# United States Court of Appeals for the Federal Circuit

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**SUMITOMO DAINIPPON PHARMA CO., LTD., SUNOVION PHARMACEUTICALS INC.,**
*Plaintiffs-Appellees*

**v.**

**EMCURE PHARMACEUTICALS LIMITED, HERITAGE PHARMA LABS INC., FKA EMCURE PHARMACEUTICALS USA INC., INVAGEN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,**
*Defendants-Appellants*

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2017-1798, 2017-1799, 2017-1800

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Appeals from the United States District Court for the District of New Jersey in Nos. 2:15-cv-00280-SRC-CLW, 2:15-cv-00281-SRC-CLW, 2:15-cv-06401-SRC-CLW, Judge Stanley R. Chesler.

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Decided: April 16, 2018

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CHRISTOPHER K. HU, Blank Rome LLP, New York, NY, argued for all defendants-appellants. Defendants-appellants Emcure Pharmaceuticals Limited, Heritage Pharma Labs Inc. also represented by JAY PHILIP LESSLER; DAVID C. KISTLER, Princeton, NJ.

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IRA J. LEVY, Goodwin Procter LLP, New York, NY, for defendants-appellants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd. Also represented by LINNEA P. CIPRIANO, CYNTHIA LAMBERT HARDMAN; WILLIAM M. JAY, Washington, DC; DAVID ZIMMER, Boston, MA; BRIAN JOSEPH PREW, Greenberg Traurig, LLP, New York, NY.

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Before MOORE, MAYER, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

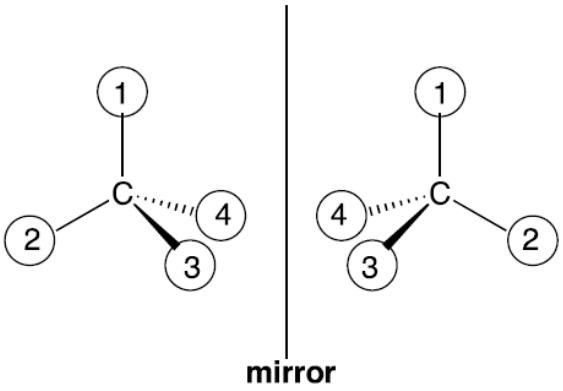
This Hatch-Waxman appeal requires us to construe the scope of a claim depicting a compound's chemical structure. Although the compound can exist in two different three-dimensional orientations that are mirror images of each other, only one is portrayed in the claim. The district court construed the claim to cover the two three-dimensional orientations in isolation—both the one shown in the claim and its mirror image—as well as mixtures of the two in any ratio. The parties then stipulated to infringement and the entry of an injunction. We agree that, at a minimum, the claim encompasses the specific orientation depicted. Because this orientation is the

active pharmaceutical ingredient in each party's commercial product, we need not determine what else falls within the claim's ambit to resolve the present dispute. We affirm.

I

Stereochemistry is the study of a molecule's three-dimensional structure. Stereoisomers are molecules with the same chemical formula and structure but different three-dimensional configurations. If two stereoisomers are non-superimposable mirror images of one another, they are called enantiomers. Compounds with chiral centers—a carbon atom bonded to four non-identical atoms or groups of atoms—provide common examples of compounds with enantiomers. Although enantiomers often have identical physical properties, such as density and boiling point, they can exhibit different pharmacological properties in the human body.

When drawing enantiomers, chemists use wedges and dashes to indicate the three-dimensional structure. A wedge designates a bond coming out of the plane of the paper towards the reader, a dashed line represents a bond extending behind the plane of the paper, and normal lines signify bonds in the same plane as the paper. A simple example of two enantiomers is shown below:



J.A. 1010. The two molecules are enantiomers because they cannot be made identical to one another without breaking and rearranging the chemical bonds. If the molecule on the right is rotated to align atoms "1" and "2" with the molecule on the left, atoms "3" and "4" are in the reverse position.

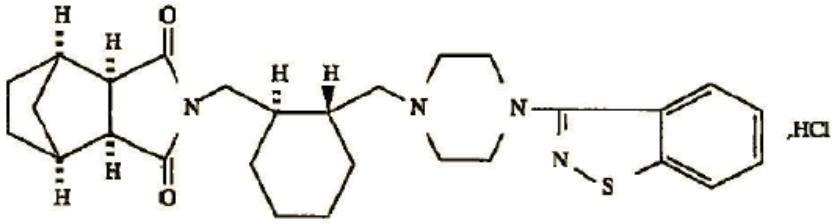
Chemists often characterize enantiomers as "(+)" or "(–)" based on their optical activity—the ability of a solution containing one enantiomer to rotate polarized light. A solution of the (+)-enantiomer rotates the plane of polarized light in a clockwise direction, and a solution of the (–)-enantiomer rotates the plane of polarized light in a counter-clockwise direction.

Mixtures can contain enantiomers in any ratio. A mixture with 50% of the (+)-enantiomer and 50% of the (–)-enantiomer is known as a "racemate" or "racemic mixture." Racemic mixtures do not rotate the plane of polarized light because the clockwise rotation caused by the (+)-enantiomer cancels out the equal but opposite counter-clockwise rotation of the (–)-enantiomer.

Having summarized the relevant organic chemistry principles, we now turn to the merits of this appeal. Sumitomo Dainippon Pharma Co. and Sunovion Pharmaceuticals Inc. own U.S. Patent No. 5,532,372. The '372 patent relates generally to "novel imide compounds and their acid addition salts" that are useful as antipsychotic agents. '372 patent col. 1 ll. 8–12. The '372 patent discloses and claims more than one billion compounds, some of which have stereo and optical isomers. *Id.* at col. 4 ll. 51–53. Lurasidone, the (–)-enantiomer of an imide compound covered by the '372 patent, is the active ingredient in Sunovion's schizophrenia and bipolar depression drug LATUDA®.

The '372 patent specification teaches several preferred embodiments in Examples 1(a) through 1(e).

Example 1(a) describes the synthesis of Compound No. 101, which the specification portrays as follows:

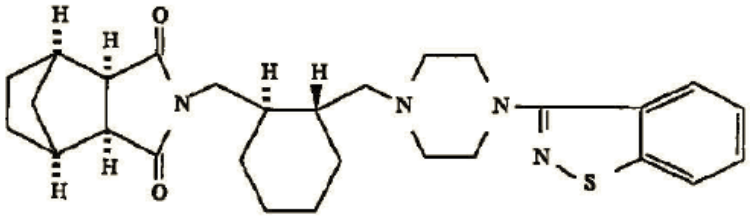



*Id.* at col. 30 ll. 40–65. Compound No. 101 is a chiral molecule because it contains a cyclohexyl linker—the region between the imide group on the left and the aryl-piperazine group on the right—with two chiral centers.

The subsequent examples, 1(b) through 1(e), describe methods for separating Compound No. 101 into its constituent enantiomers in various salt forms. Examples 1(b) and 1(c) detail the process for obtaining the (+)-enantiomer (Compound No. 102) and (–)-enantiomer (Compound No. 103), respectively, in the tartrate salt form. *See id.* at col. 31 ll. 10–54. Examples 1(d) and 1(e) then convert Compound Nos. 102 and 103 from the tartrate salt form to the hydrochloride salt form. Example 1(d) produces the (+)-enantiomer (Compound No. 104), and Example 1(e) creates the (–)-enantiomer (Compound No. 105), which is lurasidone. *See id.* at col. 32 ll. 1–22.

After Emcure Pharmaceuticals Ltd., Heritage Pharma Labs Inc., InvaGen Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively, "Appellants") filed Abbreviated New Drug Applications with the U.S. Food and Drug Administration seeking approval to market generic versions of LATUDA®, Sumitomo and Sunovion sued the Appellants for infringing claim 14 of the '372 patent. Claim 14 recites:

14. The imide compound of the formula:



or an acid addition salt thereof.

Just like depicted Compound No. 101, the claimed molecule is chiral because of the two carbons in the cyclohexyl linker. Both parties agree that the specific three-dimensional structure depicted in claim 14 is lurasidone, the (–)-enantiomer.

The claim construction question for the district court centered on what combination of enantiomers claim 14 encompassed. Appellants sought to limit claim 14 to "a racemic mixture of two enantiomers of which the structural formula is representative." *Sumitomo Dainippon Pharma Co. v. Emcure Pharm. Ltd.*, No. CV 15-280, 2016 WL 6803077, at *2 (D.N.J. Nov. 15, 2016). For support, Appellants relied on the claimed structure's similarities to Compound No. 101, which Appellants contend is a racemic mixture, organic chemistry textbooks suggesting that ordinarily skilled artisans draw a single enantiomer as a shorthand representation for a racemic mixture, and the '372 patent's prosecution history.

The district court rejected Appellants' narrow construction, which would have excluded the specific enantiomer depicted in claim 14. According to the court, even if Compound No. 101 is a racemic mixture, its resemblance to claim 14 did not justify importing that limitation from the specification into the claim. The court also concluded that the cited extrinsic evidence and prosecution history were at best irrelevant and at worst contradictory to Appellants' construction. Therefore, the court adopted

Sunovion's proposal to construe claim 14 as covering "lurasidone, lurasidone's enantiomer, as well as mixtures of these enantiomers." *Id.* at *8.

Following the district court's claim construction order, Appellants stipulated to infringement of claim 14 and the entry of permanent injunctions. Appellants then filed this appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## II

Claim construction seeks to ascribe the "ordinary and customary meaning" to claim terms as a person of ordinary skill in the art would have understood them at the time of invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). As a general rule, the ordinary and customary meaning controls unless "a patentee sets out a definition and acts as his own lexicographer, or . . . the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "While the ultimate construction of a claim term is a legal question reviewed de novo," underlying determinations based on extrinsic evidence are factual determinations that are reviewed for clear error when made by a district court. *Enzo Biochem Inc. v. Applera Corp.*, 780 F.3d 1149, 1153 (Fed. Cir. 2015) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015)).

As explained below, the plain claim language and specification demonstrate that, at a minimum, claim 14 covers what it depicts: the (–)-enantiomer. This suffices to resolve the parties' dispute because Appellants concede that the district court's judgment can be affirmed if we conclude that claim 14 at least covers the (–)-enantiomer. *See* Oral Arg. at 8:40–9:10, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-1798.mp3. We

therefore express no opinion on the remainder of the district court's construction. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

The plain claim language marks the starting point for our analysis. *Phillips*, 415 F.3d at 1312 ("[T]he claims are 'of primary importance[] in the effort to ascertain precisely what it is that is patented.'" (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876))). Claim 14 recites a specific enantiomer and its acid addition salts. Both parties agree that the structure shown in the claim is the (–)-enantiomer; moreover, Appellants do not dispute that a person of ordinary skill looking at claim 14's structure in a vacuum would understand it to be one way of depicting the (–)-enantiomer. *See* Oral Arg. at 3:09–4:21, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-1798.mp3. Of equal importance is the lack of anything in the claim language limiting its scope to a "racemate" or "racemic mixture." Absent some indication in the specification or prosecution history to the contrary, it follows that the plain and ordinary meaning of claim 14 covers at least the specific enantiomer depicted in the claim itself.

The specification confirms our understanding of claim 14's plain and ordinary meaning. Instead of suggesting that the (–)-enantiomer should be excluded, the specification describes it as a preferred embodiment. Although its structure is not shown, Example 1(e) details the steps for obtaining Compound No. 105, the (–)-enantiomer, from Compound No. 101 and even provides data on Compound No. 105's physical properties. *See* '372 patent col. 32 ll. 18–22 (listing melting point and optical rotation data). Accordingly, the intrinsic record supports including the (–)-enantiomer—the specific enantiomer that is displayed in the claim and described as a preferred embodiment—within claim 14's scope.

This outcome comports with previous cases rejecting similar attempts to limit claims to racemic mixtures. Although differences in the patents' specifications make it such that they are not factually identical to the current appeal, this does not detract from the convincing intrinsic evidence we have required in cases confining otherwise-unrestricted claims to racemic mixtures. For example, in *Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, Ranbaxy sought to limit a claim depicting a specific three-dimensional orientation to a racemic mixture. 457 F.3d 1284, 1288–89 (Fed. Cir. 2006). The compound at issue had four isomers: R-trans, S-trans, R-cis, and S-cis.[1] The specification disclaimed the R-cis and S-cis isomers, and it only disclosed reaction sequences that produced racemic mixtures. Ranbaxy argued that the specification's disclosure, combined with the convention that a racemate is often represented by drawing one of the constituent enantiomers, justified limiting the claim to a racemic mixture. We rejected these arguments because the claim itself depicted the R-trans enantiomer, and unlike other claims in the same patent, it was not limited by the "trans-(±)" designation. *Id.* at 1289. And although the specification disclaimed the two cis enantiomers, it did not include a further disavowal that would constrain the patent's scope to a trans racemate. Therefore, we construed the claim to cover the R- and S-trans enantiomers as well as any mixtures of the two.

Appellants' claim construction arguments conflict with *Pfizer* and other precedent because they seek to import limitations from the specification into the claim.

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[1] The "R" and "S" nomenclature is another way of labeling a pair of enantiomers; the "trans" and "cis" designations indicate whether the atom or group is on the same or opposite side of a plane. *Pfizer*, 457 F.3d at 1286–87.

According to Appellants, Compound No. 101 is a racemic mixture and claim 14's scope should be coextensive with Compound No. 101 because of the similarities in the compounds' structures. This argument relies on a series of inferences. Appellants begin with the premise that Compound No. 101 cannot be a pure enantiomer because Examples 1(b)–(e) describe the process for separating Compound No. 101 into the (+)- and (–)-enantiomers. *See* '372 patent col. 31 l. 12 – col. 32 l. 22. The pure enantiomers of Compound Nos. 102–05 rotate the plane of polarized light, as indicated by the patentees' inclusion of optical rotation data for these compounds. *Id.* at col. 31 ll. 22, 53; col. 32 ll. 12, 22 (listing $[\propto]_D^{25}$ values for optical activity). The '372 patent, however, does not provide any optical rotation data for Compound No. 101. Because the '372 patent included optical rotation data for compounds with optical activity, the absence of this data for Compound No. 101 suggests that it lacks optical activity, i.e., it is a racemic mixture. Setting aside the particular salt form of Compound No. 101,[2] its structure is identical to claim 14, and thus Appellants assert that claim 14 should be limited to a racemic mixture. Moreover, Appellants argue that the specification's treatment of Compound Nos. 101–05 as distinct entities further supports their contention that the structure in claim 14 depicts only Compound No. 101 and not Compound Nos. 102–05.

In our view, the specification is inconclusive regarding whether Compound No. 101 is a racemic mixture. The specification does not refer to Compound No. 101 as a "racemic mixture" or a "racemate"; indeed, those words do not appear anywhere in the specification. While Com-

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[2] The "HCl" to the right of Compound No. 101's structure indicates that it is a hydrochloride salt. *See* '372 patent col. 30 ll. 40–65. The structure in claim 14 does not contain a similar indication.

pound No. 101 does contain both the (+)- and (–)-enantiomers, the '372 patent sheds no light on the relative ratio of each enantiomer present. Appellants' inferences from the disparate reporting of optical data for Compound Nos. 101–05 are not without merit, but we need not decide this issue.

Even if Compound No. 101 is a racemic mixture, the specification neither defines claim 14's structure as Compound No. 101 nor disclaims scope in a way that confines claim 14 to a racemic mixture. *See Thorner*, 669 F.3d at 1367–68 ("Both [lexicography and disclaimer] require a clear and explicit statement by the patentee."). To act as a lexicographer, the patentee must "clearly set forth a definition of the disputed claim term." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Here, the '372 patent does not define the structure in claim 14 as a racemate or as coextensive with Compound No. 101. Claim 14 does not refer to Compound No. 101, and nothing in the specification links the two structures together. Compound No. 101 just happens to be the only other place in the patent where claim 14's structure appears. This, of course, is not enough to restrict a claim's scope. *See, e.g.*, *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 992 (Fed. Cir. 1999) ("[M]ere inferences drawn from the description of an embodiment of the invention cannot serve to limit claim terms.").

The specification also does not disclaim the (–)-enantiomer. For disclaimer, we look to the intrinsic evidence for "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). Our opinion in *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, where we concluded that the patentee disclaimed a dual lumen configuration for balloon dilation catheters, is instructive. 242 F.3d 1337 (Fed. Cir. 2001). There, the patent de-

scribed both a dual lumen (side-by-side) and coaxial lumen configuration. The specification, however, disparaged the dual lumen design, described the coaxial lumen design as "the present invention," and explained that the coaxial lumen design was the structure "for all embodiments of the present invention contemplated and disclosed herein." *Id.* at 1342–44. We held that this amounted to a disclaimer of the dual lumen configuration. By contrast, nothing in the '372 patent's specification disparages a specific enantiomer, refers to a racemic mixture as forming the basis for the present invention, or describes a racemic mixture as the basis for all of the '372 patent's embodiments. Finding no "expression[] of manifest exclusion or restriction," we cannot conclude that the patentees disclaimed the (–)-enantiomer. *See Teleflex, Inc.*, 299 F.3d at 1325.

Finally, Appellants' organic chemistry textbooks and expert testimony do not compel a different result. Extrinsic evidence is, in general, "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). This is particularly so here, where the intrinsic record demonstrates that claim 14's structure covers at least the (–)-enantiomer. *See Vitronics Corp.*, 90 F.3d at 1583 ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence."). In any event, we see no clear error in the district court's rejection of the organic chemistry textbooks as irrelevant or contradictory to Appellants' construction. *See Teva*, 135 S. Ct. at 841. And while Appellants' expert contends that it is conventional in the art to use a single enantiomer as shorthand for a racemic mixture, he does not state that a person of ordinary skill would always understand the depiction of a

single enantiomer to *exclude* the very enantiomer depicted. *See* J.A. 1015–16 ¶ 27.

## III

We have considered the parties' remaining arguments and find them unpersuasive. The district court did not err in construing claim 14 to cover the (–)-enantiomer. Determining whether claim 14 covers additional scope is unnecessary to the disposition of this appeal. The judgment of the district court is affirmed.

## AFFIRMED

### COSTS

Costs to Appellees.