United States Court of Appeals for the Federal Circuit

2008-1021

ROCHE PALO ALTO LLC (formerly known as Syntex (U.S.A.) LLC)
and ALLERGAN, INC.,

Plaintiffs-Appellees,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants-Appellants.

Alexander L. Brainerd, Heller Ehrman LLP, of San Francisco, California, argued for plaintiffs-appellees. With him on the brief were Christine Saunders Haskett, Samuel F. Ernst, and Nathan E. Shafroth. Of counsel was Keith R. Weed.

Manny D. Poktilow, Caesar, Rivise, Bernstein, Cohen & Pokotilow, LTD., of Philadelphia, Pennsylvania, argued for defendants-appellants. With him on the brief were Robert S. Silver, Mona Gupta, and William J. Castillo. Of counsel on the brief was Shashank S. Upadhye, Apotex, Inc., of Toronto, Ontario, Canada.

Appealed from: United States District Court for the Northern District of California

Judge Martin J. Jenkins

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ROCHE PALO ALTO LLC (formerly known as Syntex (U.S.A.) LLC)
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v.

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Defendants-Appellants.

Appeal from the United States District Court for the Northern District of California in case no. 05-CV-2116, Judge Martin J. Jenkins.

DECIDED: July 9, 2008

Before MICHEL, Chief Judge, PROST, Circuit Judge, and HOCHBERG, District Judge.[*]

PROST, Circuit Judge.

This is a patent infringement case under the Hatch-Waxman Act. Apotex, Inc. and Apotex Corp. (collectively "Apotex") appeal the grant of summary judgment by the United States District Court for the Northern District of California that the patent held by Roche Palo Alto LLC and Allergan, Inc. (collectively "Roche") is valid and infringed by the formulation covered by Apotex's abbreviated new drug application ("ANDA"). Roche Palo Alto, LLC v. Apotex, Inc., 526 F. Supp. 2d 985 (N.D. Cal. 2007). Because we find

[*] Honorable Faith S. Hochberg, District Judge, United States District Court for the District of New Jersey, sitting by designation.

no error in the court's holding that the reverse doctrine of equivalents is inapplicable and that claim preclusion prohibits Apotex from raising other validity challenges, we affirm.

I

A

Roche is the owner of U.S. Patent No. 5,110,493 ("the '493 patent"), which is directed to a drug formulation for treatment of eye inflammation, such as that caused by glaucoma, conjunctivitis, eye surgery, or eye injury. '493 patent, col. 1, ll. 14-28. The formulation contains a non-steroidal anti-inflammatory drug ("NSAID"), such as ketorolac tromethamine ("KT"); a quaternary ammonium preservative, such as benzalkonium chloride ("BAC"); and the nonionic surfactant, octoxynol 40 ("O_{40}"). Id., col. 3, ll. 13-19, col. 4, ll. 20-41. Claim 1 is representative:

> An opthalmologically acceptable non-steroidal anti-inflammatory drug formulation, comprising:
>
> an opthamologically acceptable non-steroidal anti-inflammatory carboxyl group-containing drug in an effective amount for ophthalmic treatment between 0.001% and 10.00% wt/vol;
>
> a quaternary ammonium preservative in an antimicrobially effective amount between 0.001% and 1.0% wt/vol;
>
> an ethoxylated alkyl phenol that conforms generally to the formula: $C_8H_{17}C_6H_4(OCH_2\text{-}CH_2)_nOH$ where *n* has an average value of 40 [O_{40}] in a stabilizing amount between 0.001% and 1.0% wt/vol; and
>
> an aqueous vehicle q.s. to 100%.

Dependent claim 7 further includes sodium chloride ("NaCl") at a concentration of 0.79% wt/vol.

The last limitation in claim 1, requiring the presence of O_{40}, was added in response to the examiner's obviousness rejection over several prior art references. Accompanying the claim amendment, the applicants submitted the Lidgate Declaration, which stated that O_{40} produced unexpected results over other nonionic surfactants,

such as O_3 and O_5. Specifically, the declaration stated that O_{40} produced a clear solution while the others did not. The examiner allowed the claims based on the unexpected results of O_{40}.

Over the years, Apotex filed two different ANDAs on two different generic drug formulations, each containing a paragraph IV certification that the '493 patent is invalid, unenforceable, or will not be infringed by the generic version of the drug. In 2001, Apotex filed its first ANDA ("ANDA-1"), directed to a generic version of Roche's ACULAR®. Subsequently, in 2005, Apotex filed its second ANDA ("ANDA-2"), directed to a generic version of Roche's ACULAR®LS. The two formulations differ in their compositions as follows:

	ANDA-1 (ACULAR®)	ANDA-2 (ACULAR®LS)
KT	0.5%	0.4%
BAC	0.01%	0.0063%
O_{40}	0.01%	0.004%
NaCl	0.8%	0.8%

Notably, the concentration of O_{40} is reduced in the ANDA-2 formulation as compared to the ANDA-1 formulation, but both are within the range claimed in claim 1 of the '493 patent. The concentration of NaCl is identical in the two formulations and encompassed by at least claim1 of the patent.

B

On June 6, 2001, Roche's predecessor, Syntex (U.S.A.) LLC ("Syntex") sued Apotex for infringement of the '493 patent based on the ANDA-1 formulation. The district court issued a claim construction order. Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214 (N.D. Cal. Nov. 19, 2002). Because claim 1 of the '493 patent expressly states a concentration range for O_{40}, the court held that the claim term "stabilizing amount" is

merely a statement of intended result and not a claim limitation. Id., slip op. at 9. Thereafter, the district court granted Syntex's motion for partial summary judgment that the ANDA-1 formulation literally infringed the '493 patent. Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214, slip op. at 4-5 (N.D. Cal. Mar. 19, 2003). Following a bench trial on Apotex's invalidity defenses of lack of utility, lack of enablement, indefiniteness, and obviousness, and its unenforceablity defense based on inequitable conduct, the court held that the '493 patent was both valid and enforceable. Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214 (N.D. Cal. Dec. 29, 2003) ("Syntex I").

On May 18, 2005, this court affirmed the district court's claim construction and holding of no inequitable conduct, but reversed its holding of validity based on non-obviousness. Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371 (Fed. Cir. 2005) ("Syntex II"). Specifically, we found that the district court clearly erred in some of its factual findings and misapplied certain legal presumptions with respect to its obviousness analysis. Id. at 1378-83. On remand, the district court again held that the '493 patent was not invalid for obviousness, Syntex (U.S.A.) LLC v. Apotex, Inc., No. 01-2214, 2006 WL 1530101 (N.D. Cal. June 2, 2006) ("Syntex III"), and we affirmed without opinion. 221 Fed. Appx. 1002 (Fed. Cir. Apr. 9, 2007).

One day after our mandate issued, the Supreme Court issued its opinion on obviousness in KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). Apotex then filed a motion to recall and stay the mandate, and to extend the time to request a rehearing in view of KSR, but the motion was denied. Apotex also filed a petition for writ of certiorari, and that petition too was denied. Apotex, Inc. v. Syntex (U.S.A.) LLC, 128 S. Ct. 209 (2007).

C

On May 24, 2005, Roche sued Apotex for infringement of the '493 patent based on the ANDA-2 formulation. Apotex asserted the defenses of non-infringement; invalidity under 35 U.S.C. §§ 101, 103, and 112; and unenforceability due to inequitable conduct. Thereafter, Roche filed a motion for summary judgment that the ANDA-2 formulation infringes the '493 patent and that the validity and unenforceability defenses should be barred based on the earlier Syntex litigation (Syntex I, Syntex II, and Syntex III) under the doctrines of issue preclusion and claim preclusion. Apotex countered by arguing that the ANDA-2 formulation escapes infringement under the reverse doctrine of equivalents. Apotex further averred that the doctrines of issue preclusion and claim preclusion were inapplicable because the ANDA-2 formulation and the ANDA-1 formulation were distinct, and the change in law exception, in view of KSR, prevented application of those doctrines.

On September 11, 2007, the district court granted Roche's motion for summary judgment. Roche Palo Alto LLC v. Apotex, Inc., 526 F. Supp. 2d 985 (N.D. Cal. 2007). First, the court found that Apotex had failed to properly establish the "principle" of the '493 invention under the first prong of the reverse doctrine of equivalents analysis. Id. at 992-93. Although Apotex contended that the "principle" of the invention was to use O_{40} to provide robust stability to the formulations by forming micelles to prevent interaction between KT and BAC, the court noted that Apotex did not support this "principle" by reference to the claim language, specification, prosecution history, and/or prior art, which are the proper sources to determine the equitable scope of the claims.

Id. Therefore, the court held that Apotex did not meet its burden of establishing a prima facie case of noninfringment under the reverse doctrine of equivalents. Id.

The district court also held that Apotex's invalidity and unenforceablity arguments, with the exception of obviousness, were prevented by issue preclusion because the invalidity of the '493 patent had already been asserted against Roche in the ANDA-1 litigation. Id. at 994-95. Following Ninth Circuit precedent, the court held that issue preclusion barred Apotex from challenging validity on any ground, even grounds that had not been raised in the first litigation. Id. at 995. With respect to the validity challenge on obviousness grounds, the court did not reach whether the Supreme Court decision in KSR constituted a change in law necessitating an exception to issue preclusion because it held that such a challenge was prevented by claim preclusion. Id. at 997.

With respect to claim preclusion, the district court held that the two accused products, ANDA-1 and ANDA-2, are "essentially the same," and thus each of the invalidity claims in the ANDA-2 litigation was prevented by claim preclusion. Id. at 997-99. The court further held that there is no "change of law" or fairness exception to claim preclusion to prevent its application despite the intervening KSR decision. Id. at 999-1000. Hence, the court held that Apotex's invalidity and unenforceability affirmative defenses were barred by claim preclusion. Id. at 1000.

Apotex appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II

We review a grant of summary judgment of non-infringement de novo, reapplying the standard used by the district court. Innogenetics, N.V. v. Abbott Labs., 512 F.3d

1363, 1378 (Fed. Cir. 2008). Summary judgment is appropriate where, drawing all reasonable inferences in favor of the non-movant, there is no genuine issue as to any material fact and no reasonable jury could return a verdict for the non-movant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 255 (1986).

The determination of infringement is a two-step process, wherein the court first construes the claims and then determines whether every claim limitation, or its equivalent, is found in the accused device. In re Gabapentin Patent Litig., 503 F.3d 1254, 1259 (Fed. Cir. 2007). While claim construction is a question of law that we review de novo, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc), non-infringement under the reverse doctrine of equivalents is a question of fact. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1124 (Fed. Cir. 1985).

We review the district court's application of the doctrine of claim preclusion de novo. Acumed LLC v. Stryker Corp., No. 2007-1115, 2008 WL 2020534, at *2 (Fed. Cir. May 13, 2008); Maldonado v. Harris, 370 F.3d 945, 949 (9th Cir. 2004); Littlejohn v. United States, 321 F.3d 915, 919 (9th Cir. 2003).

III

Apotex does not dispute that the ANDA-2 formulation falls within the literal scope of claim 1 of the '493 patent. Instead, Apotex argues that the district court erred in failing to find non-infringement by the ANDA-2 formulation under the reverse doctrine of equivalents.

The reverse doctrine of equivalents is an equitable doctrine designed "to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1581 (Fed. Cir.

1991). According to the Supreme Court:

> [W]here a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the [reverse] doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.

Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-609 (1950) (emphases added). While the patentee bears the burden of proving infringement, if the patentee establishes literal infringement, the burden shifts to the accused infringer to set forth a prima facie case of non-infringement under the reverse doctrine of equivalents. SRI Int'l, 775 F.2d at 1123-24. If the accused infringer is successful in making a prima facie case, the patentee must then rebut that prima facie case. Id. at 1124. The reverse doctrine of equivalents is rarely applied, and this court has never affirmed a finding of non-infringement under the reverse doctrine of equivalents. Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002).

Apotex, relying on the declaration of its scientific expert, Dr. Mitra, argues that a person of ordinary skill in the art would recognize that the "principle" of the '493 patent is the use of O_{40} in an amount sufficient to cause the formation of micelles and thereby provide robust stability to the formulation by preventing interactions between KT and BAC. Apotex contends that such a principle is supported by the prosecution history of the '493 patent application in that the examiner ultimately allowed the claims based on the Lidgate Declaration, demonstrating the unexpected results of formulations containing O_{40}. According to Apotex, it is of no consequence that the claims, specification, and prosecution history do not mention "micelles" and that the district court construed "stabilizing amount" to be an intended result, not a claim limitation,

since a person of ordinary skill in the art knows that O_{40} stabilizes the formulation by forming micelles. In contrast to the patented invention, Apotex asserts, the concentration of O_{40} in the ANDA-2 formulation is far below the concentration required to form micelles. Instead, in the ANDA-2 formulation, NaCl acts to ionically shield KT and BAC, preventing them from interacting. Thus, Apotex asserts, the ANDA-2 formulation is stabilized by a completely different ingredient and mechanism, and functions in a "substantially different way" from the formulation claimed in the '493 patent.

Apotex contends that because it has succeeded in making a prima facie showing of non-infringement under the reserve doctrine of equivalents, it is incumbent upon Roche to rebut that prima facie case. According to Apotex, Roche has presented only attorney arguments, not scientific evidence or expert testimony, to rebut Apotex's evidence. Even if the attorney arguments are accepted as contrary evidence, Apotex contends that there is at least a genuine issue of material fact in dispute not amenable to resolution on summary judgment. Thus, Apotex asserts, the district court erred by not drawing all inferences in favor of Apotex and not finding a genuine issue of material fact.

We agree with the district court that Apotex has failed to set forth a prima facie case of non-infringement under the reverse doctrine of equivalents because it does not properly establish the principle of the '493 patent. The "principle" or "equitable scope of the claims" of the patented invention is determined in light of the specification, prosecution history, and the prior art. Scripps Clinic, 927 F.2d at 1581. Here, however, Apotex relies exclusively on the declaration of its expert, Dr. Mitra.

As the district court noted, there is no mention of "micelle" in the claims, specification, or prosecution history of the '493 patent. Further, we previously held that there was no error in the district court's construction of claim 1 of the '493 patent to regard "stabilizing amount" not as a claim limitation, but as an intended result, given that the claim expressly sets forth a concentration range for O_{40}. Syntex II, 407 F.3d at 1378. Thus, there is no support in the claims or specification for micelle formation or for robust stabilization of the formulation by prevention of KT/BAC interactions. The prosecution history is not in evidence in this case and was not relied on by Apotex before the district court in establishing the principle of the invention. Nonetheless, there is no indication that the examiner, in allowing the claims, attributed the unexpected results of O_{40} to its superiority in forming micelles. The intrinsic evidence is therefore inconsistent with Apotex's proffered "principle" of the '493 invention.

The claims and the specification clearly encompass formulations comprising a broad concentration range of O_{40}, from 0.001% to 10% wt/vol.[1] Example 3 discloses a formulation containing O_{40} at a concentration of 0.004% wt/vol, the same concentration as in the ANDA-2 formulation.

For these reasons, we agree with the district court that Apotex did not properly support its alleged "principle" of the patented invention and consequently failed to make out a prima facie case of non-infringement under the reverse doctrine of equivalents.

[1] Apotex asserts that, if the '493 claims are construed to cover the entire claimed O_{40} concentration range, then the claims are invalid under 35 U.S.C. § 112, first paragraph, because they are not enabled throughout their full scope. Alternatively, Apotex argues that, if the claims are so construed, they are invalid as obvious under 35 U.S.C. § 103, because not all concentrations form micelles and thus produce unexpected results. Such arguments go to the validity of the claims of the '493 patent.

Roche, therefore, was not required to rebut the prima facie case. Accordingly, we find no error by the district court in rejecting Apotex's defense under the reverse doctrine of equivalents and in granting summary judgment of literal infringement of the claims of the '493 patent by the ANDA-2 formulation.

IV

Apotex next asserts that the district court erred in holding that its validity challenges to the '493 patent were barred by claim preclusion. Under Ninth Circuit law, claim preclusion applies where: "(1) the same parties, or their privies, were involved in the prior litigation, (2) the prior litigation involved the same claim or cause of action as the later suit, and (3) the prior litigation was terminated by a final judgment on the merits." Cent. Delta Water Agency v. United States, 306 F.3d 938, 952 (9th Cir. 2002) (citing Blonder-Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313, 323-24 (1971)); Mpoyo v. Litton Electro-Optical Sys., 430 F.3d 985, 987 (9th Cir. 2005).

Apotex does not dispute that the Syntex litigation (Syntex I, Syntex II, and Syntex III) ended in a final judgment and that it involved the same parties or their privies. Rather, Apotex contests only the district court's holding that the instant litigation, pertaining to its ANDA-2 formulation, and the Syntex litigation, pertaining to its ANDA-1 formulation, involved the same claim or cause of action. Whether two claims for infringement constitute the "same claim" is an issue particular to patent law and thus Federal Circuit law applies. Acumed LLC v. Stryker Corp., No. 2007-1115, 2008 WL 2020534, at *2 (Fed. Cir. May 13, 2008); Hallco Mfg. Co. v. Foster, 256 F.3d 1290, 1294 (Fed. Cir. 2001). Under the law of the Federal Circuit, an infringement claim in a

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For the reasons discussed below, we agree with the district court that such validity

second suit is the "same claim" as in an earlier infringement suit if the accused products in the two suits are "essentially the same." Acumed, 2008 WL 2020534, at *3; Foster v. Hallco Mfg. Co., 947 F.2d 469, 479-80 (Fed. Cir. 1991). Accused products "are 'essentially the same' where the differences between them are merely 'colorable' or 'unrelated to the limitations in the claim of the patent.'" Acumed, 2008 WL 2020534, at *3 (citations omitted); Foster, 947 F.2d at 480. The party asserting claim preclusion has the burden of showing that the accused products are essentially the same. Acumed, 2008 WL 2020534, at *3; Foster, 947 F.2d at 480.

Apotex avers that Roche had the burden of establishing that the ANDA-2 formulation at issue in the instant litigation and the ANDA-1 formulation at issue in the Syntex litigation were "essentially the same," yet Roche did not present any expert testimony or other evidence to that effect. In contrast, Apotex provided the Mitra Declaration, which shows that the concentration of O_{40} in the ANDA-2 formulation is insufficient to form micelles and thus the ANDA-2 formulation is materially different from the ANDA-1 formulation. Apotex further contends that the ANDA-2 formulation is not "essentially the same" as the ANDA-1 formulation because the two formulations are stabilized by completely different ingredients and mechanisms. Whereas micelle formation by O_{40} stabilizes the ANDA-1 formulation, ionic shielding by NaCl stabilizes the ANDA-2 formulation. According to Apotex, the fact that it had to file a separate ANDA for the ANDA-2 formulation is additional evidence that the ANDA-2 formulation is materially different from the ANDA-1 formulation. Thus, Apotex asserts that there is at

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challenges are barred by claim preclusion.

least a genuine issue of material fact as to whether the two ANDA formulations are "essentially the same."

We find no error in the district court's analysis. The court determined that the ANDA-1 formulation and the ANDA-2 formulation are "essentially the same" because any differences between them are unrelated to the claims of the '493 patent. Though the court recognized that there are differences in the concentrations of the ingredients in the ANDA-1 and ANDA-2 formulations, it also realized that all of the concentrations are well within the ranges claimed in the '493 patent. The fact that they are stabilized by different mechanisms, even if true, is irrelevant because both formulations are encompassed by the claims of the '493 patent. Thus, any difference in composition between the two formulations is merely colorable and the two formulations are "essentially the same."

In the alternative, Apotex asserts that principles of fairness should prevent application of claim preclusion given the change in the law of obviousness following the Supreme Court's opinion in KSR. In essence, Apotex argues that claim preclusion is not absolute and that this is a case where an exception to the finality rule should apply.

The district court, however, correctly recognized that there is no "change of law" or fairness exception to prevent application of claim preclusion. Federated Dep't Stores, Inc. v. Moitie, 452 U.S. 394, 398 (1981); see also Clifton v. Att'y Gen. of Cal., 997 F.2d 660, 663 (9th Cir. 1993) ("For us to conclude, under the facts of this case, that the district court's order has become an 'instrument of wrong' merely because it rests on a since repudiated rationale would be to nullify the doctrine of res judicata."); Wilson v. Lynaugh, 878 F.2d 846, 850-51 (5th Cir. 1989); Precision Air Parts, Inc. v. Avco Corp.,

736 F.2d 1499, 1503 (11th Cir. 1984) ("The general rule . . . throughout the nation, is that changes in the law after a final judgment do not prevent the application of res judicata and collateral estoppel, even though the grounds on which the decision was based are subsequently overruled."); Hardison v. Alexander, 655 F.2d 1281, 1288-89 (D.C. Cir. 1981). Although there may be a rare exception in cases involving "momentus changes in important, fundamental constitutional rights," Precision Air Parts, 736 F.2d at 1504, no such right is involved here.

As the Supreme Court explained:

> Nor are the res judicata consequences of a final, unappealed judgment on the merits altered by the fact that the judgment may have been wrong or rested on a legal principle subsequently overruled in another case. . . . We have observed that "[t]he indulgence of a contrary view would result in creating elements of uncertainty and confusion and in undermining the conclusive character of judgments, consequences which it was the very purpose of the doctrine of res judicata to avert."

Federated Dep't Stores, 452 U.S. at 398-99 (citations and internal quotations omitted). Thus, the KSR decision does not prevent application of claim preclusion.

Accordingly, the district court did not err in concluding that Apotex's validity challenges to the '493 patent were barred by the doctrine of claim preclusion.[2]

[2] Because we hold that the district court properly determined that Apotex's validity challenges were barred by claim preclusion, we need not reach whether the district court lawfully applied the doctrine of issue preclusion to bar the same validity challenges.

V

For the foregoing reasons, we affirm the district court's grant of Roche's motion for summary judgment that the ANDA-2 formulation literally infringes the claims of the '493 patent and that Apotex's invalidity and unenforceability challenges to the '493 patent are barred by claim preclusion.

AFFIRMED