IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF WEST VIRGINIA

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U.S. DISTRICT COURT
CLARKSBURG, WV 26301

ORTHO-MCNEIL PHARMACEUTICAL, INC., JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, LLC, and DAIICHI PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v. **Civil Action No. 1:02CV32**

(Judge Keeley)

MYLAN LABORATORIES, INC. and MYLAN PHARMACEUTICALS, INC.,

Defendants.

ORDER

This matter comes before the Court on the Defendants' Motion for Summary Judgment on the Basis of Anticipation under 35 U.S.C. § 102 (a) and (b). The motion is fully briefed, the Court has heard oral argument, and the issues presented are ripe for review. For the following reasons, the Defendants' motion is **DENIED.**

BACKGROUND.

Plaintiffs Daiichi Pharmaceutical Company, Ltd. (Daiichi), Ortho-McNeil Pharmaceutical, Inc. (Ortho), and Johnson & Johnson Research & Development, LLC (J&J) are brand-name pharmaceutical manufacturers who produce an antimicrobial pharmaceutical marketed under the name "Levaquin." Levaquin is a "pioneer" drug registered with the United States Food and Drug Administration.

Levaquin's active ingredient is a chemical compound conventionally known as levofloxacin. Levofloxacin is protected by United States Patent No. 5,053,407 (the '407 patent), which is held by Daiichi and licensed to Ortho and J&J. The '407 patent was issued in 1991 and expires in 2010.

Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (together, Mylan), have filed an Abbreviated New Drug Application ("ANDA") seeking to produce a generic version of Levaquin. Before they can do so, though, they too must obtain approval from the FDA to market the generic drug. The Hatch-Waxman Amendments to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355, create an expedited generic drug approval process for brand-name drugs that are protected by patents. To begin the process, the generic manufacturer must file an ANDA, which incorporates the testing and efficacy data previously submitted by the manufacturer of the pioneer drug with the original new drug application. 28 U.S.C. § 355(j)(2). Because the pioneer drug is protected by a patent, the ANDA applicant must make one of the following certifications with respect to each patent at issue:

> (I) that such patent information has not been filed;
> (II) that such patent has expired,
> (III) the date on which such patent will expire; or

> (IV) that such patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . .

28 U.S.C. § 355(b)(2)(A).

If an applicant makes the fourth statement (a "Paragraph IV certification"), it must give notice of the ANDA filing to the pioneer drug patent holder along with a detailed statement of the factual and legal basis for the Paragraph IV certification. 21 U.S.C. § 355(j)(2)(B)(i)-(ii). To prevent the ANDA from being approved, the patent owner must sue the applicant for patent infringement within 45 days of its receipt of the notice. 21 U.S.C. § 355 (j)(2)(B)(iii); 35 U.S.C. § 271(e)(2) (making and ANDA filing an act of patent infringment). If suit is filed, the FDA may not approve the ANDA for 30 months, unless, prior to the end of the 30-month period, a court determines that the patent is "invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iii)(I); Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d 30, 32-33 (D.D.C. 2000).

To begin marketing its generic levofloxacin tablets, Mylan filed an ANDA with a paragraph IV certification stating that the '407 patent is invalid. The plaintiffs then promptly filed the present patent infringement suit to protect their rights under the '407 patent.

Mylan now moves for summary judgment on the limited ground that the patented invention is invalid because it was anticipated in the prior art, pursuant to 35 U.S.C. § 102(a) and/or (b).

Background of the Invention.[1]

The enantiomeric chemical compound at issue in this case is levofloxacin. An enantiomer is one of a pair of isomers[2] that are non-superimposeable mirror images of each other. This mirror image structure is often likened to the relative structures of a person's right and left hands, and chemists normally refer to each enantiomer as either the dextro (Latin *dexter*, or right-handed) or levo (Latin *laevus*, or left-handed) enantiomer.

The right/left nomenclature also stems from the fact that enantiomers are "optically active." That is, an enantiomer will rotate a plane of polarized light[3] clockwise (dextrorotatory) or counterclockwise (levorotatory). This ability to rotate light is

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[1]The parties have submitted declarations of their respective experts that explain the chemistry essential to understanding the invention in this case. Plaintiffs' expert is Dr. Alexander Klibanov, Ph.D. Defendant's expert is Dr. Ulrich Jordis, Ph.D. Dr. Klibanov also testified at the hearing on this motion. Dr. Jordis was available by telephone to give testimony, but the defendants elected to not put him on the stand.

[2] An isomer is one of a number of molecules that have the same chemical formula (the same constituent atoms), but the atoms are arranged in a unique pattern. For example, C_4H_{10} can be arranged as either *n*-butane (all carbons arranged in a chain) or isobutane (three methyl groups arranged around a central carbon atom).

[3]Polarized light is normal light that has been filtered to allow the light to shine only in one direction (normal light shines in all directions).

an inherent property of the enantiomer. Moreover, a given pair of enantiomers will always rotate polarized light in equal and opposite directions. For example, if the dextrorotatory enantiomer rotates polarized light 90° to the right (clockwise), then the levorotatory enantiomer will rotate the polarized light 90° to the left (counterclockwise).

Because enantiomers have identical chemical formulae, chemists distinguish between the chemical names of enantiomeric pairs by preceding each with a symbol that reflects the direction the enantiomer rotates polarized light: "(+)" for dextrorotatory enantiomers, and "(-)" for levorotatory enantiomers.

Chemists also distinguish between enantiomers by designating an enantiomer as either "R" or "S" based upon the arrangement of certain atoms at the enantiomer's "chiral center."[4] Where one enantiomer is an "R," the other will be an "S."

Still another way that chemists distinguish between enantiomers is by the way the compound is drawn. Because each enantiomer has the same chemical formula and bonding sequence, but different spatial orientations, drawings of each enantiomer will be very similar. Chemists can designate spatial arrangements through the use of special symbols indicating the

[4]The chiral center is the section of an enantiomer that distinguishes it from its mate.

direction of a bond between particular atoms. As drawn on a sheet of paper, a bond within the plane of the paper is represented by a straight line (—). A bond protruding upward is represented by a solid wedge (▲). A bond descending downward is represented by a hatched wedge (≡).

When chemists first find or synthesize a given enantiomeric pair, the enantiomer always occur in a perfect 1:1 ratio. This solution of equal amounts of dextrorotatory and levorotatory enantiomers is known as a "racemic compound."[5] A racemic compound is optically inactive because, for every dextrorotatory enantiomer rotating polarized light to the right, there exists a levorotatory enantiomer rotating light to the left, resulting in a net rotation of zero.

Chemists also have a specific nomenclature for racemic compounds - the chemical name is preceded by either "(±)" or "RS" (or both).

Finally, enantiomeric pairs have nearly identical chemical properties, which makes separating them extremely difficult:

> The identity of most physical properties of enantiomers has one consequence of great practical significance. They cannot be separated by ordinary methods: not by fractional distillation, because their boiling points are identical; not by fractional

[5]Also referred to as a racemic mixture, or racemate.

> crystallization, because their solubilities in a given solvent are identical (unless the solvent is optically active); not by chromatography, because they are held equally strongly on a given adsorbent (unless it is optically active). The separation of a racemic [compound] into enantiomers--the resolution of a racemic modification--is therefore a special kind of job, and requires a special kind of approach.

R.T. Morrison & R.N. Boyd, Organic Chemistry, Ch. 4, at 136 (4th ed. 1983).

In this case, ofloxacin is a racemic compound comprised of one dextrorotatory enantiomer with an "R" configuration and one levorotatory enantiomer with an "S" configuration. Racemic ofloxacin is disclosed numerous times in the prior art. Levofloxacin, the subject of the '407 patent, is the levorotatory isomer with the "S" configuration.

Summary Judgment Standard.

Summary judgment is appropriate when "there is no genuine issue as to any material fact, and ... the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute about a material fact is genuine when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The movant bears the initial burden of identifying "those portions of 'the pleadings, depositions,

answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986) (quoting Fed. R. Civ. P. 56(c)).

At oral argument, the parties agreed that they had no factual disputes. Therefore, the Court's task is to first construe the claims of the '407 patent, and then determine whether Mylan is entitled to judgment as a matter of law on its anticipation defense.

Claim Construction.

When construing patent claims, the Court must look first to the intrinsic evidence in the record: "The claims, the specification, and the prosecution history." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc). The court does not look to each of these three sources equally; rather, they are a "hierarchy of analytical tools." Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1344 (Fed. Cir. 1998).

First of the three is, of course, the claim language itself. See id. ("The actual words of the claim are the controlling focus."); see also Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999) ("We begin, as with all

claim interpretation analyses, with the language of the claims."). A court should interpret technical terms in claim language as having the meaning understood by persons skilled in the art, or having experience in the field at the time of invention. Hoechst Celanese Corp. v. BP Chems. Ltd., 78 F.3d 1575, 1578 (Fed. Cir 1996). See also Pitney Bowes, Inc. V. Hewlett -Packard Corp., 182 F.3d 1298, 1309 (Fed. Cir. 1998) (". . . it is entirely appropriate, perhaps even preferable, for a court to consult trustworthy extrinsic evidence to ensure that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field."). To determine what one skilled in the art could understand, the court should consider the testimony of scientific expert witnesses. See AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1249 (Fed. Cir. 2001) (noting the value of having "scientific witnesses to aid the court in coming to a correct conclusion."); see also Key Pharmaceuticals v. Hercon Labs, Corp., 161 F.3d 709, 716 (Fed. Cir. 1999) (". . . trial courts generally can hear expert testimony for background and education on the technology implicated by the presented claim construction issues, and trial courts have broad discretion in this regard.")

Second is the specification, which the Court must consult when construing the claim language. See Markman, 52 F.3d at 979 ("Claims must be read in view of the specification, of which they are a part."); see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-41 (Fed. Cir. 2001) (stating that it is "proper" for a district court to follow Markman's invocation); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (". . . the specification is always highly relevant to the claim construction analysis.")

Third, "[t]he court has broad power to look as a matter of law to the prosecution history of the patent in order to ascertain the true meaning of language used in the patent claims." Markman, 52 F.3d at 980 (internal quotation marks omitted).

In addition to the intrinsic evidence, the Court may consult extrinsic evidence such as treatises, dictionaries and even expert testimony, if necessary. See Markman, 52 F.3d at 979 ("Expert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used.") (internal quotation marks omitted); but see Voice Technologies Group v. VMC Systems, Inc., 164 F.3d 605, 614 (Fed. Cir. 1999) ("When the intrinsic evidence is unambiguous, it is improper for the court to rely on extrinsic evidence.").

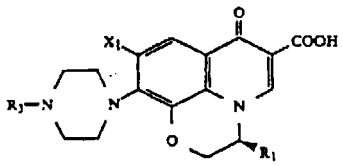
With these varying sources of information, the Court must be careful to always focus on interpreting the claim language as written. See Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1552 (Fed. Cir. 1997) (". . . a construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language.") Importantly, the Court must guard against importing limitations into the claim language from the other intrinsic and extrinsic evidence where the claim language itself does not warrant it. See Johnson Worldwide, 175 F.3d at 989-90 (". . . claim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources."); Electro Med Sys., s.A. v. Cooper Life Sci., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994) (". . . claims are not to be interpreted by adding limitations appearing only in the specification."); SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) ("Specifications teach. Claims claim.").

When a claim term is amenable to two or more interpretations based on the applicable record evidence, it should be construed to preserve the patent's validity. Harris Corp. v. IXYS Corp.,

114 F.3d 1149, 1153 (Fed. Cir. 1997); ACS Hospital Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984).

The claims of the '407 patent that are at issue read:

1. An S(-)-pyridobenzoxazine compound represented by the formula (VI)

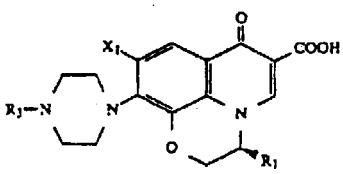


(VI)

wherein X1 represents a halogen atom, R1 represents an alkyl group having 1 to 4 carbon atoms, and R3 represents an alkyl group having 1 to 3 carbon atoms.

2. S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid according to claim 1.

4. A process for treating a patient in need of an antimicrobial therapy which comprises administering to said patient an antimicrobially effective amount of an S(-)-pyridobenzoxazine compound represented by the formula (VI)



(VI)

wherein X1 represents a halogen atom, R1 represents an alkyl group having 1 to 4 carbon atoms, and R3 represents an alkyl group having 1 to 3 carbon atoms.

5. A process for treating a patient in need of an antimicrobial therapy in claim 4 which comprises administering to said patient an antimicrobially effective amount of S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-

pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid.

The parties only dispute the proper construction of the terms "[a]n S(-)-pyridobenzoxazine compound" and "S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid."

Before addressing the dispute, the Court notes that the parties agree that, to one skilled in the art, claims 1 and 4 of the '407 patent plainly refer to "S(-)" pyridobenzoxazines in general, and that claims 2 and 5 of the '407 patent plainly refer to the "S(-)" optical isomer (enantiomer) of ofloxacin, levofloxacin.

Despite this agreement, Mylan argues that the chemical name in claims 1 and 4 needs a plain-English "purity" qualification to avoid a breadth of coverage that would include the prior art racemic ofloxacin. There are a number of problems with this position, however.

First, Mylan's argument directly conflicts with its position that the plain language of the claim refers to levofloxacin. As discussed above, chemists skilled in the art regard levorotatory enantiomers as distinct from racemic compounds or the dextrorotatory enantiomer. Additionally, each type of compound has its own unique nomenclature. "S(-)" clearly designates the

levorotatory enantiomer in this case. Had the inventor meant to designate the racemic compound, he would have used the designation "(±)" or "RS." Even Mylan's own expert testified at his deposition that it "would be an error" to use only the (-) symbol to designate a racemic compound, (Jordis Dep. at 22), and a chemist would not use a lone "S" to designate a racemic compound. (Jordis Dep. at 176).

Mylan attempts to resolve this conflict by arguing that Claim 1 is a claim for a "compound *per se*"--a claim for the chemical compound itself, wherever and whenever it occurs. In other words, the '407 patent is worded so broadly that anyone producing anything that contained even one molecule of levofloxacin would infringe the '407 patent. Mylan supports its argument by citing Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994),[6] for the proposition that a claim listing only a chemical name encompasses all occurrences of the chemical.

In that case, the patent holder, Bristol, argued that Zenith induced infringement when Zenith's product, a non-infringing pharmaceutical pill, "converted into the patented compound in the patient's stomach." Id. at 1420. Zenith argued that the patent

[6]Mylan also cites Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1564 (Fed. Cir. 1997), but that case only mentions the phrase "compound per se" outside the context of the claim construction analysis.

claims only protected pharmaceutically prepared forms of Bristol's compound, and not the compound when it was produced in the patient's stomach. Id. at 1421. The Federal Circuit disagreed, holding that the claim language itself "simply describes a compound having specified chemical properties," without any limitation to a pharmaceutical preparation. Id. at 1421-22. Thus, Bristol's patent protection extended to any occurrence of the chemical compound. Id.

Under this logic, Mylan argues that the claims of the '407 patent cover individual molecules of levofloxacin wherever they occur--even if they occur in a perfect 1:1 ratio with dextrofloxacin, i.e., as racemic ofloxacin.

Mylan's argument rests on a faulty premise. The Zenith decision predates Markman, and notably fails to adhere to Markman's directive to examine all of the intrinsic evidence before construing a claim. Indeed, the Zenith court observed that the patent's prosecution history strongly suggested that the invention was limited to a pharmaceutical preparation as Zenith argued, but it chose to discount this evidence and limit its construction as evidenced by the words of the claim only. Id. at 1422. In light of Markman, the Court doubts that such a truncated analysis is appropriate. See Marion Merrell Dow, Inc. v. Baker Norton Pharm., Inc., 948 F. Supp. 1050, 1054 n.4 (S.D.

Fla. 1996) (same); In re Omeprazole Patent Litig., 2001 WL 585534 at *3 (S.D.N.Y. May 31, 2001) (same).

Mylan also asserts that In re Williams, 171 F.2d 319 (C.C.P.A. 1948), requires a plain-English "purity" limitation in claims for enantiomers. In Williams, the court was faced with an inventor seeking to patent an enantiomer. The claim language "call[ed] for the laevo rotary form 'substantially free from the dextro rotary form.'" Id. at 151. The Court did not construe the patent claims; indeed, aside from the preceding quotation, the claim language does not appear in the opinion at all. Thus, it is impossible to determine if the Williams court required the "substantially free" language as Mylan urges. The "substantially free" language certainly distinguishes the levorotatory enantiomer from the racemic compound. However, there is no indication that such plain-English purity limitation is the only way to distinguish the prior art.

The case of In re May, 574 F.2d 1082 (C.C.P.A. 1978), suggests otherwise. May, too, involved the patentability of an enantiomer. The claims at issue in that case stated:

> 1. A method of affecting analgesic and morphine antagonistic activity without producing physical dependence in animals which comprises administering to an animal an effective dosage of an acid addition salt of the levo isomer of a compound of the structure where R is a lower alkyl group and

R 1 is hydrogen or a lower alkyl group.
2. The method of claim 1 wherein said compound is -(-)-5,9-diethyl-2'- hydroxy-2-methyl-6,7-benzomorphan.
3. The method of claim 1 wherein said compound is (-)-5-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
4. The method of claim 1 wherein said compound is (-)-5-ethyl-2'-hydroxy-2- methyl-6,7-benzomorphan.
5. The method of claim 1 wherein said compound is -(-)-5-propyl-9-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
6. The method of claim 1 wherein said salt is the hydrochloride.
7. The method of claim 6 wherein said compound is -(-)-5,9-diethyl-2'- hydroxy-2-methyl-6,7-benzomorphan.
8. The method of claim 6 wherein said compound is (-)-5-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
9. The method of claim 6 wherein said compound is (-)-5-ethyl-2'-hydroxy-2- methyl-6,7-benzomorphan.
10. The method of claim 6 wherein said compound is -(-)-5-propyl-9-methyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
11. A pharmaceutical composition for internal administration having an analgesic, non-addictive, morphine-antagonistic effect which comprises a pharmaceutical carrier and an effective amount of an acid addition salt of - (-)-5,9-diethyl-2'-hydroxy-2-methyl-6,7-benzomorphan.
12. The composition of claim 11 wherein said salt is the hydrochloride.
13. The composition of claim 11 wherein said salt is the acetate.

Id. at 1084-85.

Claims 1 and 6 were rejected because they were specifically described in the prior art. Id. at 1089-90. The remaining

claims were upheld. Notably, the upheld claims contain no plain-English purity limitations whatsoever. Instead, they distinguish the enantiomer from the racemic compound with the symbol "(-)."

Mylan argues that the distinguishing language is not "(-)" but rather the phrase "without producing physical dependence in animals," which describes a chemical attribute unique to the levorotatory enantiomer. There are two problems with this analysis, however. First, the language Mylan focused on modifies the *method* for which claim 1 sought patent protection, not the compound through which that method was effected. The compound itself is simply described as "an acid addition salt of the levo isomer of a compound [with the following structure . . . .]." Thus, the description of the compound contains no plain-English purity limitation.

Most importantly, the May court stated that, under common nomenclature, a chemical compound designated as "(-)" is "limited to the levo enantiomer." 574 F.2d at 1085.

Thus, while it is certainly necessary to distinguish a new invention over the prior art, there is no indication that an inventor must use a plain-English purity limitation as Mylan urges. Instead, an inventor may use anything that a person skilled in the relevant art would understand to limit the claim. In this case, the term "S(-)" clearly and plainly limits the

claim language to the levorotatory enantiomer. Those skilled in the art clearly understand the term "S(-)" to affirmatively denote only a levorotatory enantiomer of a racemic compound, and not the racemic compound itself. Furthermore, those skilled in the art clearly understand the terms "RS" or "(±)" to affirmatively denote a racemic compound. The inclusion of "S(-)" in the claim language, coupled with the obvious exclusion of "RS" or "(±)," militates against Mylan's assertion that an additional plain-English purity limitation is necessary to distinguish the patented invention over the prior art racemic ofloxacin.

The Specification.

The specification repeatedly refers to the invention as "optically active." (See '407 patent, col. 1, ll.6-11 ("the invention relates to optically active pyridobenzoxazine derivatives" and "optically active compounds of Ofloxacin and its analogs"); col 1, ll. 25-26 ("[t]he present inventors obtained optically active compounds of the racemic Ofloxacin"); col. 2, ll.29-40 ("to provide optically active Ofloxacin and its analogs"; "to provide a novel intermediate . . . useful for synthesizing optically active Ofloxacin"; "to provide a novel process for preparing optically active Ofloxacin and its analogs by the use of [that] intermediate"); col. 2, ll.65-67 (noting three methods for preparing "optically active Ofloxacin")). As

discussed above, enantiomers are optically active and racemic compounds are not. The repeated references to the invention's optical activity strongly suggest that the invention is an enantiomer and not a racemic compound.

The specification also directly distinguishes between levofloxacin and racemic ofloxacin. For example, in the section captioned "Background of the Invention," the specification states:

> [T]he S(-)-form of Ofloxacin has been found to have very desirable properties, i.e., increased antimicrobial activity and reduced toxicity, and is expected to be a very useful pharmaceutical agent as compared with the (±)-compound.

('407 patent, col. 1, ll. 37-42). The specification also states:

> The present inventors obtained optically active compounds of the racemic Ofloxacin and found that the S(-)-compound possesses an antimicrobial activity of about 2 times higher than that of the (±)-compound and an acute toxicity (LD50) weaker than that of the (±)-compound as determined in mice by intravenous administration.

('407 patent, col. 2, ll. 25-31).

Furthermore, at Table 2, col. 10-11 of the '407 patent, the specification provides data comparing the properties of "S(-)-Ofloxacin" with "Racemic Ofloxacin" and "R(+)-Ofloxacin."

Where the inventor specifically distinguishes the prior art in the specification, the prior art is properly excluded from the

coverage of the claims. See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343 (Fed. Cir. 2001) ("Thus, the SciMed patents distinguish the prior art on the basis of the use of dual lumens and point out the advantages of the coaxial lumens used in the catheters that are the subjects of the SciMed patents. That discussion in the written description supports the district court's conclusion that the claims should not be read so broadly as to encompass the distinguished prior art structure.").

The specification and prosecution history also suggest that the invention is a pharmaceutical preparation comprised of millions of molecules of levofloxacin, as opposed to a single molecule. Dr. Klibanov testified that the examples set forth in the specification describe different processes for resolving racemic ofloxacin into its two constituent enantiomers, and that the processes yielded a tangible chemical powder that is principally composed of levofloxacin. He also testified that a single molecule of levofloxacin would be pharmacologically useless; the repeated references in the specification and the prosecution history to the invention's pharmacological effects require the person using the patent to use a pharmaceutical preparation comprised principally of levofloxacin.

Prosecution History.

The prosecution history is replete with instances where the inventor distinguishes levofloxacin from the prior-art racemic ofloxacin. The first three claims of the '407 patent were rejected by the patent examiner twice on the grounds that they were obvious in light of the prior art disclosure of racemic ofloxacin.[7] Daiichi presented evidence of the differences between levofloxacin and ofloxacin until the examiner approved the patent as written.

Claims Construed.

An examination of the plain meaning of the claim language as understood by persons skilled in the art at the time of invention, the specification and the prosecution history indicate that "An S(-)-pyridobenzoxazine compound" and "S(-)-9-Fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid" refer to the levorotatory enantiomer of racemic ofloxacin, levofloxacin. These terms do not refer to racemic ofloxacin. Furthermore, as demonstrated by the specification's resolution methodology, as well as the specification and prosecution history's repeated emphasis on levofloxacin's unique pharmacological properties, the

[7]Notably, the examiner did not reject the claims on the basis of anticipation.

disputed language refers more specifically to a pharmaceutical preparation comprised principally of levofloxacin.

ANTICIPATION.

Mylan claims that the '407 patent is invalid under 35 U.S.C. § 102 (a) and (b), which state in pertinent part:

> A person shall be entitled to a patent unless--
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

"A claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.2d 1368, 1374 (Fed. Cir. 2001) (quotation marks omitted). "To anticipate, the reference must also enable one of skill in the art to make and use the claimed invention." Id.

35 U.S.C. § 282 states that "[a] patent shall be presumed valid." The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. The Patent Office is presumed to have done its job properly, which includes examinations by one or more examiners who are

assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents. American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984).

Mylan makes two anticipation arguments. First, Mylan argues that the disclosure of racemic ofloxacin in a 1983 article by Osada & Ogawa, as well as similar disclosures in a number of other publications published more than a year before June 20, 1984, anticipates levofloxacin. None of the publications specifically discloses levofloxacin, however--they only disclose racemic ofloxacin. Thus, the rationale behind Mylan's argument is that chemists skilled in the art know that racemic compounds are composed of both dextrorotatory and levorotatory enantiomers; therefore, the disclosure of the racemic compound discloses the constituent enantiomers.

This issue--whether the prior art disclosure of a racemic compound precludes the patentability of its constituent enantiomers on the basis of anticipation--has been resolved for some time. The court in In re May, 574 F.2d 1082 (C.C.P.A. 1978) stated that "the novelty of an optical isomer is not negated by the prior art disclosure of its racemate." Id. at 1090 (citing Williams, 171 F.2d at 320).

Mylan's second argument appears to be that, because levofloxacin is one-half of ofloxacin, the claims of the '407 patent read on ofloxacin. See Bristol-Myers, 246 F.2d at 1378 ("it is axiomatic that that which would literally infringe if later anticipates if earlier"). This argument, however, is adequately addressed by the Court's conclusion that the claim language excludes racemic ofloxacin.

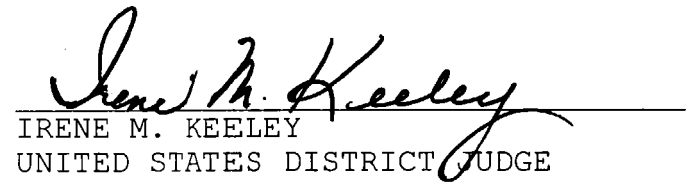
CONCLUSION.

For the reasons stated above, the defendants' motion for summary judgement on anticipation under 35 U.S.C. § 102 (a) and (b) is **DENIED.**

It is so **ORDERED.**

The Clerk is directed to transmit copies of this Order to counsel of record herein.

DATED: March 31, 2003.



IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE