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Not for Publication in West's Federal Reporter. See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also Federal Circuit Rule 32.1 and Federal Circuit Local Rule 32.1. (Find CTAF Rule 32.1)

United States Court of Appeals,
Federal Circuit.
PFIZER INC., Warner–Lambert Company LLC, and C.P. Pharmaceuticals International C.V., Plaintiffs–Appellees,
and
Northwestern University, Plaintiff–Appellee,
v.
TEVA PHARMACEUTICALS USA, INC. and Teva Pharmaceutical Industries, Ltd., Defendants–Appellants,
and
Lupin, Ltd. and Lupin Pharmaceuticals, Inc., Defendants–Appellants,
and
Actavis, Inc. and Actavis Elizabeth, LLC, Defendants–Appellants,
and
Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals, Inc., Defendants–Appellants,
and
Sun Pharma Global, Inc., Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Industries, Inc., Defendants–Appellants,
and
Wockhardt Limited and Wockhardt USA, LLC, Defendants–Appellants,
and
Alphapharm Pty. Ltd. and Mylan Pharmaceuticals, Inc., Defendants–Appellants.

Nos. 2012–1576, 2012–1601, 2012–1602, 2012–1603, 2012–1604, 2012–1605, 2012–1607.

Feb. 6, 2014.

Background: Owner and licensee of patents related to New Drug Application (NDA) for pregabalin capsules for adjunctive therapy of partial onset seizures and treatment of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia brought infringement action against manufacturers of proposed pharmaceutical products. Cases were consolidated. The United States District Court for the District of Delaware, Gregory M. Sleet, Chief Judge, 882 F.Supp.2d 643, found various claims of the asserted patents infringed, and that patents were not invalid. Manufacturers appealed.

Holdings: The Court of Appeals, Prost, Circuit Judge, held that:
(1) patent was not invalid for lack of enablement;
(2) patent was not invalid for lack of written description; and
(3) patent was not invalid due to obviousness.

Affirmed.

West Headnotes

[1] Patents 291 99

291 Patents
291IV Applications and Proceedings Thereon
291k99 k. Description of invention in specification. Most Cited Cases

Patent application's disclosure, coupled with methods for synthesis and resolution that were found to be well-known and routine in the art, sufficiently enabled person of skill in the art to prepare 3–isobutylGABA with no more than routine experimentation, and thus patent related to New Drug Application (NDA) for pregabalin capsules for adjunctive therapy of partial onset seizures and treatment of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia was not invalid for lack of enablement. 35 U.S.C.A. § 112(a).

[2] Patents 291 ⚿99

291 Patents
291IV Applications and Proceedings Thereon
291k99 k. Description of invention in specification. Most Cited Cases

Patent related to New Drug Application (NDA) for pregabalin capsules for adjunctive therapy of partial onset seizures and treatment of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia was not invalid for lack of written description; patent application disclosed structure of 3–isobutylGABA as preferred embodiment of invention, and set forth in vitro and in vivo data for compound, and described method of synthesizing compound. 35 U.S.C.A. § 112(a).

[3] Patents 291 ⚿16.25

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.25 k. Chemical compounds. Most Cited Cases

Patent related to New Drug Application (NDA) for pregabalin capsules for adjunctive therapy of partial onset seizures and treatment of neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, and fibromyalgia was not invalid due to obviousness; there was no evidence in the record of motivation for a skilled artisan to modify gabapentin for further anticonvulsant research based on prior art, there was nothing in prior art references singling out 3–isopropylGABA as promising compound to modify due to its anticonvulsant effect, and references failed to identify lead compound because they disclosed nothing concrete about 3–isopropylGABA or its mechanisms of action, including whether it had anticonvulsive properties. 35 U.S.C.A. § 103.

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases

4,322,440, 5,051,448. Cited as Prior Art.

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases

Patents 291 ⚿328(4)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(4) k. Reissue. Most Cited Cases

5,563,175, 6,001,876. Cited.

41,920. Cited.

Patents 291 ⚿328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases

6,197,819. Construed and Ruled Valid and Infringed.

***962** Appeals from the United States District Court for the District of Delaware in Nos. 09–CV–0307, 09–CV–0308, 09–CV–0309, 09–CV–0310, 03–CV–0311, 09–CV–0312, 09–CV–0313, 09–CV–0315 and 10–CV–0853, Chief Judge Gregory M. Sleet.Dimitrios T. Drivas, White & Case LLP, of New York, NY, argued for plaintiffs-appellees Pfizer Inc., et al. With him on the brief were Jeffrey J. Oelke, Adam Gahtan, Brendan G.

Woodard, Robert E. Counihan, and Ryan P. Johnson, for plaintiffs-appellees, Pfizer Inc., et al. Of counsel on the brief were Kevin M. Flowers, Matthew C. Nielsen and Mark H. Izraelewicz, Marshall, Gerstein & Borun, LLP, of Chicago, IL, for plaintiff-appellee Northwestern University.

James F. Hurst, Winston & Strawn, LLP, of Chicago, IL, argued for defendants-appellants Sun Pharma Global, Inc., et al. of counsel was Geoffrey P. Eaton, of Washington, DC.

Timothy H. Kratz, McGuireWoods LLP, of Atlanta, GA, argued for defendants-appellants Alphapharm Pty. Ltd., et al. With him on the brief were Robert L. Florence and George J. Barry, III. With him on the brief for defendants-appellants Cobalt Laboratories, Inc., et al. were E. Anthony Figg, Joseph A. Hynds, R. Elizabeth Brenner–Leifer and Christina Nichole Gifford, Rothwell, Figg, Ernst & Manbeck, P.C., of Washington, DC; for defendants-appellants Actavis, Inc., et al. were Francis H. Morrison, III, and Jonathan A. Harris, Axinn, Veltrop & Harkrider LLP, of Hartford, CT; for defendants-appellants, Teva Pharmaceuticals USA, Inc., et al. were James Galbraith, Antony Pfeffer, Matthew C. Ruedy, and ***963** Linnea P. Cipriano, Kenyon & Kenyon, LLP, of New York, NY; for defendants-appellants Lupin Ltd., et al. were Robert F. Green, Caryn C. Borg–Breen, Christopher T. Griffith, Elizabeth M. Crompton, Leydig, Voit & Mayer Ltd., of Chicago, IL; for defendants-appellants Wockhardt Limited, et al. were Joseph M. Reisman, Jay R. Deshmukh, and Thomas P. Krzeminski, Knobbe, Martens, Olson & Bear, LLP, of San Diego, CA.

Before RADER, Chief Judge, PROST and MOORE , Circuit Judges.

PROST, Circuit Judge.

Defendants–Appellants Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; Lupin, Ltd.; Lupin Pharmaceuticals, Inc.; Actavis, Inc.; Actavis Elizabeth, LLC; Cobalt Laboratories, Inc.; Cobalt Pharmaceuticals, Inc.; Sun Pharma Global, Inc.; Sun Pharmaceutical Industries, Ltd.; Sun Pharmaceutical Industries, Inc.; Wockhardt Ltd.; Wockhardt USA, LLC; Alphapharm Pty. Ltd.; and Mylan Pharmaceuticals, Inc. (collectively, "Appellants") appeal from a final judgment of the United States District Court for the District of Delaware that found various claims of the asserted patents [FN1] infringed and from the court's holdings regarding enablement,[FN2] written description,[FN3] and obviousness. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 882 F.Supp.2d 643, 732 (D.Del.2012) (" *District Court Opinion* ").

FN1. The asserted patents are: U.S. Patent Nos. 6,197, 819 ("'819 patent"); 5,563,175 ("'175 patent"); 6,001,876 ("'876 patent"); and U.S. Reissue Patent No. 41,920 ("RE '920 patent"), which is a reissue of the '876 patent.

FN2. Defendants–Appellants Sun Pharma Global, Inc.; Sun Pharmaceutical Industries, Ltd.; and Sun Pharmaceutical Industries, Inc. (collectively, "Sun") do not join the other Appellants in challenging the district court's enablement determination.

FN3. Sun, alone among the Appellants, asserted a written description invalidity defense below and now challenges the district court's finding on appeal.

Because we agree with the district court's claim construction, we affirm the finding of infringement. We also hold that challenged claim 2 of the '819 patent is not invalid for lack of enablement, insufficient written description, or obviousness. Accordingly, we affirm the judgment of the district court.

BACKGROUND

Plaintiffs–Appellees Pfizer Inc., CP Pharmaceuticals International C.V., Warner–Lambert Company LLC, and Northwestern University (collectively, "Appellees") sued each of the Appel-

lants under 35 U.S.C. § 271(e)(2)(A) after they submitted Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Lyrica®, a prescription drug for treating seizures and certain types of pain. Although Appellees asserted four patents against Appellants below, only two patents, the '819 and the RE '920 patent, are relevant on appeal. Due to its claim scope and the breadth of the injunction entered, the disposition of this appeal rests entirely on a single claim: claim 2 of the ' 819 patent.[FN4]

FN4. Prior to the bench trial, the parties stipulated that, to the extent the district court finds claim 2 to be valid and enforceable, the Appellants' respective ANDAs are covered by the claim under the court's claim construction and the proposed products infringe. *District Court Opinion,* at 662–63. Likewise, on appeal, the parties agree that Appellants' entire case is predicated upon claim 2, i.e., the other issues are moot and Appellants lose the appeal if we affirm the district court's findings with respect to claim 2. Oral Argument at 2:41–4:24, 16:50–17:09 *available at* http:// oralarguments. cafc. uscourts. gov/ default. aspx? fl =2012–1576.mp3. Accordingly, we limit our review of the district court's findings and determinations to claim 2.

***964** The broadest in scope of the asserted claims, claim 2 recites: "4–amino3–(2–methylpropyl) butanoic acid, or a pharmaceutically acceptable salt thereof." '819 patent col. 27 ll. 32–33. The district court construed the term "4–amino3–(2–methylpropyl) butanoic acid" [FN5] to mean "the chemical compound 4–amino–3–(2–methylpropyl) butanoic acid," without limitation as to stereochemical form.[FN6] *Pfizer Inc. v. Teva Pharm. USA, Inc.*, No. 09–CV–307 (D.Del. Oct. 13, 2010), ECF No. 100 ("*Markman Order* ").

FN5. 4–amino–3–(2–methylpropyl) butanoic acid is also known in the chemical nomenclature as 3–isobutylGABA.

FN6. Stereochemical form refers to the three-dimensional structure of molecules. In organic chemistry, stereoisomers are compounds with the same molecular formula or atomic composition, but different spatial arrangements. Enantiomers are a pair of stereoisomers that are non-superimposable mirror images of each other and often have distinct physical properties. Enantiomeric pairs include compounds that have one or more stereogenic centers, i.e., carbon atoms with four non-identical substituent atoms or groups of atoms. These compounds are thus said to be chiral.

To distinguish between different enantiomers of the same compound, chemists use various naming conventions. Enantiomers are called optical isomers because they rotate plane-polarized light in a particular direction. If the light rotates clockwise, then that enantiomer is labeled (+); its counterpart will rotate the light counter-clockwise and is labeled (-). A different nomenclature labels each stereogenic center (R) or (S) according to a set of scientific rules. A racemate (or racemic mixture) is an equal mixture of two enantiomers and therefore is not optically active (i.e., will not rotate plane-polarized light in either direction because its constituent enantiomeric pairs cancel one another out). Racemates are typically designated (R, S) because they are comprised of both R-enantiomers and S-enantiomers.

Pregabalin, the active ingredient in Lyrica®, is the Senantiomer of 3–isobutylGABA.[FN7] It is specifically disclosed by claim 1 of the '819 patent as "[a] compound of the formula S–(+)–4–amino–3–(2–methypropyl) butanoic acid

as a single optical isomer." '819 patent col. 27 ll. 29–31. The district court construed the claim to mean "4–amino3–(2–methylpropyl) butanoic acid in the single S-(+) isomer form only, free of the R-(-) isomer form." *Markman Order*, at 1.

> FN7. In pharmacology, often only one enantiomer of a chemical compound is responsible for certain desired therapeutic effects, while the other enantiomer is less effective or inactive. This well-known phenomenon is attributable to the distinct physical structures of enantiomers. With respect to 3–isobutylGABA, the S-enantiomer is the pharmaceutically useful stereoisomer for the treatment of seizures and pain, while the R-enantiomer is less potent.

After a bench trial in the consolidated Hatch–Waxman action, the district court held, inter alia, that claim 2 is not invalid for lack of enablement, insufficient written description, or obviousness. *District Court Opinion*, at 732. Because the Appellants stipulated to infringement, the court thereafter enjoined them from commercially manufacturing, using, offering for sale, or selling their proposed products prior to December 30, 2018—the expiration date of the '819 patent after the FDA's extension of its term under 35 U.S.C. § 156. *See id.* at 656, 730, 732.

This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. CLAIM CONSTRUCTION AND INFRINGEMENT

Claim construction is an issue of law that we review de novo. ***965***Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454–55 (Fed.Cir.1998) (en banc). In construing a claim term, we look at the term's plain and ordinary meaning as understood by a person of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005) (en banc). There are two exceptions to this general rule: (1) when a patentee sets out a definition and acts as her own lexicographer, or (2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Thorner v. Sony Computer Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed.Cir.2012). The subsequent infringement analysis is reviewed for clear error after a bench trial. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed.Cir.2006).

Appellants argue that the district court erred in construing claim 2 of the ' 819 patent to cover 3–isobutylGABA generally. They contend that the proper construction of claim 2 is that it covers only racemic (i.e., a 50:50 mixture of S- and R-enantiomers of) 3–isobutylGABA. Appellants contend that the patent specification, prosecution history, and applicant declarations submitted to the U.S. Patent and Trademark Office ("PTO") support a narrower construction of the claimed compound as a racemic mixture. Finally, they argue that because their proposed products contain non-racemic mixtures, they do not infringe.

Appellees counter that a narrower construction would ignore the plain, clear, and specific language of the claim, which places no limitation on the claimed chiral compound. Appellees submit that the patentee's inclusion of test results of the compound's racemate in the specification, juxtaposed with the lack of a racemic limitation in the claim language, demonstrates the patentee's intent not to limit the compound being claimed to its racemate. Appellees also point out that at trial, Appellants' own expert admitted that claim 2 covers "3–isobutylGABA in any isomeric form," that is, "the form is not defined." J.A. 20658.

We perceive no error in the district court's construction. The plain language of the claim does not include the narrowing limitation that the Appellants desire. The patent specification discusses 4–amino–3–(2–methylpropyl) butanoic acid as the "preferred compound" generally and without regard to its stereochemistry. *See, e.g.*, '819 patent col. 3 ll. 65–67. The specification makes clear that the patentee expressly used the word "racemate,"

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