

# United States Court of Appeals for the Federal Circuit

2007-1074

SCHWARZ PHARMA, INC. and SCHWARZ PHARMA AG,

Plaintiffs-Appellants,

and

WARNER-LAMBERT COMPANY, LLC,

Plaintiff,

v.

PADDOCK LABORATORIES, INC.,

Defendant-Appellee.

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DECIDED: October 12, 2007

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Before MICHEL, Chief Judge, and LOURIE and MOORE, Circuit Judges.

LOURIE, Circuit Judge.

Schwarz Pharma, Inc. and Schwarz Pharma AG (collectively, “Schwarz”) appeal from the order of the United States District Court for the District of Minnesota entering summary judgment of noninfringement of U.S. Patent 4,743,450 (“the ’450 patent”) in favor of Paddock Laboratories, Inc. (“Paddock”). Because the district court did not err in

its conclusion that prosecution history estoppel bars resort to the doctrine of equivalents in this case, we affirm the entry of judgment of noninfringement.

## BACKGROUND

Paddock filed Abbreviated New Drug Application 77-536 (“the ANDA”) at the Food and Drug Administration, pursuant to 21 U.S.C. § 355(j) (section 505(j) of the Federal Food, Drug, and Cosmetic Act), for approval to market generic tablets (“the Paddock drug”) containing moexipril hydrochloride (“MH”) and magnesium oxide (“MgO”). The ANDA certified, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the ’450 patent are invalid and/or not infringed by the manufacture, use, or sale of the products for which approval was sought.

The ’450 patent, issued on May 10, 1988, is entitled “Stabilized Compositions” and relates to pharmaceutical compositions containing Angiotensin Converting Enzyme (“ACE”) inhibitors combined with stabilizers to prevent certain types of degradation. ACE inhibitors are prescribed for the treatment of hypertension (high blood pressure). Without the stabilizers, the ACE inhibitors may degrade through cyclization, discoloration (through oxidation), and hydrolysis. The ’450 patent generally teaches use of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration. The ’450 patent expired on February 24, 2007.

Warner-Lambert Co., LLC (“Warner-Lambert”) owns the ’450 patent, and Schwarz held an exclusive license under it with respect to the ACE inhibitor moexipril. MH is the hydrochloric acid salt of moexipril and the active ingredient in Schwarz’s Univasc® branded drug. Schwarz has alleged that Paddock infringed claims 1, 5-8, 12,

and 16 of the '450 patent by filing the ANDA. Claims 1 and 16 are the only independent claims in the patent, and claim 1 of the patent reads as follows:

A pharmaceutical composition which contains:

- (a) a drug component which comprises a suitable amount of an ACE inhibitor which is susceptible to cyclization, hydrolysis, and discoloration,
- (b) a suitable amount of an alkali or alkaline earth metal carbonate to inhibit cyclization and discoloration, and
- (c) a suitable amount of a saccharide to inhibit hydrolysis.

'450 patent col.5 l.57 – col.6 l.2 (emphasis added). Claim 16 of the '450 patent reads as follows:

A process for stabilizing an ACE inhibitor drug against cyclization which comprises the step of contacting the drug with:

- (a) a suitable amount of an alkali or alkaline earth metal carbonate and,
- (b) one or more saccharides.

Id. at col.6 ll.54-59 (emphasis added).

Paddock filed a motion for summary judgment of noninfringement on June 30, 2006. The district court heard oral argument on the motion on August 30, 2006, and issued its Memorandum Opinion and Order granting the motion on October 20, 2006. Schwarz stipulated at oral argument that the Paddock drug did not literally infringe the '450 patent, so the district court was only required to determine if there were genuine issues of material fact with respect to infringement under the doctrine of equivalents.

The district court determined as a matter of law that arguments made by the inventors and amendments to each of the independent claims in response to an obviousness rejection by the examiner during the prosecution of the application leading to the '450 patent did not result in argument-based estoppel, but did result in amendment-based estoppel. Originally, the independent claims recited a “metal containing stabilizer” and “an alkali or alkaline earth-metal salt,” respectively, but,

following the rejection, each was amended to instead recite “an alkali or alkaline earth metal carbonate.” The court held that the change in claim language was a narrowing amendment and presumptively surrendered all metal containing stabilizers and alkali or alkaline earth metal salts except alkali and alkaline earth metal carbonates. The court also held that Schwarz had failed to rebut the presumption of surrender because magnesium oxide was a foreseeable equivalent of magnesium carbonate and because there was no objectively apparent reason for the narrowing amendment not directly related to the use of magnesium oxide. The court thus concluded that the Paddock drug could not infringe because Schwarz was estopped from claiming that the magnesium oxide used by Paddock was the equivalent of an alkali or alkaline earth metal carbonate.

In response to a motion to alter or amend the judgment, the district court issued a second Memorandum Opinion and Order on November 11, 2006, that affirmed its prior conclusion of noninfringement and explained its reasoning in even greater detail.

Schwarz timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

## DISCUSSION

### I. Jurisdiction

Paddock asserts as a preliminary matter that Schwarz lacks standing to bring this appeal because Warner-Lambert, the patent owner, did not appeal the district court’s adverse judgment. Paddock argues that Schwarz is merely an exclusive licensee of the ’450 patent who does not possess “all substantial rights” in the patent, and Paddock joined Warner-Lambert in the suit in the district court as a matter of necessity. Paddock

further argues that the same jurisdictional rule applies on appeal and that, without Warner-Lambert, Schwarz therefore lacks standing for its appeal. Paddock adds that it would be inappropriate for this court to permit joinder during the appeal to cure that defect because, although Warner-Lambert was a participant in the case below and well aware of its rights, it consciously chose not to appeal.

Schwarz responds that there is no need for Warner-Lambert to participate in the appeal for Schwarz to have standing to appeal. Schwarz notes that the requirement that an exclusive licensee join a patent owner in an infringement suit is a prudential rather than a constitutional one. Schwarz argues that it continues to have constitutional standing and that the purposes of the prudential standing requirement have already been served by the joinder of Warner-Lambert in the case below. Schwarz also states that if Warner-Lambert is a necessary party to the appeal, then its joinder can be ordered by this court.

Although we have stated the necessity of joining a patent owner in an action for infringement brought by an exclusive licensee a number of times, e.g., Propat Int'l Corp. v. Rpost, Inc., 473 F.3d 1187, 1193 (Fed. Cir. 2007), Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., 248 F.3d 1333, 1347-48 (Fed. Cir. 2001), the particular question presented here appears to be an issue of first impression before this court. The parties have not cited and we have not located any case directly on point, and we therefore turn to the principles underlying the requirement for joining a patent owner when an exclusive licensee does not possess all substantial rights in the patent.

We conclude that, when a patentee joins an exclusive licensee in bringing a patent infringement suit in a district court, the licensee does not lose standing to appeal

even though the patentee does not join in the appeal. The requirement to join the patent owner, and the ability to compel that joinder if necessary, can be traced back to Independent Wireless Telegraph Co. v. Radio Corp. of America, 269 U.S. 459 (1926).

The Supreme Court stated in that case:

[T]he owner of a patent, who grants to another the exclusive right to make, use, or vend the invention, which does not constitute a statutory assignment, holds the title to the patent in trust for such a licensee, to the extent that he must allow the use of his name as plaintiff in any action brought at the instance of the licensee in law or in equity to obtain damages for the injury to his exclusive right by an infringer, or to enjoin infringement of it.

Id. at 469. The Court also stated:

The presence of the owner of the patent as a party is indispensable, not only to give jurisdiction under the patent laws, but also in most cases to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in the one action, or by satisfying one adverse decree to bar all subsequent actions.

Id. at 468. This court has interpreted the Independent Wireless joinder requirement to be one of prudential rather than constitutional standing. Propat, 473 F.3d at 1193.

One of the reasons for requiring joinder of the patent owner discussed by the Independent Wireless court was the possibility that the alleged infringer would be subject to multiple actions. There is no such danger here, as Warner-Lambert has already been joined in the infringement action, and, if not joined in the appeal, will continue to be bound by the judgment of the trial court and of this court. An additional reason for requiring joinder of a patentee is to ensure that its rights are protected in a suit brought by the licensee. Thus, a patent should not be placed at risk of invalidation by the licensee without the participation of the patentee. Here again, no such risk exists as Warner-Lambert was joined in the infringement suit and had an opportunity to protect

its interests. Finally, and most basically, Schwarz was a plaintiff in a suit that was properly joined in the district court by the record patentee. As a party adversely affected by the district court judgment, it was entitled to appeal that judgment alone. Accordingly, Warner-Lambert need not have joined in the appeal and Schwarz has standing to appeal on its own.

## II. Prosecution History Estoppel

Schwarz next argues that estoppel does not apply in this case, as it never claimed compositions and processes involving MgO. Thus, there was no surrender when the claims were amended. Schwarz argues that, in light of the '450 patent specification, a person of ordinary skill in the art would understand that the phrases "metal containing stabilizer" and "alkali or alkaline earth metal salt" in the original claims of the application leading to the '450 patent mean only alkali or alkaline earth metal cations and carbonate, borate, or silicate anions. MgO never fell within the scope of the original claims, and prosecution history estoppel cannot apply. Schwarz also argues that even if the presumption of surrender applies, there are genuine issues of material fact as to whether MgO was a foreseeable equivalent of an alkali or alkaline earth metal carbonate. Finally, Schwarz also argues that prosecution history estoppel does not apply because the amendment in question bore no more than a tangential relationship to the equivalent in question, viz., MgO.

Paddock responds that the original claims did encompass MgO and that the amendments surrendered it. It argues that MgO is both a "metal containing stabilizer" and an "alkaline earth metal salt" within the plain meaning of those terms. It contains a metal, and it is a stabilizer. Paddock argues that the '450 patent specification does not

define these terms more narrowly as suggested by Schwarz. Paddock also argues there are no genuine issues of material fact as to the foreseeability of MgO as an equivalent because it is undisputed that MgO was a known stabilizer for pharmaceutical compositions at the time the claims were amended. In addition, Paddock argues that because the prosecution history shows no other reason than patentability for adding the carbonate limitation, Schwarz cannot claim that the rationale for the amendment was merely tangential to the examiner's rejection.

We agree with Paddock that the district court did not err in holding that Schwarz's claim of infringement under the doctrine of equivalents was barred by prosecution history estoppel. We review de novo a grant of summary judgment by a district court. Optivus Tech., Inc. v. Ion Beam Applications S.A., 469 F.3d 978, 984 (Fed. Cir. 2006). Summary judgment is appropriate if "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "[W]e review issues relating to the application of prosecution history estoppel de novo." Conoco, Inc. v. Energy & Env'tl. Int'l, L.C., 460 F.3d 1349, 1357 (Fed. Cir. 2006).

This court has summarized the doctrine of prosecution history estoppel as follows:

[P]rosecution history estoppel limits the broad application of the doctrine of equivalents by barring an equivalents argument for subject matter relinquished when a patent claim is narrowed during prosecution. We have recognized that prosecution history estoppel can occur during prosecution in one of two ways, either (1) by making a narrowing amendment to the claim ("amendment-based estoppel") or (2) by surrendering claim scope through argument to the patent examiner ("argument-based estoppel").

Id. at 1363 (citations omitted). With respect to amendment-based estoppel, the Supreme Court has stated:

A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim. There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 535 U.S. 722, 740-41 (2002).

As indicated above, the original claims did recite a metal containing stabilizer, in claim 1, and an alkaline earth metal salt, in claim 16. Warner-Lambert thus presumptively surrendered subject matter encompassed by those terms when it amended those claims and deleted those broader terms. Schwarz argues, however, that, under the heading "STABILIZER(S)," the '450 patent specification defines the claim terms more narrowly. It cites a portion of the following disclosure to support its argument:

The alkaline stabilizers of the invention include the inorganic salts of metals of Groups I and II of the Periodic Table. Thus, salts of alkali and alkaline earth metals are operable. Magnesium, calcium, and sodium are preferred. Magnesium is most preferred.

The anionic portion of the salt employe[d] may be any which does not deleteriously affect the stability of the overall formulation. Thus, borates, silicates, and carbonates are contemplated. Carbonates are preferred. Mixtures are operable.

'450 patent col.3 ll.25-39. It emphasizes the statement that borates, silicates, and carbonates are "contemplated," as if that were the broadest language in the patent from which retreat was made. But it was not the broadest language. As indicated, original claim 1 contained the broadest language; it recited a metal containing stabilizer, and it is

clear that MgO satisfied that definition. Thus, there was a surrender to alkaline earth metal carbonate, including a surrender of MgO. Similarly, with claim 16, the original language of claim 16 was also broader than after it was amended, and its amendment to read “alkaline earth metal carbonate” also constituted a surrender. Whether MgO is an alkaline earth metal salt, as found by the district court, is also undisputed by the parties. In its first opinion, the district court stated that “Plaintiffs’ expert conceded that the ordinary and accustomed meaning of an alkali or alkaline earth metal salt would encompass magnesium oxide, and that magnesium oxide is a compound that has an anionic portion that does not deleteriously affect the stability of an ACE inhibitor formulation.”

Moreover, in light of the passage from the patent quoted above, it cannot be maintained, as argued by Schwarz, that the '450 specification defined alkaline earth metal salt to mean only borate, silicate, and carbonate salts. The sentence immediately prior to the one stating that those three salts are “contemplated” clearly states that the anion may be “any” that does not negatively affect stability of the formulation. The use of the terms “alkali or alkaline earth metal salt” and “metal containing stabilizer” in the original claims reflects and is consistent with the breadth of that statement. The reference to borates, silicates, and carbonates reflects preferences, not limitations inconsistent with both the original claims and broader language in the specification. Also, the amendment was made in response to an obviousness rejection by the examiner and thus is presumed to have been made for reasons of patentability. We therefore hold that the presumption of surrender applies to MgO because it clearly falls

within the territory between the language of the original and the amended claims of the '450 patent.

As the quoted passage from Festo above indicates, it is Schwarz's burden to rebut the presumption that MgO was surrendered as an equivalent when the claims of the '450 patent were amended. As to foreseeability, this court recently held that "an alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment" and that it would be inappropriate to apply an insubstantial differences or function/way/result test in order to determine foreseeability. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 493 F.3d 1368, 1379 (Fed. Cir. 2007). On appeal, Schwarz does not seriously dispute that MgO was known as a stabilizer by those of skill in the art at the time of the amendment, but rather insists that MgO had to have been known as a stabilizer against the specific degradation pathway of cyclization or for the specific drug category of ACE inhibitors in order to have been foreseeable as an equivalent. We disagree.

While care must be taken not to sweep too broadly in defining the field of an invention, Schwarz attempts to define the field of invention too narrowly. The language of original claim 1 (and that of issued claim 1 as well) began with the words "[a] pharmaceutical composition which contains," and the language of a claim defining an invention defines the field within which foreseeability may be considered. The scope of the claim thus supports the district court's treatment of the field of invention as pharmaceutical compositions rather than being limited to pharmaceutical stabilizers that inhibit cyclization in ACE inhibitors. We therefore conclude that, because MgO was known as a stabilizer in the field of pharmaceutical compositions, Schwarz has failed to

rebut the presumption of surrender by demonstrating that MgO was not a foreseeable equivalent.

As for claim 16, a process claim, it recites a process for stabilizing an ACE inhibitor drug against cyclization. Given the prior art that discloses that MgO is a stabilizer, it does not require much of a stretch of the imagination of a person skilled in the art of pharmaceutical formulation to foresee that that stabilizer might be helpful in stabilizing ACE inhibitors.

We also do not agree with Schwarz that the presumption of surrender is rebutted because the narrowing amendment was no more than tangentially related to the use of MgO. Schwarz argues that the reference relied upon by the examiner, the Veber patent, in rejecting the originally filed claims for obviousness did not discuss the use of a stabilizer in order to prevent cyclization of ACE inhibitors. Schwarz seems to argue that the patentability of the claims could have been defended on this ground without amending the claims. Paddock responds that the change in the language of the claims at issue here was made in direct response to the obviousness rejection and that the Veber patent discloses the use of magnesium stearate, an alkaline earth metal salt that is not a carbonate, with an ACE inhibitor. Paddock adds that there is no other objectively apparent reason for the amendment to have been made.

Here, the use of MgO is directly implicated by the amendment of the claim language at issue because the language amended concerns the types of stabilizers covered by the claims and excludes MgO. The fact that the inventors may have thought after the fact that they could have relied on other distinctions in order to defend their claims is irrelevant and speculative; the inventors chose to distinguish over the Veber

patent by narrowing the range of claimed stabilizers to exclude the one disclosed in Veber, as well as others. In the argument accompanying the amendment of the claim language, the inventors argued as follows:

There is no teaching or suggestion to solve any stability problems by the formulations described in Veber. . . . Thus, the combination of the two necessary ingredients [alkali or alkaline earth metal carbonate and saccharide] demonstrates the patentability of the present invention. This is especially so as now claimed by the above amendment which focuses clearly on the use of an alkali or alkaline earth metal carbonate in combination with a saccharide.

We cannot say in such a case that the amendment was no more than tangentially related to the equivalent at issue. In fact, quite the opposite appears to be true; the narrowing amendment was directly related to the range of equivalents that Schwarz now seeks to recapture.

#### CONCLUSION

For the foregoing reasons, we affirm the district court's entry of judgment of noninfringement of the '450 patent in favor of Paddock.

AFFIRMED