United States Court of Appeals for the Federal Circuit

DURAMED PHARMACEUTICALS, INC.
(NOW KNOWN AS TEVA WOMEN'S HEALTH, INC.),
Plaintiff-Appellant,

v.

PADDOCK LABORATORIES, INC.,
Defendant-Appellee.

2010-1419

Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-1905, Senior Judge Leonard B. Sand.

Decided: July 21, 2011

CHARANJIT BRAHMA, Kirkland & Ellis, LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were COREY J. MANLEY and J. JOHN LEE; and ALEXANDER F. MACKINNON, of Los Angeles, California. Of counsel was ROBERT G. KRUPKA, of Los Angeles, California.

EDGAR H. HAUG, Frommer Lawrence & Haug, LLP, of New York, New York, argued for defendant-appellee. With him on the brief was DAVID A. ZWALLY.

Before LOURIE, GAJARSA, and DYK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Duramed Pharmaceuticals, Inc. ("Duramed") appeals from the decision of the United States District Court for the Southern District of New York granting summary judgment of noninfringement to Paddock Laboratories, Inc. ("Paddock"). *Duramed Pharms., Inc. v. Paddock Labs., Inc.*, 715 F. Supp. 2d 552 (S.D.N.Y. 2010). Because the district court did not err in holding that prosecution history estoppel bars Duramed's allegations of infringement under the doctrine of equivalents, we affirm.

BACKGROUND

Duramed owns U.S. Patent 5,908,638 ("'638 patent"), which claims conjugated estrogen pharmaceutical compositions for use in hormone replacement therapies. The claimed conjugated estrogens are extremely water sensitive and thus highly susceptible to moisture degradation during storage. *See* '638 patent col.6 ll.46-56. Accordingly, Duramed developed a formulation for conjugated estrogens that includes a moisture barrier coating ("MBC") to inhibit the absorption of moisture and reduce storage-related degradation. *See id.* col.6 ll.36-45.

Duramed filed a patent application on its formulation on July 26, 1995. Original independent claim 1 recited a conjugated estrogen pharmaceutical composition "coated with a moisture barrier coating." J.A. 254. Original dependent claim 7 limited "said moisture barrier coating" to one that "comprises ethylcellulose." J.A. 255. The examiner rejected both claims as obvious, but during an interview advised that he would allow the application if Duramed amended claim 1 to include, *inter alia*, the

limitations of claim 7. In a response received December 3, 1998, Duramed amended claim 1 to recite pharmaceutical compositions with "a moisture barrier coating comprising ethylcellulose." J.A. 304. Claim 1 of the issued '638 patent, the patent's only independent claim, accordingly reads as follows:

> 1. A pharmaceutical composition in a solid, unit dosage form capable of oral administration for the hormonal treatment of peri-menopausal, menopausal and post-menopausal disorders in a woman comprising:
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> conjugated estrogens coated onto one or more organic excipients forming a powdered conjugated estrogen composition where said composition is substantially free of inorganic excipients and further comprises about 30-70% gel-forming organic excipient and about 30-70% non-gel forming organic excipient by weight and having less than about 2.5% free water by weight and greater than 2.5% total water wherein said solid unit dosage form is coated with *a moisture barrier coating comprising ethylcellulose*.

'638 patent claim 1 (emphasis added).

In March 2009, Duramed filed suit against Paddock under 35 U.S.C. § 271(e)(2), alleging infringement of the '638 patent based on Paddock's Abbreviated New Drug Application ("ANDA") for a generic version of Duramed's hormone replacement therapy product, Cenestin®. Duramed alleged infringement of claims 1, 4, and 6-8 under the doctrine of equivalents, because Paddock's proposed generic product uses a polyvinyl alcohol ("PVA") MBC, marketed as Opadry AMB. Paddock moved for summary judgment of noninfringement, arguing that Duramed was barred by amendment-based prosecution

history estoppel from alleging that PVA met the "moisture barrier coating comprising ethylcellulose" limitation of the asserted claims.

In its motion for summary judgment, Paddock relied on several pre-amendment references, including an international patent application filed by Colorcon pursuant to the Patent Cooperation Treaty ("the Colorcon PCT"). The Colorcon PCT, published on January 25, 1996, discloses formulations of PVA-based MBCs, including Opadry AMB, but also, in a section entitled "Description of the Prior Art," notes several technical drawbacks of using PVA as an MBC. Paddock also relied on (1) U.S. Patent 3,935,326 ("the Groppenbächer patent"), which issued in 1976 and discloses the use of PVA in moisture-tight tablets; (2) an article in the December 1995 issue of "Manufacturing Chemist" that tests PVA MBCs and concludes that Opadry AMB is a highly effective moisture barrier formulation; (3) three scientific articles on PVA MBCs authored for distribution at scientific conferences in May 1995, May 1998, and November 1998; and (4) invoices indicating sales of Opadry AMB by Colorcon before September 1996.

The district court granted Paddock's motion for summary judgment of noninfringement, holding that prosecution history estoppel barred Duramed's infringement allegations. *Duramed*, 715 F. Supp. 2d at 555-56. The district court first held that Duramed's amendment adding the ethylcellulose limitation was substantially related to patentability and narrowed the scope of the asserted claims, thus triggering the presumption under *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) (*en banc*) ("*Festo IX*"), that Duramed had surrendered all territory between the original and amended claim scope. *Duramed*, 715 F. Supp. 2d at 559-60.

The district court then held that Duramed had failed to rebut the *Festo* presumption based on an argument of, *inter alia*, the unforeseeability of the use of PVA as an MBC in a pharmaceutical formulation. *Id.* at 560. Rather, the court held that PVA MBCs were foreseeable at the time of Duramed's narrowing amendment based on the Colorcon PCT's description of PVA as "a moisture barrier coating for pharmaceutical tablets and the like" and its disclosure of the Opadry AMB formulation used in Paddock's proposed generic product. *Id.* at 560-61. The court noted that several other facts reinforced this decision: (1) the pre-September 1996 invoices for the sale of Opadry AMB; and (2) the Groppenbächer patent, which teaches coating tablets with PVA to ensure "'moisture tight[ness]' and 'insolub[ility] in the gastrointestinal tract.'"[1] *Id.* at 561-62. Finally, the court rejected Duramed's argument that the Colorcon PCT's disclosure of PVA MBCs' technical drawbacks raised serious questions about PVA's effectiveness as an MBC, concluding that "even if the effectiveness of PVA was unknown in 1998, that would not mean that PVA MBCs were unforeseeable." *Id.* at 563.

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

DISCUSSION

We review a district court's grant of summary judgment *de novo*, reapplying the same standard applied by

[1] The district court did not consider Paddock's remaining pre-1998 articles based on Duramed's claim that a bench trial would be necessary to determine if the 1995 "Manufacturing Chemist" article was publicly available in a university library and if the conference articles were actually distributed to the attendees. *Id.* at 561 n.8. The court concluded that these articles were not necessary to establish foreseeability. *Id.*

the district court. *Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1380 (Fed. Cir. 2009). Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).

Under the doctrine of the equivalents, "a product or process that does not literally infringe . . . the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)). However, the doctrine of prosecution history estoppel prevents a patent owner from recapturing through the doctrine of equivalents subject matter surrendered to acquire the patent. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) ("*Festo VIII*").

Because during prosecution Duramed narrowed the scope of the '638 patent's claims in response to a prior art rejection, a presumption of prosecution history estoppel applies. *See Festo IX*, 344 F.3d at 1366-67. Nonetheless, Duramed may rebut that presumption by showing, *inter alia*, the "alleged equivalent would have been 'unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered.'" *Id.* at 1369 (quoting *Festo VIII*, 535 U.S. at 738). "[A]n alternative is foreseeable if it is disclosed in the pertinent prior art in the field of the invention. In other words, an alternative is foreseeable if it is known in the field of the invention as reflected in the claim scope before amendment." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1379 (Fed. Cir. 2007) ("*Festo X*"). Foreseeability is a

question of law based on underlying issues of fact. *Id.* at 1375.

On appeal, Duramed argues that the district court applied the wrong legal test for foreseeability and thus held that any mention of an alleged equivalent in the prior art makes that equivalent foreseeable as a matter of law. But, according to Duramed, an equivalent is not foreseeable if it was not understood by one of ordinary skill in the art to be suitable for use in the invention as originally claimed. And, in this case, Duramed asserts, the relevant art did not disclose either PVA or Opadry AMB as suitable MBCs for moisture-sensitive pharmaceutical compounds, like conjugated estrogens.

Paddock responds that the district court applied the correct foreseeability standard, which requires only that PVA be foreseeable as an MBC for pharmaceutical applications at the time of Duramed's narrowing amendment. In this case, according to Paddock, the Colorcon PCT alone renders PVA MBCs foreseeable, but this conclusion is bolstered by Colorcon's commercialization of Opadry AMB, the Groppenbächer patent, and the other references not considered by the district court.

We agree with Paddock that Duramed failed to rebut the presumption of prosecution history estoppel based on unforeseeability. We first note that, to the extent that Duramed argues that foreseeability requires that PVA must have been known as an MBC for use *with conjugated estrogens*, we have previously rejected such a restrictive definition of the field of invention. *See Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007). As we spelled out in *Schwarz*, when the language of both original and issued claims begins with the words "[a] pharmaceutical composition," that language defines the field of the invention for purposes of

determining foreseeability. *Id.* Accordingly, PVA MBCs need only to have been known in the field of pharmaceutical compositions as of the time of Duramed's narrowing amendment, *see Festo X*, 493 F.3d at 1379, which we hold that the Colorcon PCT establishes as a matter of law.

The Colorcon PCT discloses PVA MBCs for use with pharmaceutical compositions: "A dry powder moisture barrier coating composition is made to form a moisture barrier film coating for pharmaceutical tablets and the like, which comprises polyvinyl alcohol . . . ." J.A. 4466. In the "Description of the Prior Art" the PCT states that "[t]he use of the polymer polyvinyl alcohol, PVA, as a moisture barrier coating has been previously suggested," but it also notes two drawbacks of PVA MBCs: stickiness and plasticizer compatibility. *Id.* Specifically, the Colorcon PCT states:

> [P]ractical usage [of PVA] has been inhibited by the stickiness of grades of the polymer which have a fast enough rate of going into solution in water to make a dispersion to render them economical to use in making the coating. A further problem with the use of PVA is in identifying or selecting a plasticizer which does not compromise the moisture barrier properties of the final coating.

Id.

The Colorcon PCT then, in the "Summary of the Invention," discloses preferred PVA grades and identifies a plasticizer that does not compromise PVA's properties as a moisture barrier. The application states that "[e]xcellent moisture barrier properties are obtained when hot water soluble grades of PVA are used in the inventive coating," and that "[a] preferred grade of PVA for use in the inventive coating is a grade in the medium range . . . because the step of heating the water of the liquid coating

dispersion may not be necessary, while still maintaining excellent moisture barrier properties in the inventive coating." J.A. 4468-69. The Colorcon PCT next discloses that soya lecithin "surprisingly, and unexpectedly, acts as a plasticizer by locking moisture in the coating so the coating stays flexible and not brittle," and thus soya lecithin as a plasticizer "does not compromise the moisture barrier properties of the overall coating." J.A. 4469. Finally, the Colorcon PCT lists a number of PVA MBC formulations, including Opadry AMB. Accordingly, the Colorcon PCT discloses PVA MBCs, including Opadry AMB, in the field of pharmaceutical compositions, rendering such PVA MBCs "known in the field of the invention," and thus foreseeable. *Festo X*, 493 F.3d at 1379.

Duramed argues that the Colorcon PCT's disclosure fails to establish that PVA-based Opadry AMB was suitable as an MBC because it provides only conclusory statements that the inventors had solved the technical drawbacks of PVA MBCs and lacks any data on the stability of the pharmaceutical compounds coated with Opadry AMB. We disagree; foreseeability does not require such precise evidence of suitability. *See Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1312-13 (Fed. Cir. 2008). And even if the PCT disclosure indicates that PVA is less than ideal in some pharmaceutical uses as an MBC, it is still disclosed to be useful as such, and that renders it foreseeable for purposes of prosecution history estoppel. Foreseeability does not require flawless perfection to create an estoppel.

In rejecting a foreseeability rebuttal in *Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348 (Fed. Cir. 2004), we held that "the record abundantly disclosed [the alleged equivalent's] use as a release agent at the relevant time," *SmithKline Beecham Corp. v. Excel Pharms., Inc.*, 356 F.3d 1357, 1365 (Fed. Cir. 2004) (de-

scribing *Glaxo*, 356 F.3d at 1355). Our holding relied on statements from several references disclosing the alleged equivalent's use as an extended-release agent in drug formulations; it did not rely on test data showing the alleged equivalent's precise characteristics or suitability as an extended-release agent, and thus did not rely on the type of evidence Duramed demands in this case. *See Glaxo* 356 F.3d at 1355. Rather, the Colorcon PCT discloses the use of PVA as MBCs in the field of pharmaceutical compounds prior to December 3, 1998, rendering such PVA MBCs foreseeable at the time of Duramed's narrowing amendment.[2]

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[2] Although not necessary to our decision, we note that the 1995 "Manufacturing Chemist" article also supports a finding of foreseeability in the case. Like the Colorcon PCT, the "Manufacturing Chemist" article discloses PVA MBCs for use in pharmaceutical applications, and it discloses tests on the performance of PVA-based coatings with moisture-sensitive drugs. The tests compared PVA MBCs with hydroxypropyl-methylcellulose MBCs coating tablets of aspirin or erythromycin ethylsuccinate stored for twelve weeks under high relative humidity. The data reveal that "the PVA formulation gives much superior moisture protection under humid storage conditions." J.A. 4497. The article concludes that "[t]he results presented here have shown a highly effective moisture barrier formulation [based on the water soluble polymer PVA, designated Opadry AMB] has been developed." J.A. 4498. The district court did not rely on this article based on Duramed's claim that a bench trial would be necessary to determine if the article was publicly available. *Duramed*, 715 F. Supp. 2d at 561 n.8. We disagree that there is a genuine issue of material fact on the public availability of an article published in a scientific journal three years before Duramed's amendment. *See, e.g.*, *In re Lister*, 583 F.3d 1307, 1312 (Fed. Cir. 2009).

CONCLUSION

For the foregoing reasons, we affirm the district court's grant of summary judgment of noninfringement.

AFFIRMED