

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

SUMITOMO DAINIPPON	:	
PHARMA CO., LTD. et al.,	:	
Plaintiffs,	:	Civil Action No. 15-280 (SRC)
	:	Civil Action No. 15-281 (SRC)
v.	:	Civil Action No. 15-6401 (SRC)
	:	(Consolidated)
	:	
EMCURE PHARMACEUTICALS	:	
LIMITED et al.,	:	
	:	OPINION & ORDER
Defendants.	:	
	:	

CHESLER, U.S.D.J.

This matter comes before the Court on the application for claim construction by Plaintiffs Sunovion Pharmaceuticals Inc. and Sumitomo Dainippon Pharma Co., Ltd. and Defendants Emcure Pharmaceuticals Ltd., Heritage Pharma Labs Inc., Invagen Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. In this patent infringement suit involving a pharmaceutical patent, the parties seek construction of claim 14 in U.S. Patent No. 5,532,372 (“the ’372 patent”).

ANALYSIS

I. The law of claim construction

A court’s determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). “[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent’s prosecution history), the

judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

It 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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .

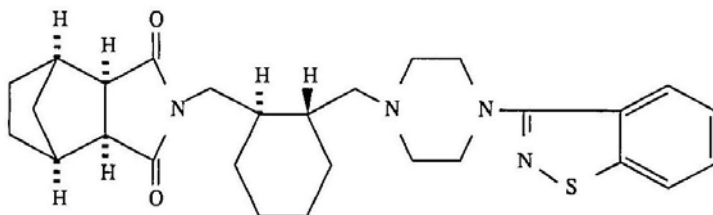
In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those 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.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed term

Claim 14 states:

14. The imide compound of the formula:



or an acid addition salt thereof.

The chemical diagram in claim 14 will be referred to as “D14.” The parties dispute what D14 represents. The parties do not dispute the meaning of the terminal phrase, “or an acid addition salt thereof,” which is not under consideration in this Opinion.¹ Any statement herein referring to the meaning of claim 14 shall be understood to refer to the disputed part of claim 14 and is not a declaration of the meaning of claim 14 in its entirety.

The parties do not dispute some fundamental principles of chemistry that are relevant to understanding claim 14. Out in the world, there is a pharmaceutical compound called “lurasidone,” which is the focus of this litigation. Lurasidone exists in right-handed and left-handed forms, both of which are termed “stereoisomers” or “enantiomers” of lurasidone. A sample of lurasidone may contain only the right-handed enantiomer, or only the left-handed

¹ Plaintiffs contend that the terminal phrase should have its ordinary meaning, while Defendants contend that the parties have no substantive dispute over the meaning of the phrase. The claim construction briefs do not show a live dispute over the meaning of the phrase.

enantiomer, or any mixture of the two. When the mixture contains the stereoisomers in equal proportion (50%/50%), the mixture is termed a “racemic mixture” or a “racemate.”

Defendants propose this construction of claim 14: “a racemic mixture of two enantiomers of which the structural formula is representative.” Plaintiffs propose that claim 14 “refers to lurasidone, lurasidone’s enantiomer, as well as mixtures thereof.” For the reasons that follow, this Court agrees that Plaintiffs’ construction is the correct one. The major problem with Defendants’ position is that it appears not to be anchored in patent law.

Defendants distinguish between what D14 “depicts” and what it “represents.” Defendants state: “the structural formula in Claim 14 depicts a single enantiomer.” (Defs.’ Opening Br. 8.) Defendants then propose this construction for claim 14: “A racemic mixture of two enantiomers of which the structural formula is representative.” Defendants subsequently state: “Defendants’ proposed construction is that the structural formula in Claim 14 represents only a racemic mixture of enantiomers of which the depicted compound is one.” (Defs.’ Opening Br. 8.) Thus, Defendants assert that D14 “depicts” a single enantiomer of lurasidone, and “represents” a racemic mixture of enantiomers.

The main problem with Defendants’ proposed construction of claim 14 is that this Court does not discern a basis for it in the Federal Circuit’s law of claim construction, nor do Defendants articulate a basis. Defendants contend that D14 depicts one thing but represents something else, leaving this Court to inquire: with what legal theory is that gap bridged? Let’s consider the possibilities.

The Federal Circuit has recognized a general rule, with two specific exceptions, to the construction of claim language:

Claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history. We have recognized only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.

Unwired Planet, LLC v. Apple Inc., 829 F.3d 1353, 1358 (Fed. Cir. 2016) (citations omitted).

Thus, as a general rule, there are three options for deriving meaning: 1) a claim term has its ordinary meaning as understood by the skilled artisan; 2) a patentee, acting as his or her own lexicographer, gives a claim term a special meaning; or 3) the Court infers a narrowed meaning based on a disavowal of scope in the specification or prosecution.

In most cases which have required claim construction by this Court, the parties have clearly selected one or another of these approaches. Not so here. Defendants do not expressly refer to any of these approaches. This leaves this Court to inquire: is this a construction based on ordinary meaning, or lexicography, or disavowal? The answer appears to be: none of the above. To start with, Defendants do not claim that the ordinary meaning of claim 14 is a racemic mixture, that skilled artisans would look at claim 14 and perceive that plain meaning.²

Could this then be a lexicography theory? Are Defendants proposing that the patentee used D14 in a non-standard way and gave it an idiosyncratic meaning?

As discussed above, patent law allows patentees to act as their own lexicographers: We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal. The standards for finding lexicography and disavowal are exacting. To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.

² Although Defendants' "shorthand" theory, discussed and rejected below, might be considered a theory of ordinary meaning.

Hill-Rom Servs. v. Stryker Corp., 755 F.3d 1367, 1371 (Fed. Cir. 2014) (citations omitted). As the Federal Circuit has further explained:

For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. As we have often stated, a patentee is free to be his own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification.

Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-980 (Fed. Cir. 1995) (citations omitted).³ Defendants do not contend that the specification contains any clear definition relevant to their proposed construction.⁴ Furthermore, the patent does not contain the words “racemic” or “racemate.”

The problem for Defendants, in a nutshell, is that their brief makes no case for a theory of plain meaning, lexicography or disavowal. With that in mind, the Court turns to Defendants’ explanation of their proposed construction.

Defendants offer two different approaches to the meaning of claim 14. The first appears in their brief under the heading, “Drawing Structural Formulae of Organic Molecules,” while the

³ See also Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citations omitted):

To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning. It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term.

⁴ Defendants’ principal approach seems just a bit similar to a lexicography theory: they say that claim 14 is directed to Compound 101, so look to Compound 101 for the characteristics of the claimed compound. The problem is that the disclosure of Compound 101 in the specification cannot reasonably be understood to be a *clear* definition of any aspect of claim 14. Defendants do not contend that the applicants intended the disclosure of Compound 101 to be a definition of any term used in claim 14.

second appears as their argument.

As to the first approach, Defendants contend that D14 depicts a single enantiomer, and that a drawing of a single enantiomer is a common shorthand in the art for a racemic mixture.

Defendants offer two textbooks in support:

Similarly, chemists also often draw one enantiomer as shorthand for a racemic mixture. This convention is described in numerous publications, including the following two examples:

When a single enantiomer is drawn, be sure to ask yourself whether this is done deliberately, in order to specify *that particular enantiomer*, or simply as a matter of convenience to avoid the work of drawing both enantiomers of the racemic pair. Usually some indication will be made if it is indeed a single enantiomer that is meant.

Organic Chemistry, Jones, M., Jr., New York, NY: W.W. Norton & Company, Inc., Second Edition, 1997, page 188 (emphasis in original).

What are the conventions of writing chemical equations when racemates are involved? Unless specifically indicated by the R/S notation, the sign of optical rotation, or some surrounding text, it is assumed that all ingredients in a reaction are racemic. To avoid the clutter of writing both enantiomers in such cases, only one is shown, the equimolar presence of the other being tacitly assumed.

Organic Chemistry: Structure and Function, Vollhardt & Schore, New York, NY: W.H. Freeman and Company, Sixth Edition, 2010, page 201.

(Defs.' Opening Br. at 7.) Defendants' point here seems to be that it is customary for chemists to draw one enantiomer as a shorthand for a racemic mixture and that this is demonstrated by the two textbook quotes. This Court need not reach the legal question of the weight to be given to this extrinsic evidence⁵ because the quotes do not support Defendants' point. The first quote

⁵ “We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms . . .” Phillips, 415 F.3d at 1318.

actually seems to say that, when you see a drawing of a single enantiomer, you cannot tell whether it was intended to represent one enantiomer or both. This does not support Defendants' position – it undermines it. The Court notes, as well, that this quote refers to a “racemic pair,” not a “racemic mixture.” Defendants have not explained why “racemic pair” here should be understood to mean “racemic mixture.” There is no support in the first example for the proposition that a drawing of a single enantiomer is shorthand for a racemic mixture of stereoisomers. If anything, this example supports the contrary proposition that a drawing of a single enantiomer has an ambiguous meaning.

The second quote addresses conventions in writing “chemical equations.” Claim 14 does not appear, however, to contain any equation: neither side contends that D14 represents a chemical equation. The second example appears to be irrelevant; certainly, Defendants do not explain how conventions in writing chemical equations apply to D14.

Defendants have offered two textbooks to support their contention that chemists often draw a single enantiomer as shorthand for a racemic mixture. One of the textbooks contradicts their assertion, while the second appears to be irrelevant to the question.⁶ This Court thus need not reach the question of what weight it should accord these pieces of extrinsic evidence. Nor need it ponder why, if D14 is a typical shorthand depiction of a racemic mixture that would be understood as such by skilled artisans, Defendants did not clearly argue that this is its ordinary meaning.

Defendants' second, and principal, claim construction argument has the following

⁶ Moreover, the application date for the '372 patent is July 5, 1991, while the earlier of the two textbooks is from 1997.

structure:

1. D14 “is directed to” Compound 101.
2. Compound 101 is a racemic mixture.

Therefore, claim 14 is a racemic mixture.

The key problems with this argument lie in the first proposition.

In the first step of their argument, Defendants offer support for the proposition that D14 “is directed to” Compound 101. It is not clear what “is directed to” means in this context. The intrinsic evidence Defendants offer clearly shows that the applicant understood D14 to represent a genus of compounds of which Compound 101 is one species. Defendants quote various statements in the Response to Restriction Requirement, dated March 30, 1995, but the clear thrust of that document⁷ is that the applicants saw the proposed claim as a broad genus which encompassed the species of Compound 101. (Kistler Dec. Ex. F.) The applicants continued to take this position in the Response to Restriction Requirement dated July 17, 1995. (Kistler Dec.

⁷ In the Examiner’s Action, dated February 24, 1995, the Examiner stated that the claims under examination encompassed “more than one independent and unique invention,” and issued a requirement that the applicants elect the single invention to be examined, as a restriction imposed under 35 U.S.C. § 121. (Kistler Dec. Ex. E.) In response, in the document dated March 30, 1995, the applicants contended that the Examiner’s Action was not a proper restriction requirement under 35 U.S.C. § 121 and asked the Examiner to reconsider, but stated that, if the Examiner maintained this requirement, “it is applicants’ desire to elect a group which encompasses compound no. 101 . . .” (Kistler Dec. Ex. F at 3.) At no point in these documents did the applicants manifest any intent to narrow the application to Compound 101; to the contrary, every statement shows an intent to claim a broad genus, within which Compound 101 is one species.

Similarly, Defendants point to the Amendment dated December 29, 1994, which refers to “the claimed compound (e.g. Compound No. 101).” (Kistler Dec. Ex. J at 8.) Again, since “e.g.” means “for example,” this demonstrates that the applicants understood the compound claim to be a genus of which Compound 101 is a species.

Ex. H.)

Furthermore, as Plaintiffs observe in their responsive brief, Defendants' contention that claim 14 "is directed to" (and should be limited to) Compound 101 runs into a substantial problem: Compound 101 is a hydrochloric acid addition salt, but the terminal clause of claim 14 states: "or an acid addition salt." The specification explains that there are many acid addition salts:

The present invention covers the acid addition salt formed between the imide compound (I) and an organic or inorganic acid. Examples of the inorganic acid are hydrochloric acid, hydrobromic acid, hydroiodic acid, sulfuric acid, etc., and examples of the organic acid are acetic acid, oxalic acid, citric acid, malic acid, tartaric acid, maleic acid, fumaric acid, etc.

'372 Patent col.4 ll.44-50. Limiting claim 14 to one particular acid addition salt, the hydrochloride, runs contrary to this passage in the specification.

The remainder of Defendants' opening brief deals with the second proposition and discusses the chemical attributes of Compound 101. This Court need not travel down this path, however, because Defendants have not persuaded that the chemical characteristics of Compound 101 are relevant to the present claim construction inquiry. The problematic part of Defendants' argument remains the first proposition. As discussed above, this proposition does not appear to be anchored in patent law. As already established, there are three principal options for assertions of claim meaning: ordinary meaning, lexicography, and disavowal. This "is directed to" argument does not appear to closely fit any of them, but it seems most like an argument based on a restriction to a single embodiment.

Defendants propose a construction which limits claim 14 to Compound 101, but they generally avoid using the words "narrow," "limit," "restrict," or "disavow." Instead, Defendants

contend that claim 14 “is directed to” Compound 101. It is only in the conclusion of Defendants’ opening brief that they say: “The intrinsic evidence demonstrates that Claim 14 of the ’372 patent is *limited* to a racemic mixture of enantiomers represented by the formula shown in the claim.” (Defs.’ Opening Br. at 23; italics added.) Defendants have not articulated a basis in patent law for limiting the claim to any particular embodiment, whether Compound 101 or another.

The Federal Circuit has – in its own words – “repeatedly warned” against limiting claims to particular embodiments: “although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.” Phillips, 415 F.3d at 1323. The Federal Circuit has explained:

The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language. Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.

Superguide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004). Moreover, the requirements for importing such a limitation are exacting: “Generally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a clear intention to limit the claim’s scope with words or expressions of manifest exclusion or restriction. i4i Ltd. P’ship v. Microsoft Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (quotation omitted). Defendants have not pointed to any expressions of manifest exclusion or restriction in the patent which could justify restricting claim 14 to any particular embodiment.

Plaintiffs, on the other hand, do not state what D14 depicts, but only what it represents: “lurasidone, lurasidone’s enantiomer, as well as mixtures of these enantiomers.” (Pls.’ Opening

Br. 6.) As Defendants contend, this formulation makes D14 a genus, with lurasidone enantiomers, homogeneously or in mixtures, as the species.

Plaintiffs begin their argument by alleging that Defendants have made pre-litigation admissions which support Plaintiffs' proposed construction.⁸ In keeping with the teachings of Phillips, this Court prefers to consider first whether the intrinsic evidence can resolve this claim construction inquiry.

The intrinsic evidence supports Plaintiffs' proposed construction. Plaintiffs point to this statement in the specification: "The imide compound (I) can have stereo and optical isomers, and this invention involves these isomers or their mixtures as well." '372 Patent col.4 ll.51-3. Defendants contend that this statement applies only to claim 1, and not claim 14. This appears to be incorrect. The specification defines "imide compound (I)" in column 3, lines 3-9. The identical definition, chemical diagram and all, appear as the first lines of the Abstract of the patent. There is nothing in the Abstract that indicates that it is inapplicable to claim 14, or to any claim, for that matter. This statement in the specification is important intrinsic evidence that the applicants understood all the imide compounds (I) in all claims to have stereo and optical isomers, and that such isomers, as well as mixtures of isomers, fall within the scope of the claims.

⁸ Plaintiffs contend that every Defendant has admitted that claim 14 covers lurasidone: 1) InvaGen stated this in its Invalidity Contentions filed in this litigation ("This compound is also known as lurasidone") (Ratliff Dec. Ex. 3 at 8-9); 2) Teva stated this in its "Detailed Statement of the Factual and Legal Bases" which accompanied its notice letter to Plaintiffs ("Claim 14 of the '372 patent is the narrowest claim that covers lurasidone . . .") (Ratliff Dec. Ex. 4 at 20); and 3) Emcure stated this in its "Detailed Statement of the Factual and Legal Bases" which accompanied its notice letter to Plaintiffs (referring to "the compound of claim 14 of the '372 patent (*i.e.*, lurasidone)") (Ratliff Dec. Ex. 5 at 17). Although this Court bases its construction of claim 14 on the intrinsic evidence, the Court does wonder what led each Defendant to change its position for the Markman.

Defendants' proposed construction of claim 14, limiting it to a racemic mixture, conflicts irreconcilably with this statement in the specification. Nor have Defendants pointed to any expression of manifest restriction that might allow their proposed construction to escape the impact of this statement. Plaintiffs' proposed construction of claim 14, on the other hand, is consistent with this statement in the specification.

Furthermore, the statements in the prosecution history cited by Defendants support the inference that the applicant intended claim 14 to be a genus of compounds, within which Compound 101 is one species. Plaintiffs' proposed construction is consistent with this, while Defendants' proposed construction is contrary to this.

Plaintiffs support their position by citing two Federal Circuit decisions in which, Plaintiffs contend, the Federal Circuit refused to limit a claim to a racemic mixture. First, Plaintiffs cite Pfizer Inc. v. Ranbaxy Labs., 457 F.3d 1284, 1289 (Fed. Cir. 2006), a case with many material differences from the instant case. It is certainly true that, in Ranbaxy, as Plaintiffs contend, the Federal Circuit refused to limit claim 1 to a racemic mixture, and that it rejected an approach that would have imported such a restriction from the examples in the specification, but this cannot be boiled down to a general principle applicable to the instant case. Id. at 1290. Similarly, Plaintiffs cite Pfizer Inc. v. Teva Pharms. USA, Inc., 555 Fed. Appx. 961, 965 (Fed. Cir. 2014), another case with material differences in which the Federal Circuit refused to restrict a pharmaceutical compound claim to racemates. These cases might best be considered as generally consistent with today's decision.

The Court notes a side dispute between the parties on which exemplary compounds in the specification are preferred embodiments. In its opening brief, Plaintiff states: "the '372 patent

illustrates a series of preferred embodiments, including lurasidone hydrochloride (Compound No. 105), lurasidone's enantiomer in a hydrochloride salt form (Compound No. 104), and a mixture of this enantiomeric pair in a hydrochloride salt form (Compound No. 101)." (Pl.'s Opening Br. 12.) In their responsive brief, Defendants argue that only Compound 101 is the preferred embodiment. (Defs.' Resp. Br. 2.) This side dispute need not be resolved, as the Court does not base its decision on either position. As discussed above, neither party has pointed to any expressions of manifest exclusion or restriction in the patent which could justify restricting claim 14 to any particular embodiment.

Defendants propose a construction which lacks a foundation in the intrinsic evidence as well as in patent law, and conflicts with the intrinsic evidence, while Plaintiffs propose a construction grounded in the intrinsic evidence and supported by patent law. This Court adopts Plaintiffs' proposed construction. The disputed section of claim 14 means: "lurasidone, lurasidone's enantiomer, as well as mixtures of these enantiomers."

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: November 15, 2016