NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

Presently before the Court in this patent infringement action are motions by defendants Mayne Pharma Limited, Mayne Pharma (USA) Inc., Hospira Australia Pty Ltd., Hospira Inc. (collectively, "Mayne"), and Sandoz, Inc., ("Sandoz," together with Mayne, "Defendants") for summary judgment of non-infringement.[1] Also before the Court is a motion by Mayne for invalidity based on anticipation.[2] Plaintiffs have opposed the motions and, with respect to the non-infringement motions, have cross-moved for infringement. The Court heard oral argument on the invalidity motion March 26, 2009 and on the non-infringement motion May 1, 2009. For the reasons below, Defendants' motions for summary judgment of non-infringement are granted

[1]These motions are found at docket entry nos. 124 and 103, respectively.

[2]Docket entry no. 115.

and Plaintiffs' cross motion is denied.[3] Mayne's motion for summary judgment of invalidity is denied.[4]

I. BACKGROUND

Plaintiffs, Sanofi-Aventis U.S. LLC, Sanofi-Aventis, Debiopharm, S.A. (collectively "Sanofi") bring this action 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 infringement of United States Patent No. 5,338,874 (the " '874 patent"), which relates to a chemical compound claimed as "optically pure oxaliplatin."[5] *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. *See* Plaintiff's Response to Mayne Statement of Undisputed Material Facts ¶ 4. According to Plaintiffs, Debiopharm, S.A. is owner of the '874 patent, and Sanofi-Aventis is its exclusive licensee. *Id.* ¶ *5-6.*

Defendants are generic drug manufacturers. Sandoz has filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 3550(j), an Abbreviated New Drug

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[3]Pursuant to the February 26, 2009 Order of Magistrate Judge Hughes, this Court's ruling on the Mayne and Sandoz non-infringement motions controls disposition of the following motions for summary judgment, deemed "me too" motions, filed by other defendants in this action: Docket entry nos. 122, 129, 131, 156 (in part), 207 and 210.

[4]Pursuant to the February 26, 2009 Order of Magistrate Judge Hughes, this Court's decision on the Mayne's anticipation motion (no. 115) controls disposition of the following motions for summary judgment, deemed "me too" motions, filed by other defendants in this action: Docket nos. 82, 116, 117, 120, 126, 151, 165, 198 and 243.

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

Application ("ANDA") No. 78-817 concerning a proposed generic drug product, an oxaliplatin solution for injection in different formulations. Similarly, defendant Mayne Pharma Limited has filed with the FDA ANDA Nos. 78-813 and 78-817 concerning proposed the drug products Oxaliplatin Injection and Oxaliplatin for Injection in different formulations.

A. Oxaliplatin

The '874 patent contains two claims. The first claims "optically pure [oxaliplatin]"[6] and sets forth the compound's chemical formula. '874 Patent, claim 1, col. 8, lines 54-64. The second claim 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.

Oxaliplatin, which is used medically as an anti-cancer agent, is an optical isomer. Expert report of Dr. Stephen Davies ("Davies Report") ¶ 48. "Isomers" are compounds that are comprised of the same elements, but which exhibit different properties because of a difference in the way the atoms are arranged in each. The molecules of optical isomers, also known as "enantiomers," are non-superimposable mirror images of each other, like a right hand and a left hand, and rotate polarized light in opposite directions. Davies Report ¶¶ 28-32.

Generally, enantiomers exist in a mixture of equal proportions that is known as a "racemic mixture" or "racemate." Davies Report ¶ 34. For example, oxaliplatin (also called "l-OHP") normally exists in a racemic mixture with a mirror-image compound called "d-OHP."

[6]The parties in this case dispute the construction of the term "optically pure" in the '874 patent. In other motions before the Court, certain defendants have asserted that the term refers to 100% pure oxaliplatin, while Plaintiffs assert that the term "optically pure" refers to a 99.95% level of purity. The Court does not address that specific issue in this Opinion, however, because resolution of the question is not necessary for disposition of the instant non-infringement motion. *See* May 1, 2009 Transcript of Oral Argument at 10:19-21 and 11:24-25.

After identifying and studying a racemic mixture (such as, for example, a racemate comprised of l-OHP and d-OHP), scientists will typically separate the mixture into its enantiomers to study the properties of each, as the biological and physical properties of a particular enantiomer cannot be determined until it is isolated and tested. *Id.* ¶ 38. This type of analysis has revealed that while oxaliplatin is effective as a cancer treatment, its mirror image twin, d-OHP, can be toxic. *See* Plaintiff's Response to Statements of Material Facts § II.A, ¶¶ 2, 3.

Once an enantiomer has been separated from its twin, the resulting compound may be referred to in terms of its "optical purity." The "optical purity" of a particular compound is typically expressed as a ratio of the amount of the desired enantiomer to the amount of the undesired enantiomer. For example, oxaliplatin that is 99.95% pure by weight means that the sample is 99.95% oxaliplatin molecules and 0.05% d-OHP molecules. *See* Plf.'s Response to Statements of Material Facts § II.A, ¶ 1.

Thus, to produce "optically pure" oxaliplatin as claimed in the '874 patent, the desired enantiomer (oxaliplatin) must be separated[7] from the undesired enantiomer ("d-OHP"). The '874 patent teaches a method for resolving oxaliplatin using High Performance Liquid Chromatography ("HPLC"). HPLC is a method of separating isomers "used by the inventors of the '874 patent" that involves dissolving a sample in a solvent and passing it through a column under pressure. Davies report ¶43(h). The isomers pass through the column at different rates and separation results.

B. Prior Art - The Kidani Patent

Oxaliplatin was discovered and patented by Professor Yoshinori Kidani, a Japanese

[7]Such separation may also be referred to as "resolution" or "purification."

researcher at a university in Japan. United States Patent No. 4,169,846 (the "'846 patent" or the "Kidani patent"), was issued in 1979 to Dr. Kidani *et al.*, and discloses a process for making oxaliplatin from a starting mixture of *cis*- and *trans*-1,2-DACH ("DACH"). Kidani patent; Davies Report ¶ 59. Prior to the issuance of the '846 patent, Dr. Kidani had been studying the anti-tumor properties of certain compounds. He made these compounds using as starting material DACH, which is a mixture of three different isomers, one geometric isomer and two optical isomers. *See* Kidani Patent, col 1, lines 52-62. As explained in the Kidani patent, Dr. Kidani separated the two DACH optical isomers "in the conventional manner," and then used these DACH isomers as starting material to make other compounds. *See id.* col. 3, lines 30-33; Davies Report ¶¶ 52-59. Kidani employed a process called "recrystalization" to further separate the isomers, and created a number of different compounds to test for tumor-reducing activity. The Kidani patent explains that Kidani was trying to find a suitable preparation of an "isomer of 1,2 diamincyclohexane platinum (II) complex" having both "superior anti-tumor activity" and "low toxicity." Kidani patent, col. 2, lines 1-13. Claimed in the Kidani patent's single claim is the chemical structure of oxaliplatin.

C. '874 Patent Prosecution History

On April 7, 1993, the '874 patent application was filed by Tanaka Kikinzoku Kogyo (the "Applicant"). *See* '874 patent at 1. The application contained two claims reciting oxaliplatin "of optically high purity." Declaration of Christina L. Saveriano ("Sandoz Decl."), Ex. 2 at 55.[8] In an Official Action dated September 21, 1993, these claims were rejected by the examiner as

[8]The page numbers for this exhibit are preceded by the identifier "ELOX" and as many as six zeros. In the interest of brevity, the Court will omit the use of the identifier and the zeros when citing to the pages of this exhibit.

anticipated under 35 U.S.C. § 102(b) or alternatively, obvious under 35 U.S.C. § 103 in light of the work by Dr. Kidani. *Id.* at 88 (citing to Kidani *et al.*, J. Med Chem. Vol. 21, No. 12, pp. 1315-1318 (1978)).

The Applicant responded to the rejection, arguing that the claimed invention was neither anticipated or obvious. The Applicant first asserted that the Kidani prior art did not actually "isolate [oxaliplatin], only the trans-l-dach from the trans-d-dach." *Id.* at 134. Such separation of the DACH starting material, according the Applicant, "is not high optical purity of the specified isomer." *Id.*

Additionally, the Applicant argued that comparative examples prepared in accordance with the Kidani method resulted in material that was "not optically pure," as tests of the oxaliplatin produced in this conventional manner showed it to be only 90% pure. *Id.* at 135. The Applicant then explained that "[o]nly after HPLC resolution (in accordance with the teachings of the present application) was optical purity obtained." *Id.* *See also* '874 patent specification, col. 8, lines 4-15 (Table 1 compares optical purity of examples "Before Resolution by HPLC" – ranging from 86.8% to 90.0% – and "After Resolution by HPLC" – all examples 100% optically pure).

The examiner accepted the Applicant's argument and allowed the claims, but required an amendment to claim 1 that replaced language referring to oxaliplatin "of high optical purity" with the phrase "optically pure" oxaliplatin. *Id.* at 141. The examiner agreed with the Applicant that the Kidani prior art did not teach oxaliplatin "as an optically pure isomer" and that it was clear from Kidani that "other isomers can be in the final product." *Id.* The '871 patent issued on August 16, 1994.

II. DISCUSSION

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. Mayne and Sandoz Non-Infringement Motions

Mayne and Sandoz are seeking summary judgment of non-infringement of the '874 patent claims. These Defendants argue that the claims of the '874 patent must be limited to optically pure oxaliplatin that has been produced using the HPLC method taught by the patent. If the claims of the '874 patent are construed in such a way, Defendants argue that their oxaliplatin products would not infringe, as there appears to be no dispute that the oxaliplatin used in Defendants' ANDA products is produced using a method other than HPLC.[9]

a. Claim Construction Principles

Courts determine patent infringement by construing the patent's claims and then applying that construction to the accused product. *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370 (1996), therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

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

[9]HPLC can be used both as a tool to analyze the optical purity of a compound and a method for resolving a compound (*i.e.*, separating enantiomers). At issue on this motion is the use of HPLC as a method for resolving oxaliplatin and not the use of HPLC for analyzing its optical purity.

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*, 52 F.3d at 980 ("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." *Id.* 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.*

b. The Instant Motions

The key issue in this non-infringement motion is that of claim construction. Defendants argue that the claims of the '874 patent should be construed as "product-by-process" claims and, if the claims are so construed, Defendants assert that they do not infringe the patent. "A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (citations omitted). Specifically, Defendants assert that, properly construed, the claims of the '874 patent are limited to "optically pure" oxaliplatin that is produced through the use of the HPLC method taught by the '874 patent. Because -- as Defendants allege and Plaintiff does not dispute -- Defendants' products are not made using the HPLC process taught in the '874 patent, if the '874 patent claims are construed as product-by-process claims Defendants do not infringe. Plaintiffs, on the other hand, contend that the '874 patent claims are "compound claims," *i.e.*, they claim a chemical compound of a particular level of purity and the claims are not limited by the process employed to achieve such purity. Consequently, according to Plaintiffs, Defendants' optically pure oxaliplatin products does, in fact, infringe.

There is no dispute that nothing on the face of the claims of the '874 patent limits the claims to "optically pure" oxaliplatin that is produced through the use of HPLC. Nevertheless, "process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Andersen Corp. v. Fiber Composites*, LLC, 474 F.3d 1361, 1375 (Fed. Cir. 2007). In support of their argument,

Defendants rely upon a line of cases supporting this principle including *Andersen* and *Chimie v. PPG Industries, Inc.*, 402 F.3d 1371 (Fed. Cir. 2005).

In *Andersen*, the relevant patents claimed certain polymer and wood fiber composite structures with no limitation on the process used to create the composite. In the specifications, however, the patentee stated that a process referred to as "pelletization" was important to the claimed invention. The Federal Circuit found that although the patentee asserted that "the novelty of the invention of the . . . patents lies in the physical properties of those inventions," the specification "indicates that the claimed physical properties of the composite structural members are attributable to the process that is used to make them, a process that includes pelletization." Andersen, 474 F.3d at 1375. As such, the Court rejected a broad construction "covering all composite structural members, regardless of the process by which they were produced" and construed the claims to require the use of pelletization. *Id.* 1373-74.

Similarly in *Chimie*, the Federal Circuit affirmed the construction of a claim covering "silicia particulates" to include the patentee's process for producing the particulates. The court found the limitation appropriate because, during patent prosecution, the patentee distinguished "both its product and process claims from [the prior art] and did so by focusing on the necessity of using [its process] to obtain the claimed product." *Chimie*, 402 F.3d at 1384. In particular, the patentee distinguished a certain prior art reference because that reference did not use a particular step found in the patentee's process. Therefore, according to the patentee, the prior art process was not be capable of "ultimately providing a homogeneous and solid particulate product" as the claims required. *Id.* at 1384-85. *See also Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) (no infringement where patentee's prosecution

arguments limited patent claims to compound formed by one-step process)); *AFG Ind., Inc. v. Cardinal IG Co., Inc.*, 224 Fed. Appx. 956 (Fed. Cir. 2007) ("the process by which a product is produced can limit a product claim when, as here, the process is relied on for patentability and validity"); *Brady Constr. Innovations, Inc. v. Perfect Wall, Inc.*, 290 Fed. Appx. 358 (Fed. Cir. 2008) (no infringement where patentee "limited its invention" to particular process during prosecution) (citing *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 113 Fed. Appx. 930 (Fed Cir. 2004) ("Our case law makes clear that statements made during prosecution may limit what began as an apparatus claim to a product-by-process claim.").

Turning first to the specification of the '874 patent, Defendants argue that the claimed optical purity of '874 compound is repeatedly attributed to the HPLC process described in the specification. *See Andersen*, 474 F.3d at 1372-73 (product claim found to be limited by process used where the specification "indicate[d] that the claimed physical properties of the composite structural members [were] attributable to the process . . . used to make them."). They point to, for example, the section of the '874 patent specification titled "Detailed Description of the Invention," where it is noted that the "invention may be prepared in accordance with" the "illustrative method" thereafter described. '874 patent, col. 2 lines 51-52. Subsequently, described is a process by which the claimed oxaliplatin "contaminated with no optical isomers" can be obtained "by means of high performance liquid chromatography (hereinafter referred to as 'HPLC')." *Id.*, col 3, lines 44-48. A "representative process of preparing" the invention is then described in three examples, each of which use HPLC to produce oxaliplatin of 100% optical purity. The results are summarized in Table 1 of the specification. The table compares the lower optical purity of the examples "Before Resolution by HPLC" with the optical purity obtained

"After Resolution by HPLC," which was 100% *Id.* col. 8.

The specification of the '874 patent also describes testing of a "Comparative Example" that was produced using the prior art process reported by Kidani. *Id.* cols 7-8. The results of the analysis of this example, also set out in Table 1, compare the lower optical purity of the oxaliplatin obtained using the Kidani process, *i.e.*, 90% (*see* Table 1, column labeled "Before Resolution by HPLC") with the 100% optical purity obtained "After Resolution by HPLC." Defendants point out that no other method for achieving the "optically pure oxaliplatin" of claims 1 and 2 is described in the '874 patent specification. Sandoz Brf. at 10. Indeed, it appears that much of the '874 specification is intended to show that higher levels of optical purity are obtained through the HPLC process taught in the '874 patent than through the methods taught in the prior art. The use of HPLC to obtain high levels of optical purity is a key distinction pointed to in the specification of the '874 patent between the "optically pure" oxaliplatin claimed in the '874 patent and that of the prior art.

Additionally, Defendants argue that the patent's prosecution history similarly exhibits the Applicant's emphasis on the HPLC process such that construction of the '874 patent claims as product-by-process claims is warranted. *See Brady Constr. Innovations, Inc. v. Perfect Wall, Inc.*, 290 Fed. Appx. 358 (Fed. Cir. 2008) (no infringement where patentee limited invention to a particular process during prosecution). In responding to the examiner's initial rejection of the patent application, the Applicant argued that the process employed by Kidani in the prior art did not actually "isolate" oxaliplatin, "only the trans-1-dach from the trans-d-dach." and "[t]his is not high optical purity of the specified isomer." Sandoz Ex. 2 at 134. It is clear, therefore, that according to the Applicant, achieving the optical purity of the claimed invention required

resolution of the oxaliplatin itself and not merely the starting material (*i.e.*, the DACH). The Applicant then went on to explain that "[o]nly after HPLC resolution (in accordance with the teaching of the present application) was optical purity obtained." *Id.* at 135. Thus, the Applicant did not attempt to rebut the examiner's rejection by simply pointing to the lesser purity of the prior art compound, it was unequivocal that "[o]nly after HPLC resolution" was the claimed purity achieved. Importantly, these representations by the Applicant were the basis for securing the '874 patent. *Id.* at 141 ("The primary reason for allowance of the instant claims are applicants' convincing arguments in Paper No. 6.)

In further support of their argument, in addition to references to HPLC in the specification and patent prosecution history, Defendants point to Plaintiffs' own contentions made during this litigation in support of patent validity. *See AFG Ind., Inc. v. Cardinal IG Co., Inc.,* 224 Fed. Appx. 956, 2007 WL 964606 (Fed. Cir. Mar. 30, 2007) ("the process by which a product is produced can limit a product claim when, as here, the process is relied on for patentability and validity"). Defendants assert that in defense of motions for summary judgment of anticipation of the '874 patent claims based on the Kidani patent and other references, Plaintiffs emphasized the use of HPLC to distinguish the invention of '874 patent from the prior art.

Indeed, in several instances in response to the anticipation motions, Plaintiffs pointed to the HPLC process in the '874 patent to distinguish the prior art. For example, Plaintiffs explained that the'874 patent inventors "developed a specific HPLC method and show that they were able to manufacture a product of a pharmaceutical grade with a specified purity." Sandoz Ex. 8 (Plaintiffs' Responses to Mayne's Statement of Undisputed Facts) at 34. While it is true,

as Plaintiffs argue, such a statement may be construed as a reference to HPLC's use as an analytical tool (*i.e.*, its use in measuring purity as opposed to its use as purifying method), other references by Plaintiffs leave no doubt that Plaintiff distinguished prior art on the basis of the HPLC method of purifying, not merely analyzing, oxaliplatin. For example, Plaintiffs explained that

> [t]here are two different ways to make optically pure oxaliplatin. The first is to resolve impure oxaliplatin using high performance liquid chromatography ("HPLC"), which is the method taught by the '874 patent. There is no mention of HPLC in the Kidani patent or any other prior art reference.

Sandoz Ex. 9 (Plaintiffs' Combined Brief in Opposition to Mayne's and Barr's Motions for Summary Judgment of Invalidity) at 26.

Plaintiff's expert, Dr. Davies, similarly distinguishes the invention of '874 patent from prior art's oxaliplatin based on the inventor's use HPLC process, attributing the higher optical purity of the '874 compound to that process. In his report, Dr. Davies notes that

> The ['874 patent] specification discloses that application of the tartrate salt technique disclosed in the [Kidani patent] to commercially available DACH from various suppliers led to oxaliplatin having far less than 99.95% optical purity. By using the methods disclosed in the '874 patent, which do not appear in the [Kidani patent], the optical purity was increased to that level.

Davies Report ¶ 71. Dr. Davies further states that "[b]y using the techniques that are not in the [Kidani patent], optically pure oxaliplatin was obtained, that is, by collecting HPLC fractions at the appropriate time points." *Id.*

In view of the '874 patent specification and the prosecution history as well as Plaintiffs' validity arguments in this litigation, the Court finds that the claims in the '874 patent are properly construed as product-by-process claims. While Plaintiff is correct that "product claims generally

are not limited by how the product is produced," *AFG Ind.*, 224 Fed. Appx. at 958 (citing *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000)), "exceptions may arise when the product's distinction from the prior art depends on how it was produced, for when validity of the patent depends on use of a particular process, the claims are construed in the manner that will sustain their validity." *Id.* at 958-59. Here, Plaintiffs' argument that they never relied on the HPLC method of purification to distinguish prior art is belied by the record. As detailed above, Plaintiffs attributed the claimed optical purity of oxaliplatin covered by the '874 patent to the HPLC process described in the specification and distinguished the prior art on that basis. As such, contrary to Plaintiff's arguments, the line of cases cited by Defendants is applicable here. As noted earlier, "process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Andersen*, 474 F.3d at 1375. Therefore, the term "optically pure oxaliplatin" in claim 1 of the '874 patent shall be construed to mean optically pure oxaliplatin that has been resolved by means of the HPLC method described in the '874 patent specification. Because claim 2 of the '874 patent is dependent on claim 1, claim 2 is also limited to optically pure oxaliplatin that is resolved by the HPLC process described in the '874 patent specification.

Turning now to the question of infringement, based on the above construction of the '874 patent claims, the Court finds that Defendants do not infringe the '874 patent either literally or under the doctrine of equivalents. *See Asyst Tech., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2006) (equivalents was precluded under "all elements rule" and "specific exclusion principle")*; Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1378 (Fed. Cir. 2005) (same). It is undisputed that neither Mayne's ANDA products, nor the raw material used to make its

ANDA products, contain oxaliplatin resolved using the HPLC method. *See* Plaintiffs' Combined Responses to Defendants' Statements of Material Facts Regarding Their Motions For Summary Judgment of Non-Infringement of U.S. Patent No. 5,338.874 at 20-21. Similarly, it is undisputed that Sandoz's ANDA products do not contain oxaliplatin resolved using HPLC. *Id.* at 26. As such, Defendants' motion for summary judgment is granted.

C. Invalidity Motion

The Court's ruling on the Defendants' non-infringement motions renders Mayne's motion for summary judgment of invalidity based on anticipation effectively moot. However, even if the Court were to reach Mayne's motion, the Court would deny it. Mayne seeks summary judgment of invalidity with respect to the '874 patent, arguing that '874 patent is anticipated by Dr. Kidani's work, as well as by an article by Dr. Masahide Noji in 1981describing tests involving "circular dichroism" data, which is a method of measuring optical purity, and a 1984 article by Dr. Michael Bruck, whose team of scientists investigated oxaliplatin's structure. According to Mayne, each of these prior art references independently anticipates "optically pure" oxaliplatin. Mayne Brf. at 14-21.

The question of anticipation turns on whether "the prior art reference discloses and enables the claimed invention." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005). With respect to disclosure, "the dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching" that every claim element was disclosed in that single reference." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003) (alterations in original, quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390, 21 USPQ2d 1281, 1284 (Fed. Cir.

1991). As far as enablement, the reference must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008). Only if the prior art reference discloses all of the claim limitations and enables the subject matter that falls within the scope of the claims at issue does the reference anticipate. *Perricone*, 432 at 1376.

Importantly, anticipation is a question of fact. *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 995 (Fed. Cir. 2006); *Minn. Mining & Mfg. Co. v. Chemgue, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002). To make finding of anticipation on summary judgment, a court must determine that no facts material to the question are disputed; or that even if all factual inferences are drawn in favor of the non-movant, there is no reasonable basis on which the non-movant can prevail. *Cooper v. Ford Motor Co.*, 748 F.2d 677, 679 (Fed. Cir. 1984).

"Typically, testimony concerning anticipation must be testimony from one skilled in the art." *Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315, 64 USPQ2d 1832, 1841 (Fed. Cir. 2002). Such testimony "must identify each claim element, state the witnesses' interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference." *Id.* Here, the parties offer various expert reports and declarations in support of their respective arguments. These experts disagree on whether one skilled in the art would understand the prior art references to disclose the optically-pure oxaliplatin claimed in the '874 patent. There is further disagreement among the experts as to whether the prior art references enable one skilled in the art to create optically pure oxaliplatin without undue experimentation. As such, summary judgment on the question of anticipation is inappropriate. *Edwards Systems Technology, Inc. v. Digital Control Systems, Inc.*, 99 Fed. Appx. 911, 921 (Fed.Cir.2004) ("a

classic 'battle of the experts ... renders summary judgment improper.").[10]

III. CONCLUSION

For the reasons above, Defendants motions for summary judgment are granted. Defendants cross-motion for infringement is denied. Mayne's motion for summary judgment of invalidity is denied. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

[10]With respect to the anticipation motion, Mayne relies in large part on the opinion of its expert, Dr. Michael Cleare. Plaintiffs have moved to strike, in part, the report of Dr. Cleare, based on Mayne's alleged violation of the Federal Rules governing expert disclosures. However, Plaintiffs have not shown that Mayne failed to disclose materials relating to basis for Dr. Cleare's opinions and the data or other information considered by him in forming them. *See* Fed. R. Civ. P. 26(a)(2)(B). Moreover, Plaintiffs' motion to compel production of the disputed material was denied by the Magistrate Judge. Plaintiffs' motion to exclude portions of Dr. Cleare's expert report, therefore, is denied.