wait for treated area to dry; and

(3) subsequently apply sunscreen or insect repellant ('450

patent)

(3) subsequently apply a second medication consisting of a topical medication (078 patent)

(3) subsequently apply a sunscreen, an insect repellant or a second medication consisting of a topical medication (110 patent).

Actavis contends that these three steps are required when applying PENNSAID in accordance with the methods claimed in Horizon's patents. Actavis states that its ANDA product only requires steps one, and it does not require the subsequent application of sunscreen, insect repellant, or a second topical medication. Actavis argues that its package labeling does not induce infringement, therefore, because the language [redacted] is a warning that may or may not implicate steps two and three. In other words, Actavis argues that the label contemplates an "if/then" scenario: If a patient wants to cover the treated area with clothing or wishes to apply sunscreen, insect repellant, cosmetics, topical medications, or any other substance to the treated area, then the patient should wait until the treated area is dry. Actavis argues that unlike the methods claimed in Horizon's patents, the patient using Actavis's ANDA product is not required by its

label or its ANDA product's claimed methods to do any of these things if the patient does not wish to do them.

In response, Horizon argues that step three is not required by its patents - i.e., its patents do not require that a patient must apply sunscreen or insect repellant or a second topical medication. Horizon contends that the only reason those three items are specified in its method patents' claims is because of the treated area's increased photosensitivity (hence the need for sunscreen), and to prevent PENNSAID from "dragging in" to the patient's skin dangerous pesticides or another topical medication. Horizon further argues that Actavis's labeling will induce infringement because inevitably at some point in time a patient will want to apply sunscreen, insect repellant, or a second topical medication to the treated area. When that patient does so in accordance with Actavis' package labeling, Horizon contends that Actavis has induced that patient to infringe on Horizon's patents.

When a generic version's package labeling is required to be materially identical to the brand's, it would seem difficult for a generic's proposed ANDA labeling to escape a claim of induced infringement unless the brand's underlying patent claims are deemed invalid or determined to be distinguishable from the ANDA product's claims. The issue of invalidity is not currently

before the Court,[6] but a construction of Horizon's method claims strongly suggests that those claims require the post-PENNSAID application of sunscreen, insect repellant, or a second topical medication. The Court does not need to directly rule on either of these issues in order to resolve Actavis's motion for summary judgment, however, because Horizon has not met its burden to show that Actavis's label recommends, encourages, or promotes a use of its ANDA product with the intent to directly infringe on Horizon's claimed methods.

Illustrative are two cases that analyzed similar arguments presented in this action. In one case, the brand patent holder alleged that the generic's ANDA product labeling constituted a violation of 35 U.S.C. § 271(b) because it would induce a patient to directly infringe on the brand's method patent claim, which provided, "A method of treating an adult subject having attention deficit hyperactivity disorder, said method comprising orally administering to said subject a pharmaceutically effective amount of L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof with intake of food by said subject." Shire LLC v. Amneal Pharmaceuticals, LLC, 2014 WL 2861430, at *5 (D.N.J. 2014), affirmed in part, reversed in part and remanded

[6] Actavis contends that the method claims in Horizon's patents are invalid due to obviousness. That issue is to be decided during a bench trial before this Court.

on other grounds, 802 F.3d 1301 (Fed. Cir. 2015). The proposed product label provided that the medication was to be taken "with or without food," and the brand claimed that the generic label would induce infringement of its claim that the medication was to be "with intake of food." The court rejected the brand's argument:

> The problem is that the statement that the medication may be taken with or without food cannot be reasonably understood to be an instruction to engage in an infringing use. As Defendants contend, it is indifferent to which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement. Plaintiffs point to the statements of their expert, . . . but none of his conclusory assertions get around the simple fact that the proposed label does not contain any instruction to take the medication with food. Plaintiffs have failed to raise a material factual dispute over whether the proposed label encourages infringement of method claims requiring administration with food.

Shire, 2014 WL 2861430, at *5.

Similarly, the court in In re Depomed Patent Litigation, 2016 WL 7163647, at *58 (D.N.J. 2016) was tasked with determining whether the generic's proposed ANDA product label would induce a party to infringe on the brand's method patent claim, which provided, "1. A method of treating polyneuropathic pain in a subject suffering therefrom, said method comprising administering to said subject an effective polyneuropathic pain inhibiting amount of (1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propl)phenol or a pharmaceutically acceptable salt thereof." The proposed label provided, "Tapendadol extended-

release is an opioid agonist indicated for the management of: Pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." In re Depomed Patent Litigation, 2016 WL 7163647, at *59.

The brand argued that the generic specifically intended for its product to be used to treat polyneuropathic pain, because polyneuropathic pain often manifests as severe chronic pain and that it is likely that some doctors, pharmacists, and patients will use the generic's ANDA product to treat polyneuropathic pain. Id. The court found that the brand could not meet its burden on induced infringement, explaining:

> As the instruction in [the generic's] label only instructs the user to administer the drug to treat severe chronic pain, which undisputedly includes nociceptive pain, it cannot reasonably be understood to be an instruction to engage in the infringing use of administering the drug to treat polyneuropathic pain. Thus, even if the label permits administration for polyneuropathic pain, permission is different from encouragement.
>
> Plaintiffs rely heavily on the language of the Federal Circuit in AstraZeneca LP v. Apotex, Inc., where the court stated: "[T]he district court found that [the defendant] had the requisite specific intent to induce infringement because [the defendant] included instructions in its proposed label that will cause at least some users to infringe the asserted method claims." 633 F.3d, 1042, 1060 (Fed. Cir. 2010). Plaintiffs contend that [the generic's] label fits this description. However, even if "some users" may use [the generic's] product to treat polyneuropathic pain in a way that infringes, . . . the Court does not agree that [the generic's] label "includes instructions . . . that will cause" those users to infringe. In Apotex, the court determined that following the label instruction to

> "titrat[e] down from the recommended starting doses would necessarily lead to [the infringing] once-daily usage." Here, on the other hand, doctors can and likely will follow the instructions on [the generic's] label to prescribe [the generic's] product for noninfringing purposes, such as treating nociceptive and mononeuropathic pain. Furthermore, to the extent doctors prescribe [the generic's] product for infringing polyneuropathic pain treatments, it will not be because they have been encouraged by [the generic's] label to do so.

Id. at *63-64 (some internal and other citations omitted).

Just like the generic's labeling in Shire and In re Depomed, no evidence in this case demonstrates that Actavis's proposed label does more than simply permit, rather than require or direct, the post-product application of sunscreen, insect repellant, or a second topical medication. While both labels direct the application of the product, what the label instructs the patient to do after the product is applied is much broader than the claims in Horizon's patents. [redacted] Horizon's claims only concern the method of the post-PENNSAID application of sunscreen, insect repellant, and other topical medications.

Although [redacted] in the proposed label may be

understood to permit an infringing use, and accepting that it is inevitable that at some point a patient will [redacted] after using the ANDA product, that permission does not amount to encouragement because [redacted] of what a patient might wish to apply to his knee after treatment, if anything is to be applied at all. The medical reason for specifying [redacted] is important, but the post-treatment application of clothing, water, lotions, cosmetics, and any other substances before the area is dry ostensibly has other medical implications. Horizon, however, has only claimed the application of its product in connection with the subsequent application of "sunscreen, insect repellant, and other topical medications," which is a different method than the post-treatment application of nothing, or the application of anything else.[7]

In short, no material disputed facts exist as to whether the proposed product label recommends, encourages, or promotes an infringing use, or suggests that an infringing use should be

[7] Horizon argues that Actavis could have avoided infringement if [redacted] was ther topical agent. (Br. 28.) The suggestion that Horizon's claims cover all "subsequent topical agents" appears too broad.

performed. The proposed product label directs a patient on how to apply the ANDA product, and provides guidance to the patient on how to proceed from there if he wishes to have anything else come in contact with is knee afterward. Actavis's proposed product label does not constitute induced infringement in violation of 35 U.S.C. § 271(b).

CONCLUSION

For the foregoing reasons, Actavis's motion for summary judgment on Horizon's claims that Actavis's proposed ANDA product label induces infringement of Horizon's '450, '078, and '110 patents under 35 U.S.C. § 271(b) must be granted. An appropriate Order will be entered following oral argument on Tuesday, March 21, 2017 regarding the parties' differing positions on when the Order on this motion, as well as other Court Orders, shall be docketed.

This Opinion shall remain under seal until the resolution of the parties' consolidated motion to seal their submissions relating to Actavis's motion for summary judgment. In their motion to seal, the parties shall indicate which, if any, portions of this Opinion should be redacted in accordance with Local Civil Rule 5.3.

Date: March 16, 2017
At Camden, New Jersey

s/ Noel L. Hillman
NOELL. HILLMAN, U.S.D.J.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, et al.,

Plaintiffs,

v.

ACTAVIS LABORATORIES, UT, INC., et al.,

Defendants.

Civil No. 14-7992 (NLH/AMD)

ORDER

For the reasons expressed in the Court's Opinion filed today,

IT IS on this 16th day of March, 2017

ORDERED that entry of the Order resolving the MOTION for Summary Judgment by ACTAVIS LABORATORIES, UT, INC. [245] be, and the same hereby is, CONTINUED pending oral argument on Tuesday, March 21, 2017 regarding the parties' differing positions on when the Order on this motion should be entered.

s/ Noel L. Hillman
NOELL. HILLMAN, U.S.D.J.

At Camden, New Jersey