**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)

**OPINION**

**APPEARANCES:**

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**HILLMAN, District Judge**

Presently before the Court in this Hatch-Waxman Act[1] action is the dispute over the construction of claims in nine patents relating to PENNSAID® 2%, which is the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis ("OA") of the knees. Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and

[1] The Third Circuit Court of Appeals recently explained,

> With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, Congress attempted to balance the goal of "mak[ing] available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement, see H.R.Rep. No. 98-857, pt. 2, at 30 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2714. The Act seeks to accomplish this purpose, in part, by encouraging "manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." S. Rep. No. 107-167, at 4 (2002).

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 394 (3d Cir. 2015).

Horizon Pharma USA, Inc.) is the current owner and assignee of the patents-in-issue, and of the PENNSAID® 2% New Drug Application ("NDA"); all rights therein were acquired from third parties. These patents are: 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").

The patents may be segregated into groups in accordance with their related specifications. The first group of Horizon patents - the '838, '613, '809, '913 and '591 patents - share substantially identical specifications and claim priority to the same provisional application filed on October 17, 2006. According to Horizon, the inventors recognized a significant unmet need for, *inter alia*, topical OA pain treatments suitable for chronic use that will deliver the active agent to the underlying tissue in sufficient concentration. The second group of Horizon patents - the '450, '078, '164 and '110 patents - also share substantially identical specifications, and claim priority to the same provisional application filed on October 31, 2012. Horizon states that the inventors recognized a need for, *inter alia*, improved methods of dosing topical diclofenac formulations.

Horizon has filed several Hatch-Waxman actions alleging patent infringement against generic companies seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents. This particular action concerns claim construction issues relevant to Actavis Laboratories UT, Inc. ("Actavis"). Horizon brought this action in response to Actavis' assertion that the generic copy of PENNSAID® 2% described in Actavis' Abbreviated New Drug Application No. 207238 ("ANDA"), if approved by the FDA, would not infringe any valid and enforceable patent owned by Horizon.[2]

A claim construction hearing was held on March 3, 2016. Following the conclusion of the parties' arguments, the Court directed the parties to submit supplemental briefing, and on June 7, 2016, the Court, having considered the entire record and additional briefing and argument by counsel, issued an oral Opinion on the Court's final construction of the patent claims. This Opinion formally memorializes the Court's findings as to its construction of the patent claims at issue pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

[2] 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.

## I. LAW OF CLAIM CONSTRUCTION

Claim construction is "an issue for the judge, not the jury." Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996); see also Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015) ("This ultimate interpretation is a legal conclusion."). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art [the "POSA"] in question at the time of the invention." Id. at 1313. Claim construction begins with the intrinsic evidence of the patent -- the claims, the specification, and the prosecution history -- and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period. Teva Pharms., 135 S. Ct. at 841.

As part of construing claims, the Court can assess whether a claim term is indefinite, and reach "'a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims.'" In re Aoyama, 656 F.3d 1293, 1299 (Fed. Cir. 2011) (quoting Personalized Media Commc'ns, L.L.C. v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998)). For a

claim term to be definite under 35 U.S.C. § 112, ¶ 2 (2012),[3] "a patent's claims, viewed in the light of the specification and prosecution history, [must] inform those skilled in the art about the scope of the invention with reasonable certainty." Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2129 (2014).

It is permissible to read in testing conditions from the specification without violating the basic canon of construction not to import limitations from the specification into the claims, but only where this will "reconcile[ ] the ambiguous claim language with the inventor's disclosure." Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1378-79 (Fed. Cir. 2005). Where, however, the specification discloses multiple methods for evaluating a claim limitation without guidance to a person of ordinary skill in the art about which method to use, the claim limitation is indefinite. Dow Chem. Co. v. Nova Chems. Corp. (Can.), 803 F.3d 620, 634-35 (Fed. Cir. 2015); Teva Pharms. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1344-45 (Fed. Cir. 2015), on remand from 135 S. Ct. 831 (2015).

[3] The statute has been subsequently amended under the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), such that this provision has been replaced by 35 U.S.C. § 112(b). Because the applications predate the AIA, the pre-AIA version of § 112 applies. Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1377 n.1 (Fed. Cir. 2015), on remand from 134 S. Ct. 2120 (2014).

## II. DISPUTED TERMS

As set forth above, there are nine patents asserted in this matter. Of these, five patents - U.S. Patent Nos. 8,252,838; 8,563,613; 8,871,809; 9,066,913; and 9,101,591 - are part of the "'838 Patent Family" and all agreed to have the same specification. The other four patents - U.S. Patent Nos. 8,546,450; 8,217,078; 8,618,164; and 9,132,110 - are part of the "'450 Patent Family" and similarly agreed to have the same specification.

All of the disputed terms for the Court to construe are contained within the '838 Patent Family, thus all references to the specification will be to the specification of the '838 Patent.

### A. "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity"

| **Horizon's Proposed Construction** | **Defendants' Proposed Construction** |
|---|---|
| Less than 0.1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months | This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If impurity A is construed to mean USP Diclofenac Related Compound A RS, then the remainder of the term should be given its plain and ordinary meaning. |

**Court's construction:** indefinite as to the identity of "impurity A"

Horizon's construction seeks to equate the claim term "impurity A" with USP Diclofenac Related Compound A RS ("USP Compound A").[4] Horizon acknowledges that no reference to USP Compound A exists in the intrinsic evidence, but relies on the fact that a POSA would know that "impurity A" would refer to USP Compound A. Actavis submits that the language of the specification and absence of testing information within the specification make the identity of "impurity A" impossible to know. Actavis also argues that even if "impurity A" is knowable, the verb "produces" mandates an assessment of the amount of "impurity A" before storage to determine a baseline amount to compare against the amount of "impurity A" after the six month storage period to calculate what was "produced" during the storage period, as opposed to what was present as a result of the synthesis of diclofenac sodium.

Looking to the specification, as mentioned, USP Compound A is never mentioned. Horizon's position is that because the relevant pharmacopoeias at the time -- the U.S. Pharmacopoeia ("USP"), the European Pharmacopoeia ("Ph. Eur."), and the

[4] The chemical name for this compound is either *N*-(2,6-dichlorophenyl)indolin-2-one (see USP (26th ed. 2003) at 1975 (Pl.'s Ex. 16); USP (24th ed. 2000) at 1786 (Pl.'s Ex. 17)) or 1-(2,6-dichlorophenyl)-1,3-dihydro-2*H*-indol-2-one (see Ph. Eur. (5th ed. 2004) at 1420 (Pl.'s Ex. 18); Ph. Eur. (6th ed. 2005) at 1687 (Pl.'s Ex. 19)). The literature references referred to by both experts refer to USP Compound A by both names.

British Pharmacopoeia ("BP") -- identify five degradants for sodium diclofenac by letters (e.g., A, B, C), a POSA would know that "impurity A" meant the first impurity for sodium diclofenac, which is disclosed in the USP as USP Compound A. Actavis does not appear to disagree that this is a possibility, but it argues that without any further identifying information given about "impurity A," it would be impossible for a POSA to know what "impurity A" is.

The only identity information provided for "impurity A" in the specification are retention times derived from a high performance liquid chromatography ("HPLC") characterization. However, the specification merely says "the samples were tested for impurities by high performance liquid chromatography (HPLC)." '838 Patent at 23:50-52. The specification provides no additional information about the conditions under which the HPLC experiment were undertaken -- most notably, details regarding the column, the mobile phase, and the flow rate are not given. (See Marvin C. McMaster, HPLC: A Practical User's Guide 53-56 (2d ed. 2007).)

Actavis' expert explains that the disclosure is insufficient for a POSA to replicate and understand the HPLC results to identify "impurity A." (Michniak-Kohn Decl. ¶¶ 52-54.) Dr. Kohn also explains that the specification fails to inform a POSA whether "impurity A" is produced as a result of

the diclofenac, or as a result of any of the other excipients in the formulation. (Id. ¶ 51.) Horizon's expert responds that the literature available at the time would demonstrate that "impurity A" was USP Compound A. (Walters Resp. Decl. ¶ 16–20.)

Dr. Walters assumes that the HPLC experiment was carried out using a pharmacopoeia chromatographic system (see Walters Resp. Decl. ¶ 16), but the specification does not support this position. The word "pharmacopoeia" appears nowhere in the '838 Patent, and Dr. Walters has not explained why a POSA would know that the HPLC tests described in the '838 Patent were undertaken using a pharmacopoeia chromatographic system. Looking to the pharmacopoeia excerpts submitting by Horizon, they do not comport with the HPLC characterization data disclosed in the specification. Both editions of the Ph. Eur. and the USP provide detailed descriptions of a reference solution, the mobile phase, the flow rate, and details about the column. (See Ph. Eur. (6th ed. 2005) at 1686–87; Ph. Eur. (5th ed. 2004) at 1421; USP (26th ed. 2003) at 595–96; USP (24th ed. 2000) at 546.) Further, even assuming that the HPLC experiment in the '838 Patent was undertaken using pharmacopoeia chromatographic systems, the relative retention times disclosed in the specification only comport with the characterization of diclofenac given in the USP (0.6 for USP Compound A and 1.0 for

diclofenac),[5] and do not comport with the information given in the Ph. Eur. (0.48 for USP Compound A and 1.0 for diclofenac).[6] The specification provides no guidance as to which of the proposed pharmacopoeia chromatographic systems a POSA could use to evaluate the identity of "impurity A."

Further, in neither of the literature references relied upon by Dr. Walters that he asserts use pharmacopoeia chromatographic systems does the reference omit the details of the HPLC experiment (see Roy (2001) at ACT-PENN0014822 (explicitly relying on the BP for the HPLC conditions while still explaining in detail the conditions used); Hajkova (2002) at HZNPENN_00071424 (explicitly relying on the USP for baseline HPLC conditions while also disclosing conditions for a newly described HPLC experimental setup)) or identify USP Compound A by anything other than its actual chemical formula and/or structure (see Roy (2001) at ACT-PENN0014821 ("a stable intermediate, 1-(2,6-dichlorophenyl)indolin-2-one, which is commonly known as the indolinone derivative"); Hajkova (2002) at

[5] This corresponds to 6.6 minutes for "impurity A" and 11 minutes for diclofenac as disclosed in the specification.

[6] This would correspond to either an elution of "impurity A" at 5.28 minutes if diclofenac eluted at 11 minutes as disclosed, or an elution of diclofenac at 13.75 minutes if "impurity A" eluted at 6.6 minutes as disclosed.

HZNPENN_00071423 ("The main impurity, 1-(2,6-dichorophenyl)indolin-2-one (DPI, Fig. 1) . . . .")).

The identity of "impurity A" as claimed in claim 4 of the '913 Patent is unknowable to a reasonable certainty to a POSA. Accordingly, "impurity A" is indefinite. The Court need not reach the issue of whether "produces" requires an assessment of the amount if "impurity A" before storage to provide a baseline to compare against the amount of "impurity A" after the six month storage period.

**B. "the formulation degrades by less than 1% over 6 months"**

| **Horizon's Proposed Construction** | **Defendants' Proposed Construction** |
|---|---|
| Less than 1% of Impurity A (USP Diclofenac Related Compound A RS) present in a formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months | This term is indefinite because it does not inform a person of ordinary skill with reasonable certainty of what is claimed. If construed, the term should be given its plain and ordinary meaning. |

**Court's construction:** indefinite

Horizon seeks to do two things in their construction: (1) explain storage conditions by relying on Example 6 of the specification; and (2) explain what it means if something "degrades" by using "impurity A" from Example 6. Actavis responds that this is improper importation of limitations from the specification into the claims, and that even if this were permissible, the specification provides multiple methods of

storage without specifying when one is proper, making the terms indefinite.

Having already concluded that the identity of "impurity A" is indefinite, this term must also be indefinite. No other explanation for how to identify the means of degradation is provided. Even if the Court were to try to identify another way to evaluate degradation, the specification does not provide guidance. The specification refers to stability and degradation as two sides of the same coin, a point which Horizon also made during the hearing. (See Hr'g Tr. at 45:22–46:1.) However, stability is referred to as a catch all for a number of things, especially in Example 3 when the gels "remain stable for at least six months demonstrating: no phase separation, negligible shift in pH, and low amounts of degradation products (<0.04%)." '838 Patent at 16:39–41; see also id. at 12:56–58 (referring to discoloration and phase separation in the context of stability), 20:37–64 (referring to appearance for stability), 23:30–24:32 (referring to production of "impurity A" for stability). For purposes of claim construction, it is presumed that claim terms are used consistently throughout a patent. Phillips, 415 F.3d at 1314. Thus, it is unclear when "stability" and therefore "degradation" is referring to production of "impurity A," or something else, such as appearance, phase separation, and/or pH shift.

Thus, no matter how the Court tries to interpret the term, the result is indefiniteness. Either degradation is equated with "impurity A", which has already been deemed indefinite, or the Court is presented with multiple methods for how to evaluate stability -- and accordingly how to evaluate degradation -- without further guidance, rendering the term indefinite.

The Court need not reach the issue of whether Horizon's proposed construction would impermissibly import limitations from the specification with respect to storage conditions.

**C. "consisting essentially of"**

| **Horizon's Proposed Construction** | **Defendants' Proposed Construction** |
|---|---|
| Legal issue – no construction needed in Markman phase; also, meaning cannot be ascertained in the absence of proper context | Comprising; if interpreted otherwise, the claims are invalid as indefinite and/or lacking adequate written description under 35 U.S.C. § 112 |

**Court's construction:** indefinite due to indefiniteness of the basic and novel properties of the invention

**1. "Consisting Essentially Of" and the "Basic and Novel Properties" Require Construction**

"Consisting essentially of" is a transitional phrase that has a well-established legal meaning in Federal Circuit case law. "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the

invention." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). This presents a middle ground between the open-ended "comprising" that does not exclude any unrecited claim elements and the closed "consisting of" that excludes any elements not explicitly recited in the claim. AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

When asked to construe this term, courts have generally declined to construe the term, or declined to provide any further construction beyond the well-established legal meaning of the term. See, e.g., Depomed, Inc. v. Sun Pharma Global FZE, Civ. No. 11-3553 (JAP), 2012 WL 3201692, at *13 (D.N.J. Aug. 3, 2012); Biovail Labs. Int'l SRL v. Abrika, LLLP, No. 04-61704, 2006 WL 6111777, at * 18 (S.D. Fla. Aug. 24, 2006); Classified Cosmetics, Inc. v. Del Labs., Inc., No. 03-4818, 2004 WL 5645578, at *5 (C.D. Cal. June 14, 2004).

When, however, the "basic and novel properties" themselves are in dispute, courts have construed the term in order to define the "basic and novel properties" to delineate what must be shown for the purposes of infringement or invalidity. See, e.g., AK Steel, 344 F.3d at 1239-40 (determining the basic and novel property of the invention by referring to the specification); L'Oreal S.A. v. Johnson & Johnson Consumer Cos., Inc., No. 12-98-GMS, Docket Item 183, slip op. at 1 n.2 (D. Del. Nov. 5, 2014) ("As with claim construction, the court determines

the basic and novel properties of an invention as a matter of law, while resorting to the same sources of evidence used for claim construction."); Trs. of Boston Univ. v. Everlight Elecs. Co., Ltd., 23 F. Supp. 3d 50, 63-65 (D. Mass. 2014) (noting that "[t]he caselaw is somewhat unclear as to how to determine the 'basic and novel properties' of an invention" and that "[t]his is a turgid, difficult nook of patent law"); Momentus Golf, Inc. v. Swingrite Golf Corp., 312 F. Supp. 2d 1134, 1144 (S.D. Iowa 2004) (identifying "[t]he novel property" of the claimed invention in construing "consisting essentially of"), rev'd, 187 F. App'x 981 (Fed. Cir. 2006) (reversing judgment of noninfringement for misconstruing what would materially alter the basic and novel property); Kim v. Conagra Foods, Inc., No. 01-2467, 2003 WL 2122266, at *8 (N.D. Ill. May 23, 2003) (identifying "the novel property of the claimed invention" in discussing claim construction); General Elec. Co. v. Hoechst Celanese Corp., 698 F. Supp. 1181, 1187 (D. Del. 1988) (holding that "the determination of the basic and novel characteristic of [the asserted patent] is part of determining the scope of the claim" and then declining to do so due to a disputed issue of fact under pre-Markman case law). It further appears that where the parties can agree on the basic and novel properties, then the issue of what materially affects those properties is not raised until the infringement and invalidity analyses. See,

e.g., PPG Indus., 156 F.3d at 1354 ("[The parties] agreed that the basic and novel characteristics of the glass are color, composition, and light transmittance.").

Based on the weight of authority, the Court will construe "consisting essentially of" in accordance with the well-established legal meaning, "consisting of only the specified materials and those that do not materially affect the basic and novel properties of the claimed invention." Because the parties dispute what those basic and novel properties or characteristics are, the Court will go on to identify them.[7]

**2. Nautilus Applies to the "Basic and Novel Properties"**

A major dispute between the parties is whether the Nautilus standard applies to the determination of the "basic and novel properties." The parties agree that no court has yet to apply the Nautilus standard for indefiniteness to this issue, and the Court has been unable to identify any. Accordingly, this is an issue of first impression. Horizon submits that because Nautilus applies only to the bounds of claims that it should not be read so broadly as to apply to the basic and novel properties in construing "consisting essentially of." Actavis counters that because the basic and novel properties are part of defining

[7] The Court will not address the timing issues variously raised by the parties about the basic and novel properties.

the scope of the claim, Nautilus should apply to them as well. The Court agrees with Actavis that the basic and novel properties are part of the scope of the claim, and as such are part and parcel of the claims.

As a primary matter, the Federal Circuit has found that the definiteness requirement of 35 U.S.C. § 112, ¶ 2 applies to a "consisting essentially of" claim. See PPG Indus., 156 F.3d at 1354-55. For example, in PPG Industries, PPG held a patent for tinted glass used in automobiles, and filed an infringement action against Guardian, claiming that Guardian's glass product infringed PPG's patent. At the Markman phase, the district court was tasked with construing the following claim term: "A green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of: [various specific ingredients] and a colorant portion consisting essentially of: [various specific ingredients]." Id. at 1352. The parties agreed that that the basic and novel characteristics of PPG's glass were color, composition, and light transmittance. Id. at 1354. Guardian argued that its glass contained iron sulfide, an ingredient not listed in PPG's patent, as a colorant, and it therefore did not infringe. Id. at 1353.

PPG argued that the district court was required to determine as a part of claim construction whether iron sulfide could have a material effect on the basic and novel

characteristics of the claimed glass. Id. at 1354. If iron sulfide did not materially affect PPG's patented glass product, then Guardian's glass could be found to be infringing. The Federal Circuit affirmed the district court, which left the material-effect determination for the jury. The Federal Circuit explained,

> Claims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention," 35 U.S.C. § 112, para. 2, that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

Id. at 1355. The Federal Circuit emphasized that PPG's patent "contained some inherent imprecision resulting from the use of the term 'consisting essentially of.'" Id. It also emphasized that "PPG was entitled to provide its own definition for the terms used in its patent claim, including the transition phrase 'consisting essentially of,'" and that "PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and

novel characteristics of the invention." Id. The Federal Circuit found that because PPG failed to do so at the claim construction phase, whether the iron sulfide present in Guardian's glass materially affected the basic and novel properties of PPG's glass was for a jury to decide. Id.

The PPG Industries case affirms that claims containing the phrase "consisting essentially of" must meet the definiteness requirement of 35 U.S.C. § 112, ¶ 2, but the case also recognizes that the phrase itself is imprecise. In order to assess the definiteness of a patent claim that contains an imprecise phrase, the construction of the term "consisting essentially of" can be separated into two categories: (1) the specific listed ingredients or steps, and (2) the unlisted ingredients or steps that do not materially affect the basic and novel properties of the invention. At the claim construction phase, a court may construe the second category of a "consisting essentially of" claim term as long as the patent holder shows, through the specification and prosecution history, that a person skilled in the art would know that a particular unlisted ingredient could materially affect the basic and novel properties of the patent. If the patent holder fails to do so, a jury must determine whether an unlisted ingredient or step materially affects the basic and novel properties of the invention.

The lesson to be applied to this case, therefore, is that a court's assessment of the basic and novel properties may be performed at the claim construction phase because under certain circumstances the basic and novel properties of an invention are part of the construction of a claim containing the phrase "consisting essentially of."

The Supreme Court's decision in Nautilus simply reaffirms the long-established requirement that a patent's claims must be definite. The Supreme Court issued such a decision to make clear that centuries-old precedent applying the definiteness requirement of 35 U.S.C. § 112, ¶ 2, is still the standard today. See Nautilus, 134 S. Ct. at 2124, 2130 (finding that the current terminology "can leave the courts and the patent bar at sea without a reliable compass"). The Supreme Court directed, "In place of the 'insolubly ambiguous' standard, we hold that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Id.

Through this direction, the Supreme Court recognized the delicate balance between the inherent limitations of language and the need for language precise enough to afford clear notice of what is claimed in order to avoid a zone of uncertainty for inventors. Id. at 2129. Indeed, the Supreme Court observed

that "absent a meaningful definiteness check . . . patent applicants face powerful incentives to inject ambiguity into their claims," and that "[e]liminating that temptation is in order." Id. (citations omitted). The Supreme Court noted that the "patent drafter is in the best position to resolve the ambiguity in patent claims." Id. (citation omitted).

After setting forth the redefined standard for assessing definiteness under 35 U.S.C. § 112, ¶ 2, the Supreme Court remanded the case to the Federal Circuit so that it could apply the standard to the claim at issue: a heart rate monitor that "'comprise[s],' among other elements, an 'elongate member' (cylindrical bar) with a display device; 'electronic circuitry including a difference amplifier'; and, on each half of the cylindrical bar, a live electrode and a common electrode 'mounted ... in spaced relationship with each other.' Id. at 2126 (noting that parties presented differing views on the definiteness of the term "spaced relationship").

The Nautilus decision replaced the Federal Circuit's amorphous standard for assessing whether a claim is indefinite with a standard that will allow only claims that meet the statutory definiteness requirement to stand. Because the basic and novel properties of an invention are part of the construction of a claim containing the phrase "consisting essentially of," the Nautilus standard applies to the assessment

of an invention's basic and novel properties. Accordingly, the construction of the basic and novel properties is governed by 35 U.S.C. § 112, ¶ 2 and the accompanying analysis from Nautilus.

**3. The Basic and Novel Properties of the Claimed Invention Are Indefinite**

Horizon has identified five basic and novel properties for the claimed invention, relying on the specification of the '828 Patent: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. '838 Patent at 4:24–35, 9:1–10:47. Actavis argues that these are not identified as the basic and novel properties in the specification, and that these comparative terms do not provide the "reasonable certainty" required by Nautilus.

Relying on the canons of claim construction, the Court agrees with Horizon that the specification does identify these five properties as the "Characteristics of the Gel Formulation." '838 Patent at 9:1–10:47. Further, these characteristics are identified early on in the summary of the invention as being the characteristics that demonstrate improvement over the prior art. '838 Patent at 4:23–35. This is sufficient to identify these as the basic and novel properties of the claimed invention. See

L'Oreal, slip op. at 1 n.2 (identifying basic and novel properties even when not clearly titled as such).[8]

The focus now shifts to Actavis' position that the identified basic and novel properties are indefinite under 35 U.S.C. § 112, ¶ 2. Actavis argues that these generic comparative terms are too imprecise to be definite. As an exemplar of their argument, Actavis points to the first identified basic and novel property -- better drying time.[9]

In the section of the specification that identifies the basic and novel properties, under the subheading for "Drying Time," the specification explains that "[r]elative to previously disclosed [liquid] compositions . . . the compositions of the invention dry quicker . . . . The drying time difference is evident when equal amounts of the two products are tested on opposite limbs. Within thirty (30) minutes the compositions of the invention are almost completely dry whereas a significant amount of the previously described liquid formulation remains."

[8] Even if the Court were to accept Actavis' invitation to extrapolate out the requirements of means-plus-function claiming under 35 U.S.C. § 112, ¶ 6 to require a clear identification, which it does not do so, the '838 Patent would accomplish this.

[9] The parties briefed the definiteness of the claim term "a greater drying rate" in their opening Markman briefs and submitted expert declarations on the issue. Subsequently, Horizon dropped claims including this term, and the issue was not briefed again in responsive Markman briefs or in responsive expert declarations.

'838 Patent at 10:5–21. No data is ever provided in the specification for this on-limb testing. This section of the specification then discusses how to test for drying time more quantitatively and refers to data from an example later in the specification. See '838 Patent at 10:22–30.[10]

Turning to Example 5 and Table 12 which discuss drying time, there is an apparent problem in the assertion from earlier in the specification that the claimed invention would be drier within thirty minutes. Example 5 is conducted using the "more quantitative[ ]" method, wherein the formulations are spread on a plate and weighed at various time intervals, with "dryness" being determined by the percentage of weight remaining on the plate. See '838 Patent at 21:38–22:49. Example 5 discusses three different gel compositions, all of which are embodiments of the claimed invention of the '838 Patent. See id. Of the three gel compositions, only two of the described compositions are "drier" than the prior art liquid comparative at thirty

[10] The specification refers to Table 11 and Figure 10. '838 Patent at 10:29–30. However, these contain transdermal flux data and not weight and drying time, whereas Table 12 and Figure 11 contain the weight and drying time data. Accordingly, the Court finds this is a typographical error and one a POSA reviewing the '838 Patent would readily understand to look to Table 12 and Figure 11 rather than Table 11 and Figure 10. Cf. Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1215 & n.8 (Fed. Cir. 2008) (permitting courts to redraft claim language "when there is an obvious administrative or typographical error not subject to reasonable debate") (citing Hoffer v. Microsoft Corp., 405 F.3d 1326, 1331 (Fed. Cir. 2005)).

minutes. '838 Patent at Table 12. The third formulation shows 100% of the weight remaining at thirty minutes as compared to the prior art liquid comparative which shows 95.6% of its weight remaining. Id. Only at four hours does the third formulation begin to show that it is drier than the prior art liquid comparative (86.8% vs. 93%). Id.

The contradictions specifically within Example 5 are even more problematic. Example 5 claims that "even within the first five minutes, the three gel formulations displayed more rapid drying than the liquid formulation." '838 Patent at 21:63-65. This is simply not supported by the data, which shows that at five minutes the third formulation had 100.3% of its weight present as compared to 98.1% of the prior art liquid comparative. '838 Patent at Table 12.

In short, the specification describes two different methods for evaluating "better drying time," and the two methods do not provide consistent results at consistent times. Further, the claimed results are not seen across all formulations of the claimed invention, and when "dryness" is evaluated at any time shorter than four hours, not all formulations of the claimed invention actually exhibit "better drying time." Horizon's expert urges the Court to only evaluate the drying rate at the twenty-four hour mark. (See Walters Opening Decl. ¶¶ 89-96.) However, Dr. Walters' reasoning does not comport with the plain

language of the specification, as explained. Even considering his references to the prosecution history, these still do not provide any clarity on the appropriate time frame under which to evaluate the drying rate. (See id. ¶ 92; Walters Ex. P.) More persuasive is Dr. Kohn's reasoning that a POSA would not know under what standard to evaluate the drying rate of the claimed invention. (See Michniak-Kohn Decl. ¶¶ 23–31.)

The result is that the "better drying rate" basic and novel property is indefinite. If a POSA reading the patent would understand the five principles identified by Horizon to be the basic and novel properties of the claimed invention, then once one of them is indefinite, they all become problematic. As stated, the purpose of the requirement of 35 U.S.C. § 112, ¶ 2 is to "inform those skilled in the art about the scope of the invention with reasonable certainty." Nautilus, 134 S. Ct. at 2129. Once one property does not have "reasonable certainty," it follows that the group of properties itself does not have the requisite "reasonable certainty." Consequently, the term "consisting essentially of" must be construed as indefinite due to the inability for a POSA to have "reasonable certainty" about what the basic and novel properties of the invention are, and thus the POSA would lack "reasonable certainty" about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention.

**III. CONCLUSION**

For the foregoing reasons, the disputed terms are all held to be indefinite under 35 U.S.C. § 112, ¶ 2.

Date: August 17, 2016
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. 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 17th day of August, 2016

**ORDERED** that the Court's construction of the disputed claim terms in 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") is as follows:

1. "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity" is indefinite as to the identity of "impurity A"

2. "the formulation degrades by less than 1% over 6 months" is indefinite

3. "consisting essentially of" is indefinite due to indefiniteness of the basic and novel properties of

the invention.

s/ Noel L. Hillman

At Camden, New Jersey NOEL L. HILLMAN, U.S.D.J.

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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

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**HILLMAN, District Judge**

Before the Court is the motion of Plaintiff Horizon (Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.) for reconsideration (Docket No. 192) of the Court's August 17, 2016 Markman Opinion (Docket No. 188). Horizon is the current owner and assignee of the patents-in-issue and of the PENNSAID® 2% New Drug Application, which is the first FDA-approved twice-daily topical diclofenac sodium formulation for the treatment of the pain of osteoarthritis of the knees.

Horizon has filed several Hatch-Waxman actions alleging patent infringement against generic companies seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents, and this particular action concerns Horizon's claims against Actavis Laboratories UT, Inc.

("Actavis").[1] Horizon brought this action[2] in response to Actavis' assertion that the generic copy of PENNSAID® 2% described in Actavis' Abbreviated New Drug Application No. 207238 ("ANDA"), if approved by the FDA, would not infringe any valid and enforceable patent owned by Horizon.

In the Markman phase of the case,[3] the Court was tasked with construing the following terms in the '838 Patent Family[4]:

A. "the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity"

B. "the formulation degrades by less than 1% over 6 months"

C. "consisting essentially of"

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[1] Another group of cases filed by Horizon against a generic company seeking to market copies of Horizon's PENNSAID® 2% formulation prior to the expiration of Horizon's patents is against Lupin Ltd. and Lupin Pharmaceuticals, Inc. Because the Court's findings in the Actavis actions directly impact the claims in the Lupin actions, Lupin filed a brief in opposition to Horizon's motion for reconsideration and appeared at the January 4, 2017 hearing on that motion. (See Civil Action No. 15-3051, Docket No. 137.)

[2] 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.

[3] Claim construction is "an issue for the judge, not the jury." Markman v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996).

[4] There are nine patents asserted in this matter. Of these, five patents - U.S. Patent Nos. 8,252,838; 8,563,613; 8,871,809; 9,066,913; and 9,101,591 - are part of the "'838 Patent Family" and all agreed to have the same specification. The other four patents - U.S. Patent Nos. 8,546,450; 8,217,078; 8,618,164; and 9,132,110 - are part of the "'450 Patent Family" and similarly agreed to have the same specification.

The Court found each of these terms to be indefinite. (Docket No. 188 at 12, 14, 27.) Specially with regard to "consisting essentially of," the Court noted that Horizon identified five basic and novel properties for the claimed invention: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability. (Id. at 23.) The Court found that the basic and novel property of "better drying time" was indefinite, which therefore caused the term "consisting essentially of" to be indefinite. (Id. at 27.)

Horizon has filed the instant motion for reconsideration, arguing that the Court erred in two ways:

> The Court did not consider the alleged "indefiniteness" on a claim-by-claim basis, but instead broadly held the term "consisting essentially of" to be indefinite. When claims requiring use of hydroxypropyl cellulose (HPC) as a thickening agent are considered as independent inventions, those claims should not be found to be indefinite because the test results for such inventions are consistent. The only evidence of alleged inconsistent testing results was in the context of different claimed inventions that require carbopol thickening agents; and
>
> The Court's finding of indefiniteness is based on allegedly "unrebutted" expert testimony that the patent discloses two methods for comparing drying rates, which provide inconsistent results. However, Horizon's responsive expert evidence on this issue was not presented to the Court because of an agreement between the parties to not brief the definiteness of "greater drying rate" in Responsive Markman briefs. At the time of the Markman briefing and Markman Hearing, Actavis had not sought leave to amend their contentions to include the argument that the basic and novel properties were themselves indefinite. Indeed, to date, the only indefiniteness argument presented with respect to

> "consisting essentially of" in Actavis' Contentions is that a person of ordinary skill ("POSA") cannot identify the basic and novel properties.

(Docket No. 192-1 at 7.) Horizon also objects to the Court's application of Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2129 (2014) to the analysis of the invention's basic and novel properties. (Docket No. 192-1 at 10.)

The Court will grant Horizon's request that it reconsider its Markman decision, but after having fully considered the parties' briefing and oral argument, the Court stands by its prior findings.[5]

With regard to Horizon's argument that it was precluded from fully presenting its evidence to support its construction

[5] A motion for reconsideration may be treated as a motion to alter or amend judgment under Fed. R. Civ. P. 59(e), or as a motion for relief from judgment or order under Fed. R. Civ. P. 60(b), or it may be filed pursuant to Local Civil Rule 7.1(i). The purpose of a motion for reconsideration "is to correct manifest errors of law or fact or to present newly discovered evidence." Max's Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). A judgment may be altered or amended only if the party seeking reconsideration shows: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. Id. A motion for reconsideration may not be used to re-litigate old matters or argue new matters that could have been raised before the original decision was reached, P. Schoenfeld Asset Mgmt., L.L.C. v. Cendant Corp., 161 F.Supp.2d 349, 352 (D.N.J. 2001), and mere disagreement with the Court will not suffice to show that the Court overlooked relevant facts or controlling law, United States v. Compaction Sys. Corp., 88 F.Supp.2d 339, 345 (D.N.J. 1999).

of the term "better drying time," the Court does not agree. The timeline of events, detailed by Actavis in its presentation at the January 4, 2017 hearing, demonstrates that Horizon had ample notice of Actavis's indefiniteness challenge to "better drying time," and several opportunities – including during the two Markman hearings on March 2, 2016 and June 7, 2016, the supplemental briefing in between, and during the ten weeks after the second Markman hearing and the issuance of the Court's Markman Opinion on August 17, 2016 – to voice its concerns about presenting all of its evidence to support its construction of "better drying time."

Similarly, Horizon chose to present its position on the `838 Patent Family as a whole, and has only raised the request that each claim of every patent should be considered individually in its motion for reconsideration. It is clear that Horizon was not "sandbagged" by the course of the claim construction process that took place over many months.

Even considering, however, Horizon's belated arguments to support its construction of "better dying time" and request for claim-by-claim construction, the Court comes to the same conclusion as detailed in the Markman Opinion. As the Court summed up its analysis, (1) the specification describes two different methods for evaluating "better drying time," and the two methods do not provide consistent results at consistent

times, (2) the claimed results are not seen across all formulations of the claimed invention, and when "dryness" is evaluated at any time shorter than four hours, not all formulations of the claimed invention actually exhibit "better drying time," and (3) Horizon's expert Dr. Walters' reasoning does not comport with the plain language of the specification, and his references to the prosecution history do not provide any clarity on the appropriate time frame under which to evaluate the drying rate, while Actavis' expert Dr. Kohn is more persuasive that a POSA would not know under what standard to evaluate the drying rate of the claimed invention. (Docket No. 188 at 26-27.) Thus, Horizon's requested relief in its motion for reconsideration, even if granted, does not change the Court's conclusion.

Putting aside the construction of "better drying time," the finding that the term "consisting essentially of" is indefinite is also confirmed by the finding that the stability and degradation claims are indefinite. As noted above, one of the basic and novel properties of Horizon's claimed invention is "favorable stability." The Court did not specifically address this term in the context of assessing the definiteness of the basic and novel properties, but earlier in the Markman Opinion the Court extensively analyzed the terms "the topical formulation produces less than 0.1% impurity A after 6 months at

25°C and 60% humidity" and "the formulation degrades by less than 1% over 6 months." In construing those terms, the Court found that the identity of "impurity A" was unknowable to a reasonable certainty to a POSA. (Docket No 188 at 7-12.) The Court further found that the patent did not provide guidance on how to evaluate degradation because it was either equated with "impurity A", which had already been deemed indefinite, or could be determined by multiple methods for how to evaluate stability without further guidance. (Id. at 7-13.) Thus, the Court concluded that both terms relating to stability were indefinite.[6]

The finding that the claim terms relating to stability are indefinite renders the claim term "consisting essentially of" indefinite. This is because the basic and novel property of "favorable stability" is indefinite. As stated in the Court's Markman Opinion, if a POSA reading the patent would understand the five principles identified by Horizon to be the basic and novel properties of the claimed invention, then once one of them is indefinite, they all become problematic. (Id. at 27.) When one property does not have "reasonable certainty," it follows that the group of properties itself does not have the requisite "reasonable certainty." Consequently, the term "consisting

[6] Horizon has not specifically challenged this finding in its motion for reconsideration.

essentially of" must be construed as indefinite due to the inability for a POSA to have "reasonable certainty" about what the basic and novel properties of the invention are, and the POSA would lack "reasonable certainty" about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention. (Id.) Thus, regardless of the Court's construction of "better drying time," the indefiniteness of the stability terms also warrants the finding that "consisting essentially of" is indefinite.

Finally, with regard to Horizon's argument that the standard for an indefiniteness analysis reiterated by the Supreme Court in Nautilis should not be performed as to the basic and novel properties, the Court stands by its Markman Opinion, which explained why Nautilis should, and does, apply here. (Id. at 17-23.)

Horizon's bases for reconsideration were ably briefed and argued at the January 4, 2017 hearing, such that Horizon persuaded the Court to reconsider its August 17, 2016 Markman Opinion. But after reconsideration, the Court is not persuaded to disturb the prior result.

An appropriate Order will be entered.

Date: January 6, 2017
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. 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)

**OPINION**
**FILED UNDER SEAL**

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On behalf of Defendants

**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 nonsteroidal anti-inflammatory drug indicated for the treatment of the pain of osteoarthritis of the knee(s). (1)

## ---------- DOSAGE AND ADMINISTRATION ----------

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

The recommended dose is 2 pump actuations on each painful 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 of the knee. (2.1)
- Wash hands completely after administering the product. (2.2)
- Wait until the area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances. (2.2)
- Until the treated knee(s) is completely dry, avoid skin-to-skin contact between other people and the treated knee(s). (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 effective dosage for the shortest duration consistent with individual patient treatment goals [*see Warnings and Precautions (5.2)*].

For relief of the pain of osteoarthritis (OA) of the knee(s), the recommended dose is 40 mg of diclofenac sodium (2 pump actuations) on each painful knee, 2 times a day.

Apply PENNSAID 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 of the pump. No further priming of the bottle should be required.

After the priming procedure, PENNSAID is properly dispensed by completely depressing the pump 2 times to achieve the prescribed dosage for one knee. Deliver the product directly into the palm of the hand and then apply evenly around front, back, and sides of the knee.

Application of PENNSAID in an amount exceeding or less than the recommended dose has not been studied and is therefore not recommended.

### 2.2 Special Precautions

- Avoid showering/bathing for at least 30 minutes after the application of PENNSAID to the treated knee.
- Wash and dry hands after use.
- Do not apply PENNSAID to open wounds.
- Avoid contact of PENNSAID with eyes and mucous membranes.
- Do not apply external heat and/or occlusive dressings to treated knees.
- Avoid wearing clothing over the PENNSAID-treated knee(s) until the treated knee is dry.
- Protect the treated knee(s) from natural and artificial sunlight.
- 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.
- Until the treated knee(s) is completely dry, avoid skin-to-skin contact between other people and the treated knee(s).
- Do not use combination therapy with PENNSAID and an oral NSAID unless the benefit outweighs the risk and conduct periodic laboratory evaluations.

(Docket No. 255 at 11-12.)

The primary language in dispute is, "Wait until the area is completely dry before covering with clothing 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). Accordingly, the above portion of Horizon's PENNSAID label and Actavis's proposed label are essentially the same, with "PENNSAID" in Horizon's label simply being replaced with "diclofenac sodium topical solution" in Actavis's proposed label.

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 "Wait until the area is completely dry before covering with clothing or applying sunscreen, insect repellant, cosmetics, topical medications, or other substances" 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. The proposed ANDA label says that if a patient wants anything - such as clothing, sunscreen, insect repellant, lotion, moisturizer, cosmetics, topical medications, other substances, water, or another person's skin - to come in contact with a treated knee, the knee must be completely dry before doing so. Horizon's claims only concern the method of the post-PENNSAID application of sunscreen, insect repellant, and other topical medications.

Although the inclusion of "sunscreen, insect repellant, and other topical medications" 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 apply one of those items to his knee after using the ANDA product, that permission does not amount to encouragement because those items are just three examples 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 "sunscreen, insect repellant, and other topical medications" 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 its instruction for safe use with subsequent topical agents was replaced by an instruction prohibiting application of any other 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
NOEL L. 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
NOEL L. HILLMAN, U.S.D.J.

At Camden, New Jersey

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC.,<br><br>*Plaintiffs,*<br><br>v.<br><br>ACTAVIS LABORATORIES UT, INC.,<br><br>*Defendant.* | Civil Action No. 1:14-cv-07992; 1:15-cv-07742; 1:16-cv-00645-NLH-AMD |

**FINAL JUDGMENT**

This matter having been tried before this Court from March 21, 2017 through March 30, 2017, the Court having heard testimony on behalf of Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. ("Plaintiffs"), and Defendant Actavis Laboratories UT, Inc. ("Defendant"), the Court having considered the written post-trial submissions of the parties, and the Court having issued its Opinion on May 12, 2017 (Dkt. 371);

The Court having held *Markman* hearings on March 3, 2016 and June 7, 2016, the Court having considered the written submissions of the parties, and the Court having issued Opinions and Orders on August 17, 2016 (Dkts. 188, 189) and January 6, 2017 (Dkt. 234);

The Court having received Defendant's Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 8,217,078, 8,546,450, and 9,132,110 (Dkt. 245), the Court having considered the written submissions of the parties, and the Court having issued an Opinion granting Defendant's Motion for Summary Judgment on March 16, 2017 (Dkt. 300);

**IT IS ORDERED AND ADJUDGED**, for the reasons set forth in the Court's Opinion dated May 12, 2017, that Judgment is entered in favor of Plaintiffs and against Defendant on all claims and counterclaims regarding the validity of claim 12 of U.S. Patent No. 9,066,913;

**IT IS ORDERED AND ADJUDGED**, pursuant to the Stipulation And Order Regarding Infringement (Dkt. 233), that the use, offer for sale, or sale of Actavis' ANDA Product (*i.e.*, the generic version of PENNSAID® 2% that is the subject of Actavis' ANDA No. 207238, submitted under 35 U.S.C. § 271(e)(2)(A)) within the United States or administration of Actavis' ANDA Product for the treatment of the pain of osteoarthritis of the knee(s) according to its prescribing information within the United States would infringe claim 12 of U.S. Patent No. 9,066,913;

**IT IS ORDERED AND ADJUDGED**, for the reasons set forth in the Court's Opinions dated August 17, 2016 and January 6, 2017 (Dkts. 188, 189, 234), that Judgment is entered in favor of Defendant and against Plaintiffs on all claims and counterclaims regarding the invalidity of claims 49-52 and 55-61 of U.S. Patent No. 8,252,838, claims 1-5, 9-19, and 22-24 of U.S. Patent No. 8,563,613, claim 4 of U.S. Patent No. 9,066,913, claims 10-15, 17, 19, 24, and 25 of U.S. Patent No. 9,101,591, claims 2-5 and 8-11 of U.S. Patent No. 9,168,304, claims 2-5 and 9-12 of U.S. Patent No. 9,168,305, and claims 2-5 and 9-12 of U.S. Patent No. 9,220,784;

**IT IS ORDERED AND ADJUDGED**, for the reasons set forth in the Court's Opinion dated March 16, 2017 (Dkt. 300), that Judgment is entered in favor of Defendant and against Plaintiffs on all claims and counterclaims regarding the noninfringement of claims 10, 11, 15, and 17 of U.S. Patent No. 8,546,450, claim 14 of U.S. Patent No. 8,217,078, and claims 3, 11, and 13 of U.S. Patent No. 9,132,110; and

**IT IS ORDERED AND ADJUDGED**, that all claims for infringement of any claim of the following patents that is not expressly enumerated above are dismissed with prejudice: U.S. Patent Nos. 8,217,078; 8,252,838; 8,546,450; 8,563,613; 8,618,164; 8,871,809; 9,066,913; 9,101,591; 9,132,110; 9,168,304; 9,168,305; and 9,220,784;

**IT IS ORDERED AND ADJUDGED**, that all counterclaims for any claim of the following patents that is not expressly enumerated above are dismissed without prejudice: U.S. Patent Nos. 8,217,078; 8,252,838; 8,546,450; 8,563,613; 8,618,164; 8,871,809; 9,066,913; 9,101,591; 9,132,110; 9,168,304; 9,168,305; and 9,220,784;

**ORDERED** that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration ("FDA") of Defendant's ANDA No. 207238 shall be a date which is not earlier than the expiration of U.S. Patent No. 9,066,913, or any later expiration or exclusivity to which Plaintiffs are or become entitled; and it is further,

**ORDERED** that, pursuant to 35 U.S.C. § 271(e)(4)(B), Defendant and its officers, agents and employees, and those acting in privity or in concert with any of them, and their successors and assigns, are enjoined from engaging in the commercial use, offer for sale or sale within the United States, of products that are the subject of Actavis' ANDA No. 207238 until the expiration of U.S. Patent No. 9,066,913.

Dated this 22nd day of May, 2017

Noel L. Hillman

Honorable Noel L. Hillman
United States District Court Judge