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**

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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.