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FEDERAL CIRCUIT SAYS UNCLEAR MEANS OF EVALUATING BASIC AND NOVEL PROPERTIES RENDERS CLAIM INDEFINITE

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In *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*,[1] the Federal Circuit affirmed the New Jersey district court's judgment of invalidity, noninfringement, and nonobviousness on various claims of Horizon Pharma USA's ("Horizon") patents. The patents at issue are for Horizon's product PENNSAID 2%, an anti-inflammatory drug for treatment of pain of osteoarthritis in the knees.[2] The patents were twelve patents that consisted of four method-of-use patents and eight formulation patents.[3] Claim 10 of U.S. Patent No. 8,546,450 ("the '450 patent"), which instructs the user to apply the medicine to the painful area of the knee, wait for the medicine to dry, then subsequently apply sunscreen or repellant on the area, is representative of the asserted method-of-use patent claims.[4] Claim 49 of U.S. Patent No. 8,252,838 ("the '838 patent"), which specifies that the formulation of the drug consists essentially of specific percentages of diclofenac sodium, dimethyl sulfoxide, ethanol, propylene glycol, hydroxypropyl cellulose, and water, is representative of the asserted formulation patent claims.[5] Actavis Labs. UT, Inc. ("Actavis") filed an Abbreviated New Drug Application ("ANDA") for a generic version of PENNSAID 2%.[6] The filing of an ANDA constitutes artificial patent infringement under 35 U.S.C. § 271(e)(2)(A).[7]

Horizon filed suit against Actavis in the District of New Jersey on December 23, 2014.[8] In its *Markman* order on August 17, 2016, the district court found three terms in the formulation patent claims to be indefinite.[9] First, the district court found the term "impurity A" to be indefinite because identity of "impurity A" was unknowable to a person of ordinary skill in the art ("POSITA").[10] The Federal Circuit found that because neither the claim nor the specification explicitly defined the term, the district court had not clearly erred in its finding.[11] Second, the district court found that the term "the formulation degrades by less than 1% over 6 months" was indefinite because the means to evaluate degradation was not clear.[12] The Federal Circuit affirmed the reasoning that because this term relied on "impurity A," which was found to be indefinite, for its

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[1] 940 F.3d 680 (Fed. Cir. 2019).
[2] *Id.* at 683.
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *Id.* at 684.
[7] *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1126 (Fed. Cir. 2018).
[8] *HZNP Medicines*, 940 F.3d at 684.
[9] *Id.*
[10] *Id.*
[11] *Id.* At 691.
[12] *Id.* at 684.

construction, it was logically also indefinite.[13] Third, the district court found that the term "consisting essentially of" was indefinite, because the "basic and essential" properties that could not be materially affected by any included but unlisted ingredients were indefinite.

The Federal Circuit's review of the third determination was the lengthiest. The parties did not dispute the district court's definition of "consisting essentially of" as "consisting of only the specified materials and those that do not materially affect the basic and novel properties of the claimed invention."[14] The majority supported this definition by reasoning that "consisting essentially of," as distinguished from "consisting of," necessarily encompasses items that are not explicitly listed.[15] Interpreting cases such as *PPG Indus. v. Guardian Indus. Corp.*[16] and *AK Steel Corp. v. Sollac & Ugine*,[17] the majority stated it was proper for district courts to incorporate the basic and novel properties into the term at the claim construction stage, as the district court in this case did.[18]

Further, the majority, like the district court, said that in order to meet the requirement of clear notice of what is being claimed, the basic and novel properties of the invention must be provided with objective boundaries.[19] The district court had determined that the specification identified five basic and novel properties of the drug's formulation: better drying time, higher viscosity, increased transdermal flux, greater pharmacokinetic absorption, and favorable stability.[20] It then determined that the property of "better drying time" was indefinite, which the Federal Court affirmed.[21] The finding of indefiniteness was based and affirmed on the inconsistency between test results for the *in vivo* and *in vitro* tests described in the specification of the '838 patent. Because these two tests did not provide consistent results at consistent times, the district court concluded that a POSITA would not know the standard under which

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[13] *Id.* at 692.
[14] *Id.* at 693.
[15] *Id.*
[16] 156 F.3d 1351 (Fed. Cir. 1998) (holding that it was appropriate for the jury to determine whether amounts of iron sulfide, which was in the accused product but not listed in the "consisted essentially of" claim, had a material effect on the basic and novel characteristics of the invention).
[17] 344 F.3d 1234 (Fed. Cir. 2003) (holding that it was appropriate for the district judge to determine the threshold amount of silicon that would materially alter the basic and novel properties of the invention because the intrinsic evidence spoke to silicon's effects on the relevant properties).
[18] *HZNP* Medicines, 940 F.3d at 696.
[19] *Id.* at 695.
[20] *Id.* at 685.
[21] *Id.* at 696.

to evaluate drying time.[22] On appeal, Horizon asserted that a POSITA would understand that the two tests have structural differences that would render the results reconcilable with each other.[23] The Federal Circuit rejected this argument, saying that Horizon's attempt to distinguish between "drying time" and "drying rate" in the context of the patent was moot.[24] Thus, the majority wrote, the district court did not err in finding the property of "better drying time" indefinite, which in turn made the phrase "consisting essentially of" indefinite.[25] Judge Newman, in her partial dissent, said that the incorporation of the basic and novel properties into the scope of the claims was incorrect as a matter of law and casted countless patents into uncertainty.[26]

The Federal Circuit also reviewed the district court's grant of summary judgment of noninfringement and finding of nonobviousness of claim 12 of U.S. Patent No. 9,066,913 ("the '913 patent"), a formulation patent. The infringement issue centered around the representative claim 10 of the '450 patent, which recited a method for applying the medication to a painful area of the knee, waiting for the treated area to dry, then applying sunscreen or an insect repellent.[27] The majority affirmed the district court's finding that Actavis's ANDA label did not induce infringement.[28] It reasoned that Actavis's instruction to wait for the applied drug to dry before applying other substances such as insect repellent or sunscreen was more permissive than instructive, as some patients may choose to not apply the repellent or sunscreen after application of the drug.[29] Although the label's instructions map closely to the patented method, the possibility of noncompliance with all parts of the method meant that there was no material issue as to induced infringement.[30] Judge Newman disagreed, writing that the fact that patients may not always comply with instructions "does not insulate the provider from infringement liability."[31]

As for obviousness, the district court had determined that claim 12 of the '913 patent was not a routine optimization of the prior

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[22] *Id.* at 697.
[23] *Id.* at 698.
[24] *Id.*
[25] *Id.* at 698–99.
[26] *Id.* at 708.
[27] *Id.* at 700.
[28] *Id.* at 701.
[29] *Id.* at 701.
[30] *Id.* at 702.
[31] *Id.* at 709 (citing *Vanda Pharm. Inc.*, 887 F.3d at 1129).

art of PENNSAID 1.5%.[32] The majority rejected Actavis's argument that the various chemical components of PENNSAID 2% were like dials on a stereo receiver that could be adjusted.[33] The majority agreed with the district court's conclusion that in addition to the inherently interdependent nature of the system at issue that distinguished it from the stereo analogy, the added unpredictability of chemical reactions under the human skin made the patent claim nonobvious.[34] Judge Newman concurred in this judgment.[35] Although many of Horizon's patent claims were struck down for indefiniteness, it seems that the difficulty of concocting a new pharmaceutical composition protected its patented product to some degree. *HZNP Medicines* serves as a caution to future patentees to be exact in detailing the edges of its list of ingredients. Formulation claims that use the language "consisting essentially of" must be accompanied by information in the specification that gives guidance as to what would constitute a material alteration of the invention's basic and novel properties.

[32] *Id.* at 703.
[33] *Id.* at 703.
[34] *Id.*
[35] *Id.* At 704.