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

| | |
|---|---|
| SANOFI-AVENTIS U.S. LLC., *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>SANDOZ, INC,<br><br>Defendant. | Lead Civil Action No. 07-2762 (JAP)<br>(consolidated case)<br><br>**OPINION** |

PISANO, District Judge.

This action is brought pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271 (commonly referred to as the "Hatch-Waxman Act") alleging, *inter alia*, infringement of United States Patent No. 5,338,874 (the " '874 patent"). Presently before the Court is a motion by Fresenius Kabi Oncology plc and Dabur Pharma Limited (together "Dabur") for summary judgment of non-infringement of claims 1 and 2 of the '874 patent. Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis, Debiopharm, S.A. (together "Sanofi") oppose the motion and have cross-moved for summary judgment of infringement. For the reasons set forth herein, Dabur's motion for summary judgment of non-infringement is denied, and Plaintiff's cross-motion for summary judgment of infringement is granted.

## I. Background[1]

### A. The '874 Patent

The '874 patent relates to a chemical compound claimed as "optically pure oxaliplatin."[2] *See* '874 patent at claim 1. Sanofi-Aventis U.S. LLC holds approved new drug application 21-492 and 21-759 for ELOXATIN, an FDA approved treatment for colorectal cancer, the active ingredient of which is oxaliplatin. Debiopharm, S.A. is owner of the '874 patent, and Sanofi-Aventis is its exclusive licensee.

The '874 patent contains two claims. The first claims "optically pure [oxaliplatin]" and sets forth the compound's chemical formula. '874 Patent, claim 1, col. 8, lines 54-64. As explained in more detail in the Court's June 18th Opinion, "optical purity" refers to the ratio of the amount of a desired enantiomer[3] in a compound to the amount of an undesired enantiomer in that compound. The second claim of the '874 patent refers to oxaliplatin "as claimed in claim 1" and adds the limitation of a melting point between 198° C and 292° C. *Id.*, claim 2, col. 8, lines 65-68.

### B. Defendants' Oxaliplatin Product

Dabur is a generic drug manufacturer that filed with the United States Food and Drug

---

[1]The background facts of this case were detailed in the Court's June 18, 2009 summary judgment Opinion and, therefore, only those facts relevant to the instant motion will be recited here.

[2]Cis-oxalato (trans-l-1,2-cyclohexanediamine) Pt(II) is a chemical name for oxaliplatin used in the '874 patent.

[3]Enantiomers are the molecules that make up compounds known as "optical isomers." Oxaliplatin is an optical isomer.

Administration ("FDA") Abbreviated New Drug Applications ("ANDA") 78-810 and 78-811which concern a new drug product containing oxaliplatin. Dabur submitted a Drug Master File ("DMF") to the FDA in which it described the oxaliplatin it will use in its proposed product. The DMF specifies that the level of the d-OHP enantiomer (the undesired enantiomer) in Dabur's product as being not less than 0.02% and not more than 0.10%. Declaration of Claude Hariton ("Hariton Dec."), Ex. 1. The ANDAs include the same specification for the level of the d-OHP enantiomer. *Id.*, Exs. 2 and 3.

C. The Present Motion

As issue in the present motion is the construction of the term "optically pure" as used in claim 1 of the '874 patent. Dabur argues that the term as used in the '874 patent should be construed to mean oxaliplatin that contains no d-OHP enantiomer. Def. Brf. at 9. Should the Court adopt Dabur's construction, there appears to be no dispute between the parties that Dabur would be entitled to summary judgment of non-infringement, as it is uncontested that its oxaliplatin product contains a measurable amount of the d-OHP enantiomer.

Plaintiffs, on the other hand, propose that the claim term "optically pure" should be interpreted as oxaliplatin having an optical purity of 99.95% or better. Should the Court adopt Plaintiffs' construction, there appears to be no dispute that Plaintiffs would be entitled to summary judgment of infringement, as it is uncontested that Dabur's oxaliplatin product has an optical purity that is 99.95% or better.

## II. Analysis

### A. Summary Judgment Standard

A court shall grant summary judgment under Rule 56(c) of the Federal Rules of Civil Procedure "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N.Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n.3 (3d Cir. 1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. In so presenting, the non-moving party may not simply rest on its pleadings, but must offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of

the matter," but need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of North America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

B. Infringement

Dabur moves the court for summary judgment of non-infringement; Plaintiffs cross-move for summary of infringement. An infringement analysis requires two steps -- the first is proper construction of the relevant claims, and the second is a comparison of those claims to the accused product. *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed. Cir.2 009). Because claim construction is "a question of pure law, [it] is amenable to summary judgment, and disagreement over the meaning of a term within a claim does not necessarily create a genuine issue of material fact." *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995). Although "[l]iteral infringement of a properly construed claim is a question of fact," a court may decide the issue of infringement on summary judgment where, "after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused device is encompassed by the claims." *Wavetronix LLC v. EIS Electronic Integrated Systems*, 573 F.3d 1343, 1358 (Fed. Cir. 2009).

C. Claim Construction Principles

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit

emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d 1312 (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed.2d 577 (1996) ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention--the inventor's lexicography--must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decision making process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

*Id.* (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir.1998)).

In the process of determining the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include "the words of the claims themselves, the remainder of the

specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314. While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises. *Id.*

D. "Optically pure"

As noted above, Dabur argues that the term "optically pure" should be construed to mean oxaliplatin that contains no d-OHP enantiomer. In support of this proposed construction, Dabur first points to the specification of the '874 patent. As Dabur points out, the "optically pure" oxaliplatin claimed in the patent is described in the specification as having "complete optical purity" that results from a process that includes "completely and optically resoluting the isomers." '874 patent, Abstract, line 3; col. 2 , lines 16-17. The specification further states that the compound contains "no [d-OHP enantiomer]." *Id.*, col 2, lines 22-23. *See also id.*, col. 3, lines 44-45 (describing the claimed oxaliplatin as "contaminated with no optical isomers.").

Dabur also points to the three examples contained in the specification. Each of these examples describe a process that results in a compound having "100%" optical purity. *See id.*, col. 4, lines 63-67; col. 6, lines 41-45; col. 7, 19-23.

Turning to the prosecution history, Dabur asserts it contains further support for its proposed contruction. During prosecution of the '874 patent, the applicants argued that the

claimed oxaliplatin was patentable over the prior art because the prior art oxaliplatin was not "optically pure." Response to Official Action dated Dec. 21, 1993 at 3-4 (Declaration of Minaksi Bhatt ("Bhatt Dec.") at Ex. 4). In response, the Examiner issued a Notice of Allowability in which he allowed the claim, but required an amendment to claim 1 that replaced language referring to oxaliplatin "of high optical purity" with the phrase "optically pure" oxaliplatin. Notice of Allowability at 3 (Bhatt Dec. at Ex. 5). The Examiner agreed with applicants' "convincing arguments" that the prior art "does not teach[] [oxaliplatin] as an optically pure isomer." The Examiner also noted that it was "clear from [the prior art] that also other isomers can be in the final product." *Id.* Therefore, the Examiner found the claimed oxaliplatin to be unobvious over the prior art. *Id.* The implication that Dabur apparently draws from this portion of the prosecution history is that the distinguishing factor between the claimed oxaliplatin and the prior art is allegedly the complete absence of the d-OHP enantiomer in the claimed compound.

As noted above, Plaintiffs assert that the claim term "optically pure" means oxaliplatin having an optical purity of 99.95% or better. They argue that it would be understood by a person skilled in the art ("POSA") that "optically pure" or "100% pure" does not and cannot mean that the compound is completely free of any d-OHP enantiomer. Rather, according to Plaintiffs, based upon the level of detection for the analytical test used to determine optical purity in the '874 patent, a POSA would understand that "optically pure" or "100% pure" means having an optical purity of 99.95% by weight or higher.

Having carefully considered the relevant evidence, the Court agrees with Plaintiffs

and finds that the proper construction of the term "optically pure" in claim 1 of the '874 patent is oxaliplatin "having an optical purity of 99.95% by weight or higher." This construction is supported by both the intrinsic and extrinsic evidence.

First, the language of the '874 patent makes clear that the novelty of the '874 patent was not the complete absence of the d-OHP enantiomer in the compound but rather the improved level of purity over the prior art. In this regard, the specification states that "an object of the present invention is to proved a platinum complex compound having optically high purity." '874 patent, col. 1, lines 64-66. It further states that "[a]nother object of the invention is to provide platinum complex compound that is useful as a raw material of a pharmaceutically active agent because of its high purity." *Id.*, col 1., line 67 to col. 2, line 2. Simply put, a plain reading of the specification leads to the conclusion that the compound claimed is of high optical purity, but not necessarily a compound completely devoid of even a single d-OHP enatiomer.

Second, the specification of the '874 patent incorporates by reference United States Patent No. 5,298,642 (the "'642 patent"). *See* '874 patent, col. 2, lines 14-21 ("The [oxaliplatin] of optically high purity of the present invention may be prepared by completely and optically resoluting the Pt(II) optical isomers by means of a process of optically resoluting an optically active platinum complex compound disclose [sic] in an application of the same Applicant of the same date."). A patent may incorporate another by reference where, as here, the host document "clearly identif[ies] the subject matter which is incorporated and where it can be found." *See Callaway Golf Company v. Acushnet*

*Company*, 576 F.3d 1331, 1346 (Fed. Cir. 2009).

The specification of the '642 patent makes clear that optically pure oxaliplatin will not be completely devoid of an unwanted enatiomer because "an optical isomer of 100% purity cannot be obtained in most cases and that "[i]t is desirable . . . to optically resolute the dextrorotatory substance and the levorotatory substance at nearly 100% efficiency." '642 patent, col. 1, lines 50-54. The '642 patent uses the same analytical method as the '874 patent and states that when the value 100% is reported after analysis, the inventors meant 99.95% by weight or better. '642 patent, col. 5, lines 28-32 ("The optical purity of the (+)589-cis-[Pt(OX)(R,R-dach)] was 100% ((-)589-cis-[Pt(OX)(R,R-dach)] was below 0.05%)). Thus, even where the specification of the '874 patent refers to 100% optical purity, the inventors understood this and intended this to mean 99.95% by weight or better.

Third, contrary to Dabur's assertion, a fair reading of the prosecution history shows that the factor that distinguished the oxaliplatin claimed in the '874 patent from the prior art was not the complete absence of any impurity. Rather, the substitution by the examiner of "optically pure" reflected the significant difference in purity level between the claimed compound and that of the prior art, which according to the applicants' testing had an optical purity of up to 90%. Response to Official Action at 3. The term "optically high purity" that was used in the original claims was broad enough, in the Examiner's view, to cover the oxaliplatin produced by the prior art process, which, therefore necessitated the amendment to the claim language. As such, Plaintiffs in no way disclaimed oxaliplatin having 99.95% optical purity or higher as Dabur alleges.

Finally, the extrinsic evidence shows that a POSA would understand that the term optically pure as used in the '874 patent does not mean the complete absence of the d-OHP enantiomer in the compound. Plaintiffs' expert, Dr. Davies, explains that

> A POSA at the time of the '874 patent would not have understood a claim of 100% optical purity to mean the sample is completely free of molecules of the other enantiomer. Rather, a POSA would understand that chemical purification techniques, including HPLC, simply are not capable of completely removing an impurity, and analytical techniques, such as HPLC, are limited in their abilities to detect impurities. Taken together, these concepts would lead a POSA to understand that a sample of "optically pure" oxaliplatin that was prepared from a mixture of oxaliplatin and the d-OHP enantiomer would always contain some of the d-OHP enantiomer, that would be an amount below the detection limit of the HPLC analytical process disclosed in the patent.

Declaration of Stephen Davies ("Davies Dec.") ¶ 11.

Similarly Plaintiffs' expert Dr. Fanfarillo states that

> The limit of detection for d-OHP (S,S-oxaliplatin) as interpreted by a person of ordinary skill in the art in 1993, was 0.05% by weight as disclosed in United States Patent Nos. 5,298,642. Because the exact same method appears in the '874 patent, it would be understood that the HPLC method found in the '874 [patent] has the same limit of detection, 0.05% by weight.

Declaration of Micheal Fanfarillo ("Fanfarillo Dec.") ¶ 4b (footnote omitted).

In response to Plaintiffs' experts, Dabur submits a declaration from its expert Dr. Haddad, who opines that the actual limit of detection of the d-enatiomer in 1993, based upon his own experimentation, was below the 0.05% claimed by Plaintiffs. *See* Declaration and Expert Report of Paul Haddad. However, Dr. Haddad's opinion does address the central question that must be decided by the Court, namely, how a POSA at that time would have understood the claim term "optically pure." His opinion, therefore, does nothing to alter the

Court's decision adopting Plaintiffs' proposed construction of that term.

E. Infringement

Having construed the relevant claim term, the Court now turns to the second step of the infringement analysis, which is to compare the accused product to the claims of the patent. Here, Dabur does not dispute that its infringes under the claim construction adopted by the Court, as its oxaliplatin product has an optical purity of 99.95% by weight or better. Consequently, Plaintiffs' cross-motion for summary judgment of infringement shall be granted.

III. Conclusion

For the reasons stated above, the Court shall construe the term "optically pure" in the '874 patent as meaning "having an optical purity of 99.95% by weight or higher." Dabur's motion for summary judgment, therefore is denied, and Plaintiffs' cross-motion for summary judgment is granted. An appropriate Order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J

Dated: March 12, 2010