United States Court of Appeals for the Federal Circuit

SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Plaintiff-Appellee,

v.

ELI LILLY AND COMPANY,
Defendant-Appellant.

2010-1105

Appeal from the United States District Court for the Eastern District of Michigan in case no. 07-CV-15087, Judge George Caram Steeh.

Decided: July 28, 2010

JAMES F. HURST, Winston & Strawn LLP, of Chicago, Illinois, argued for plaintiff-appellee. With him on the brief were GAIL J. STANDISH and PETER E. PERKOWSKI, of Los Angeles, California.

CHARLES E. LIPSEY, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Reston, Virginia, argued for defendant-appellant. With him on the brief were ROBERT D. BAJEFSKY, HOWARD W. LEVINE, ROBERT F. SHAFFER and JESSICA R. UNDERWOOD, of Washington, DC. Of counsel

on the brief was JAMES P. LEEDS, Eli Lilly and Company, of Indianapolis, Indiana.

Before BRYSON, GAJARSA, and PROST, *Circuit Judges*.

PROST, *Circuit Judge*.

Appellant Eli Lilly and Company ("Lilly") appeals from a final judgment of the U.S. District Court for the Eastern District of Michigan, finding claims 2, 6, and 7 of U.S. Patent No. 5,464,826 ("'826 patent") invalid for obviousness-type double patenting over U.S. Patent No. 4,808,614 ("'614 patent"). Because the district court correctly found these claims of the '826 patent invalid, we affirm.

BACKGROUND

Lilly markets the drug Gemzar® for the treatment of various forms of cancer. The active ingredient in Gemzar® is gemcitabine. Both patents at issue in this suit, the '614 patent and the '826 patent, cover gemcitabine and are therefore listed in the Food and Drug Administration's ("FDA's") Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") with respect to Gemzar®. The '614 patent claims gemcitabine, as well as a method of using gemcitabine for treating viral infections. The '826 patent, however, claims a method of using gemcitabine for treating cancer.

The '614 patent, entitled "Difluoro Antivirals and Intermediate Therefor," issued on February 28, 1989 and expired on May 15, 2010. The '614 patent resulted from a divisional application, filed December 4, 1984, as a continuation-in-part of U.S. Patent Application Serial No.

473,883 ("original '883 application"), filed on March 10, 1983.[1] '614 patent at [60], col.1 ll.7-11.

The specification of the original '883 application described only gemcitabine's utility for antiviral purposes. The continuation-in-part that resulted in the '614 patent added a description of gemcitabine's anticancer utility to the specification. Specifically, the specification of the '614 patent explains:

> In addition to the antiviral utility of the present compounds, certain of the compounds of the present invention have also demonstrated *excellent oncolytic activity* in standard cancer screens. A *particularly preferred compound with this utility is [gemcitabine].* This compound demonstrated activity in tumor systems L1210V lymphocytic leukemia, 6C3HED lymphosarcoma, CA-755 adenocarcinoma, P1534J lymphatic leukemia and X5563 plasma cell myeloma.

Id. col.17 ll.53-63 (emphases added). Claims 1, 2, and 8 of the '614 patent are directed to a class of nucleosides, which includes gemcitabine, whereas dependent claim 12 is directed solely to gemcitabine. *Id.* col.19. l.56-col.22 l.15. Claims 13 and 14 of the '614 patent recite a method of using the claimed nucleosides, including gemcitabine, for treating Herpes viral infections. *Id.* col.22 ll.16-24. The '614 patent does not claim a method of using any of the claimed nucleosides for treating cancer.

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[1] Lilly and Sun Pharmaceutical Industries, Ltd. ("Sun") did not dispute before the district court or on appeal that the '614 patent is entitled to the benefit of the filing date of the original '883 application. *See* Lilly's Principal Br. 8, 21; Lilly's Reply Br. 12, 19.

On December 4, 1984, the same day that Lilly filed the continuation-in-part that resulted in the '614 patent, Lilly filed another patent application that ultimately issued as the '826 patent. The '826 patent, titled "Method of Treating Tumors in Mammals with 2',2'Difluoronucleosides," issued on November 7, 1995. The '826 patent expires on November 7, 2012, which is two-and-a-half years after the expiration of the '614 patent. Lilly did not file a terminal disclaimer with respect to the '826 patent.

Each claim of the '826 patent is directed to a method of treating cancer with an effective amount of a class of nucleosides, which includes gemcitabine. Specifically, claim 1 of the '826 patent recites "[a] method of treating susceptible neoplasms[, i.e., cancer,] in mammals comprising administering to a mammal in need of such treatment a therapeutically effective amount" of the class of nucleosides. '826 patent col.23 l.41-col.24 l.46. Claim 2 of the '826 patent, which depends from claim 1, is specifically directed to a method of using gemcitabine "or a pharmaceutically acceptable salt thereof" for this purpose. *Id.* col.24 ll.46-48. Dependent claims 6 and 7 are directed to treating specific "susceptible neoplasms," including "leukemias, sarcomas, carcinomas, and myelomas," with the entire class of nucleosides and gemcitabine respectively. *Id.* col.24 ll.59-64.

In 2006, Sun, a generic drug manufacturer, filed an Abbreviated New Drug Application ("ANDA") with the FDA in which Sun sought approval to market a generic version of Lilly's Gemzar® and certified that both the '614 patent and the '826 patent were invalid or not infringed. On November 29, 2007, Sun filed this declaratory judgment action against Lilly, seeking declaratory relief that the '826 patent is invalid and not infringed. Lilly filed

counterclaims for infringement of the '826 patent and the '614 patent.

On August 17, 2009, the district court granted Sun's motion for partial summary judgment that the asserted claims, namely claims 2, 6, and 7, of the later '826 patent are invalid for obviousness-type double patenting over the earlier '614 patent. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 647 F. Supp. 2d 820 (E.D. Mich. 2009) ("*Summary Judgment Order*"). Relying primarily on our decisions in *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), and *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), the district court concluded that, given the '614 patent's disclosure of gemcitabine's anticancer use, claim 12 of the earlier '614 patent, which claims gemcitabine, and claims 2, 6, and 7 of the later '826 patent, which claim a method of using gemcitabine for cancer treatment, are not patentably distinct as a matter of law. *Summary Judgment Order*, 647 F. Supp. 2d at 824-25.

Upon motion by Lilly, the district court, pursuant to Federal Rule of Civil Procedure 54(b), entered final judgment that the '826 patent is invalid. Lilly timely appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

"Double patenting is a question of law, which we review without deference." *Pfizer*, 518 F.3d at 1363. Similarly, we review "a district court's grant of summary judgment without deference." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). "A court considering summary judgment must draw all

reasonable inferences in favor of the nonmovant." *Geneva*, 349 F.3d at 1379.

"The doctrine of double patenting is intended to prevent a patentee from obtaining a timewise extension of [a] patent for the same invention or an obvious modification thereof." *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1375 (Fed. Cir. 2008). The proscription against double patenting takes two forms: (1) statutory double patenting, which stems from 35 U.S.C. § 101 and prohibits a later patent from covering the same invention, i.e., identical subject matter, as an earlier patent, and (2) obviousness-type double patenting, which is a judicially created doctrine that prevents a later patent from covering a slight variation of an earlier patented invention. *Perricone*, 432 F.3d at 1372-73; *see Geneva*, 349 F.3d at 1377-78.

The second type of double patenting, obviousness-type double patenting, prohibits "claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *In re Basell*, 547 F.3d at 1375. An obviousness-type double patenting analysis, which "compares claims in an earlier patent to claims in a later patent or application," *Geneva*, 349 F.3d at 1378 n.1, consists of two steps, *Pfizer*, 518 F.3d at 1363. First, the court "construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences." *Id.* Second, the court "determines whether those differences render the claims patentably distinct." *Id.* "A later claim that is not patentably distinct from," i.e., "is obvious over[] or anticipated by," an earlier claim is invalid for obviousness-type double patenting. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

Our prior obviousness-type double patenting decisions in *Geneva* and *Pfizer*, which addressed factual situations closely resembling that presently before the court, control this case. In both cases, we found claims of a later patent invalid for obviousness-type double patenting where an earlier patent claimed a compound, disclosing its utility in the specification, and a later patent claimed a method of using the compound for a use described in the specification of the earlier patent. *See Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1385-86. We held that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." *Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1385-86.

In *Geneva*, the earlier patent claimed a compound, potassium clavulanate, and the specification disclosed its effectiveness in inhibiting ß-lactamase in humans. 349 F.3d at 1384-86. The later patent then claimed a method of using the compound to effect ß-lactamase inhibition in humans or animals. *Id.* In our obviousness-type double patenting analysis, we determined that to ascertain the scope of the earlier patent's claim to the compound itself, we had to examine the specification of the earlier patent, including the compound's disclosed utility. *Id.* at 1385. Upon reviewing this disclosure, we concluded that the claims of the two patents were not "patentably distinct" and thus the later patent was invalid for obviousness-type double patenting, because the later patent "claim[ed] nothing more than [the earlier patent's] disclosed utility as a method of using the . . . compound." *Id.* at 1385-86.

Similarly, in *Pfizer*, the earlier patent claimed several compounds and the specification disclosed their use in treating inflammation and inflammation-associated disorders. 518 F.3d at 1363 & n.9; *see* U.S. Patent No.

5,563,165 ("'165 patent"), at [57], col.1 ll.11-14, col.3 ll.3-27. The later patent then claimed a method of using these compounds for treating inflammation, inflammation-associated disorders, and specific inflammation-associated disorders, including arthritis, pain, and fever. *Pfizer*, 518 F.3d at 1363 & n.9; *see* U.S. Patent No. 5,760,068 ("'068 patent") col.97 l.49-col.108 l.29. After rejecting the patentee's objection to our consideration of the specification of the earlier patent, we determined that the later patent "merely claims a particular use described in the [earlier] patent of the claimed compositions of the [earlier] patent." *Pfizer*, 518 F.3d at 1363 & n.8. As such, we concluded that the asserted claims of the later patent were not "patentably distinct" from the claims of the earlier patent, and thus the later patent was invalid for obviousness-type double patenting. *Id.* at 1368.

Lilly attempts to distinguish *Geneva* and *Pfizer* from this case, arguing that the holding of these cases should be limited to their facts. Lilly contends that in both cases, the specification of the earlier patent disclosed a single use for the claimed compound, which was an essential part of the patented invention and thus necessary to patentability. Lilly argues that the double-patenting analysis of *Geneva* and *Pfizer* does not apply to the later '826 patent claims reciting a method of using gemcitabine for cancer treatment because, though the specification of the earlier '614 patent disclosed gemcitabine's use in treating both viral infections and cancer, the antiviral use provided the essential utility necessary to the patentability of the '614 patent's claim to gemcitabine. Lilly objects to what it characterizes as the district court's extension of the obviousness-type double patenting analysis of *Geneva* and *Pfizer* to any utility disclosed in the specification of an earlier patent. We reject Lilly's argument.

It is true that, as the *Geneva* court recognized, the earlier patent in *Geneva* disclosed a "single use" for the claimed compound, namely inhibition of ß-lactamase. 349 F.3d at 1384-86. However, the reasoning and holding of *Geneva* are not so limited. *Id.* Our later decision in *Pfizer* demonstrates this point. We disagree with Lilly's attempt to characterize *Pfizer* as involving a single disclosed utility, as well as with its argument that the decision's rationale turned on this alleged single utility.

First, Lilly's classification of *Pfizer* is factually erroneous because the earlier patent's specification unambiguously disclosed more than one utility for the claimed compound. Specifically, the specification of the earlier patent described the compound's use in treating both inflammation *and* inflammation-associated disorders.[2] The specification also enumerated nearly fifty different inflammation-associated disorders, including pain, headaches, fever, arthritis, asthma, bronchitis, skin-related conditions, and gastrointestinal conditions, for which the claimed compounds "would be useful." '165 patent col.3 ll.3-27. The specification's discussion of the compounds' use for both inflammation and inflammation-associated disorders, as well as the diverse range of ailments expressly included in the "inflammation-associated disorders" category, shows that the specification disclosed

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[2] *See, e.g.*, '165 patent, at [57] ("A class of . . . compounds is described for use in treating inflammation *and* inflammation-related disorders.") (emphasis added); *id.* col.1 ll.11-14 ("This invention . . . specifically relates to compounds . . . for treating inflammation *and* inflammation-associated disorders, such as arthritis.") (emphasis added); *id.* col.3 ll.3-27 ("Compounds of Formula I would be useful for the treatment of inflammation in a subject, *and* for treatment of other inflammation-associated disorders.") (emphasis added).

more than one use for the claimed compounds. The later patent even claimed the compounds' use for inflammation, inflammation-associated disorders, and specific inflammation-associated disorders, including arthritis, pain, and fever, in separate dependent claims, further evidencing that the utilities disclosed in the specification of the earlier patent are distinct. *See* '068 patent col.108 ll.18-27. Therefore, we do not agree that *Pfizer* involved a single disclosed utility that was alone essential to the patentability of the claimed compounds.

Moreover, the analysis in the *Pfizer* decision shows that obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound. *Pfizer* never implies that its reasoning depends in any way on the number of uses disclosed in the specification of the earlier patent. *See* 518 F.3d at 1363. Instead, its broad analysis reflects that the court considered the multiple uses for the compound that were discussed in the specification of the earlier patent. Indeed, the *Pfizer* decision ultimately invalidated claims in the later patent that were separately directed to these multiple uses, including inflammation, inflammation-associated disorders, and the specific inflammation-associated disorders of arthritis, pain, and fever. *Id.* at 1363 & n.9; *see* '068 patent col.108 ll.18-27.

Thus, the holding of *Geneva* and *Pfizer*, that a "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use," extends to any and all such uses disclosed in the specification of the

earlier patent.[3] *Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1385-86. Indeed, as both cases recognized,

> [i]t would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, *setting out at length in the specification* the *useful purposes* of such composition, . . . and then prevent the public from making any beneficial use of such product by securing patents *upon each of the uses* to which it may be adapted.

Pfizer, 518 F.3d at 1363 n.8 (emphases added); *Geneva*, 349 F.3d at 1386 (quoting *In re Byck*, 48 F.2d 665, 666 (CCPA 1931)).

Furthermore, we reject Lilly's argument that the district court erred in consulting the specification of the issued '614 patent, as opposed to the specification of an earlier application, to ascertain the relevant disclosed uses of the compound gemcitabine for its obviousness-type

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[3] In rejecting Lilly's proposed single, essential utility test, we also note that such a test would be unworkable. Where an earlier patent specification describes multiple uses for a compound, a court would be unable to identify the one use that was "essential" or "necessary" to patentability. Indeed, Lilly's counsel repeatedly conceded at oral argument that "many times [a court] may not able to tell" which use was essential to patentability, as would be required under Lilly's test. Oral Arg. at 3:39-6:03, *available at* http://oralarguments.cafc.uscourts.gov/mp3/2010-1105.mp3; *see id.* at 9:48-10:42 ("In many cases, we concede th[is] could be a difficult inquiry."); *id.* at 13:20-13:58. Additionally, the characterization of the single essential utility might be arbitrary in application. For example, a broadly defined "single" utility might in actuality encompass multiple utilities, leading to significant problems in applying Lilly's proposed standard.

double patenting analysis. Both *Geneva* and *Pfizer* make clear that, where a patent features a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes. In *Geneva*, we acknowledged the general rule that an earlier patent's specification is not available to show obviousness-type double patenting. 349 F.3d at 1385. We have held, however, that there are "certain instances" where the specification of an earlier patent may be used in the obviousness-type double patenting analysis. *In re Basell*, 547 F.3d at 1378. Specifically, the specification's disclosure may be used to determine whether a claim "merely define[s] an obvious variation of what is earlier disclosed and claimed," "to learn the meaning of [claim] terms," and to "interpret[] the coverage of [a] claim." *Id.* As we recognized in *Geneva*, a court considering a claim to a compound must examine the patent's specification to ascertain the coverage of the claim, because a claim to a compound "[s]tanding alone . . . does not adequately disclose the patentable bounds of the invention." 349 F.3d at 1385. In examining the specification of the earlier patent, the court must consider "the compound's disclosed utility." *Id.*

We affirmed this holding in *Pfizer* by rejecting the patentee's objection to our reliance on the specification of the earlier patent that claimed the compounds at issue and explaining that "[t]here is nothing that prevents us from looking to the specification to determine the proper scope of the claims." *Pfizer*, 518 F.3d at 1363 (citing *Geneva*, 349 F.3d at 1386). Thus, we have expressly held that, where a patent claims a compound, a court performing an obviousness-type double patenting analysis should examine the specification to ascertain the coverage of the claim.

In response to Lilly's arguments, we determine that where such examination of the specification is appropriate in an obviousness-type double patenting analysis, the specification that must be considered is that of the issued patent. Lilly contends that the district court should have evaluated the '614 patent's claim to gemcitabine based on the specification that existed as of the undisputed effective filing date of the '614 patent, namely the specification of the original '883 application. The original '883 application disclosed only gemcitabine's antiviral use, not its anticancer use; Lilly added a description of gemcitabine's anticancer use to the specification in a continuation-in-part application that eventually resulted in the '614 patent. Lilly therefore asks this court to ignore the '614 patent's description of gemcitabine's use in cancer treatment, because this disclosure was not part of the original '883 application.

To support this argument, Lilly cites only the basic tenet of claim construction, as stated in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005), that claim terms should be given their ordinary and customary meaning and this meaning is the one 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." *Phillips*, however, does not support the proposition that a court should ignore portions of the patent specification in construing claims. Instead, *Phillips* makes clear that claim terms must be construed in light of the entirety of the patent, including its specification, and that the specification to be consulted is that of the issued patent, not an earlier application.

Specifically, *Phillips*, as well as the rest of our claim construction precedent, expounds that a "person of ordi-

nary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the *entire patent, including the specification*." *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1374 (Fed. Cir. 2009) (emphasis added); *Aquatex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1380 (Fed. Cir. 2005); *Phillips*, 415 F.3d at 1313. In other words, "the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading *the entire patent*." *ICU Med.*, 558 F.3d at 1375 (emphasis added); *Phillips*, 415 F.3d at 1321. *Phillips* further explains the "fundamental rule" that claim terms "are construed with *the meaning with which they are presented in the patent document*." 415 F.3d at 1316 (emphasis added). As such, "[t]he construction that stays true to the claim language and most naturally aligns with *the patent's description* of the invention will be . . . the correct construction." *Id.* (emphasis added).

In sum, our claim construction precedent establishes that claim terms must be construed in light of the entire issued patent. This precedent leaves no room for debate that the relevant specification for claim construction purposes is that of the issued patent, not an early version of the specification that may have been substantially altered throughout prosecution. There is no support for Lilly's argument that the district court should have consulted the specification of the original '883 application, which was changed before the '614 patent issued, to construe the issued patent claims. Lilly cannot avoid portions of the specification of the '614 patent by resorting to the specification as originally filed.

We note that, where necessary in the obviousness-type double patenting analysis, consulting the specification of the issued patent, as opposed to an earlier version

of the specification, is consistent with the policy behind double patenting. As we stated in *In re Kaplan*, 789 F.2d 1574, 1579-80 (Fed. Cir. 1986), "[a]ll proper double patenting rejections, of either type, rest on the fact that a patent has been *issued* and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent" of the same invention or an obvious variation thereof. In other words, the double patenting doctrine is concerned with the issued patent and the invention disclosed in that issued patent, not earlier drafts of the patent disclosure and claims.

In conclusion, the district court correctly followed the double patenting analysis of the *Geneva* line of cases, which address the situation in which an earlier patent claims a compound, disclosing the utility of that compound in the specification, and a later patent claims a method of using that compound for a particular use described in the specification of the earlier patent. As the district court recognized, claim 12 of the earlier '614 patent claims the compound gemcitabine. Following our precedent in *Geneva*, the district court properly considered the uses for gemcitabine disclosed in the specification of the issued '614 patent, specifically its use in treating viral infections and cancer, to determine the scope of this claim. *See Geneva*, 349 F.3d at 1385; *Summary Judgment Order*, 647 F. Supp. 2d at 824-25. In light of the earlier '614 patent's description of gemcitabine's use in treating cancer, the asserted claims of the later '826 patent, which recite a method of using gemcitabine to treat cancer, are not patentably distinct from the '614 patent's claim to gemcitabine. The asserted claims of the later '826 patent simply claim the anticancer use disclosed in the specification of the '614 patent as a method of use claim. *See Pfizer*, 518 F.3d at 1363; *Geneva*, 349 F.3d at 1385. Therefore, we affirm the district

court's judgment that the asserted claims, claims 2, 6, and 7, of the '826 patent are invalid for obviousness-type double patenting over the '614 patent.

AFFIRMED