NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

APTALIS PHARMATECH, INC., IVAX INTERNATIONAL GMBH,
Plaintiffs-Appellees

v.

APOTEX INC., APOTEX CORP.,
Defendants-Appellants

2017-1344

Appeal from the United States District Court for the District of Delaware in No. 1:14-cv-01038-SLR-SRF, Judge Sue L. Robinson.

Decided: January 4, 2018

JOHN R. LANE, Fish & Richardson, PC, Houston, TX, argued for plaintiffs-appellees. Also represented by SUSAN E. MORRISON, Wilmington, DE; JONATHAN ELLIOT SINGER, San Diego, CA.

WILLIAM R. ZIMMERMAN, Knobbe, Martens, Olson & Bear, LLP, Washington, DC, argued for defendants-appellants. Also represented by THOMAS P. KRZEMINSKI; KAREN MARIE CASSIDY, CRAIG S. SUMMERS, Irvine, CA.

Before REYNA, WALLACH, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

In this Hatch-Waxman case, Apotex Inc. and Apotex Corp. appeal from the district court's claim construction of "extended release coating" and its finding that Apotex's product infringes U.S. Patent Nos. 7,790,199 and 7,829,121. We conclude that the district court erred by not construing the term "extended release coating" to require a continuous outer film, as taught by the intrinsic evidence. Accordingly, we vacate the infringement finding and remand for further proceedings.

I.

The goal of a drug delivery system is to achieve rapidly a therapeutically effective concentration of drug in the body and to maintain that concentration throughout the treatment period. When a patient swallows a tablet, gastrointestinal fluids dissolve the drug inside the tablet, and the drug is absorbed into the body. In an immediate release formulation, the majority of the drug dissolves within an hour because the tablet disintegrates once it is swallowed, and the body's gastrointestinal fluids contact and dissolve the drug. Therefore, patients seeking continuous relief from their symptoms must take an immediate release formulation several times per day.

An extended release formulation, as its name implies, can sustain therapeutically effective drug concentrations over a prolonged period by releasing the drug at a slower rate. These formulations employ controlled release materials that surround the drug and create a barrier through which gastrointestinal fluids must travel to access the drug, or "active" substance. The controlled release material decreases the rate at which gastrointestinal fluids penetrate the tablet to dissolve the drug and the rate at

which the dissolved drug escapes the tablet to be absorbed into the body.

Aptalis Pharmatech, Inc. and Ivax International GmbH own the '199 and '121 patents (collectively, the "asserted patents"), which relate generally to extended release dosage forms of cyclobenzaprine hydrochloride, a skeletal muscle relaxant.[1] Instead of requiring three daily doses of cyclobenzaprine, as in the prior art, the asserted patents disclose an extended release cyclobenzaprine formulation that provides twenty-four hour relief from muscle spasms with a single dose.

The asserted patents teach two different formulations that use a water insoluble polymer coating to achieve an extended release profile. The parties refer to these alternatives as membrane systems and matrix systems. In a membrane system, a water insoluble polymer coating is applied onto an active-containing core:

> The active core of the dosage form of the present invention may comprise an inert particle such as a sugar sphere, or an acidic or alkaline buffer crystal, which is coated with a skeletal muscle relaxant such as cyclobenzaprine . . . . The drug layered beads may be coated with a protective seal coating of OPADRY® Clear to produce IR [immediate release] Beads. . . .
>
> ER [extended release] Beads can be produced by applying a functional membrane comprising a water insoluble polymer alone or in combination with a water soluble polymer onto IR Beads.

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[1] The asserted patents share a common specification, and unless otherwise noted, all citations are to the '199 patent.

'199 patent col. 3 l. 67 – col. 4 l. 17. In a matrix system, the water insoluble polymer is mixed together with the drug and compacted into a tablet:

> [T]he drug substance, optionally a binder such as PVP, a dissolution rate controlling polymer (if used), and optionally other pharmaceutically acceptable excipients are blended together in a planetary mixer or a high shear granulator such as Fielder and granulated by adding/spraying a granulating fluid such as water or alcohol. The wet mass can be extruded and spheronized to produce spherical particles (beads) using an extruder/marumerizer.

Id. at col. 6 ll. 23–31.

Although the specification discloses two different extended release formulations, the claims are not expressly limited to a specific formulation by name (i.e., "membrane system" or "matrix system"), as demonstrated by representative claim 1:

> 1. A pharmaceutical dosage form comprising a population of extended release beads, wherein said extended release beads comprise:
>
> an active-containing core particle comprising cyclobenzaprine hydrochloride as the active; and
>
> *an extended release coating comprising a water insoluble polymer membrane surrounding said core*, wherein said water insoluble polymer membrane comprises a polymer selected from the group consisting of ethers of cellulose, esters of cellulose, cellulose acetate, ethyl cellulose, polyvinyl acetate, neutral copolymers based on ethyl acrylate and methyl methacrylate, copolymers of acrylic and methacrylic acid esters with quaternary ammonium groups, pH-insensitive ammonio

> methacrylic acid copolymers, and mixtures thereof;
>
> wherein the total amount of cyclobenzaprine hydrochloride in the pharmaceutical dosage form is 30 mg;
>
> wherein following a single oral administration of the pharmaceutical dosage form, the pharmaceutical dosage form provides a maximum blood plasma concentration (C_{max}) of 19.851±5.8765 ng/mL of cyclobenzaprine HCl and an $AUC_{0\text{-}168}$ of 736.60±259.414 ng·hr/mL.

Id. at col. 10 ll. 23–45 (emphasis added).

After Apotex filed an Abbreviated New Drug Application seeking to produce and market a generic version of AMRIX®,[2] Aptalis sued Apotex for infringing claims 1, 2, and 5 of the '199 patent, as well as claims 14, 16, and 17 of the '121 patent. Apotex argued that it does not infringe because its products contain a matrix-style formulation.

The parties' dispute centers on the construction of "an extended release coating comprising a water insoluble polymer membrane surrounding said core," which is found in every asserted claim. Before the district court issued its claim construction order, the parties stipulated to a construction for part of the disputed term. They agreed that "a water insoluble polymer membrane surrounding said core" means "a water insoluble polymer covering that surrounds the active core." J.A. 1619. The district court subsequently construed "extended release coating," the remainder of the disputed claim term, as "[a] layer of any

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[2] The asserted patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* for Aptalis' AMRIX® extended release product.

substance that is applied onto the surface of another, the purpose of which is to delay the release of a drug in order to maintain the drug at therapeutically effective concentrations over an extended period of time." J.A. 23. Applying this claim construction, the district court found that Apotex's ANDA product contained an extended release coating and infringed the asserted claims of the '199 and '121 patents. *Aptalis Pharmatech, Inc. v. Apotex Inc.*, 220 F. Supp. 3d 544, 550–55 (D. Del. 2016) ("*Dist. Ct. Op.*").

Apotex appealed the district court's claim construction and its infringement finding. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II.

Claim construction seeks to ascribe the "ordinary and customary meaning" to claim terms as a person of ordinary skill in the art would have understood them at the time of invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "Where the district court's claim construction relies only on intrinsic evidence, the construction is a legal determination reviewed de novo." *Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1002 (Fed. Cir. 2016) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015)).

When construing claims, "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). This case tiptoes that line. The specification does not provide a lexicographic definition of "coating," and the prosecution history contains no clear and unmistakable disavowal of claim scope. Nonetheless, Apotex contends that the intrinsic evidence would have taught an ordinarily skilled artisan at the time of

the invention that an "extended release coating" is limited to a continuous outer film, not simply "[a] layer of any substance that is applied onto the surface of another." For the reasons explained below, we agree and adopt Apotex's proposed construction of "extended release coating" as "a continuous outer film applied onto the surface of the active-containing core to provide an extended release of the active core." *See* Appellants Br. 21.

We begin, as we must, with the plain claim language. *Phillips*, 415 F.3d at 1312 ("[T]he claims are 'of primary importance[] in the effort to ascertain precisely what it is that is patented.'" (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876)). Here, the claim language recites an "extended release *coating* comprising a water insoluble polymer membrane *surrounding* said [active-containing] *core*." '199 patent col. 10 ll. 28–29 (emphases added). It is clear that the coating must surround the core. As the district court recognized, dictionaries define "surround" as "to enclose on all sides." *Dist. Ct. Op.*, 220 F. Supp. 3d at 548 n.10.[3] A coating that surrounds the core or encloses it on all sides connotes a continuous coating, i.e., one that covers the entire surface of the core. And, because the extended release coating must surround the core, the plain claim language suggests that the coating must be located outside of the core. In other words, the water insoluble polymer membrane is an outer coating relative to the core. Our construction reflects these limitations by requiring a "continuous outer film applied onto the surface of the active-containing core."

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[3] The parties do not dispute that "surrounding," as used in the '199 patent, means "to enclose on all sides"; instead, they dispute whether "surround" means that the coating must be "continuous." *See* Appellants Br. 22; Appellees Br. 39.

The specification bolsters our conclusion that the extended release coating must be a continuous outer film. *See Phillips*, 415 F.3d at 1315 ("[T]he specification 'is always highly relevant to the claim construction analysis.'" (internal citation omitted)). First, every embodiment in the specification that discusses a coating describes a process in which the water insoluble polymer coating is external to the active-containing core. *See, e.g.*, '199 patent col. 4 ll. 15–17 ("ER Beads can be produced by applying a functional membrane comprising a water insoluble polymer alone or in combination with a water soluble polymer onto IR Beads."); *id.* at col. 5 ll. 38–41 ("The [active]-containing particle may be coated with an extended release (ER) coating comprising a water insoluble polymer or a combination of a water insoluble polymer and a water soluble polymer to provide ER beads."); *id.* at col. 4 ll. 33–36 ("ER beads include a core particle (IR (immediate release) bead) containing a skeletal muscle relaxant and an ER (extended release) coating comprising a water insoluble polymer surrounding the core."); *id.* at col. 5 ll. 60–64 (describing process of "coating the IR bead with a plasticized water-insoluble polymer alone such as ethylcellulose or in combination with a water soluble polymer such as hydroxypropylmethylcellulose to form an Extended Release (ER) bead"); *id.* at col. 7 ll. 32–35 (disclosing the step of "coating the active drug particle with a solution or suspension of a water insoluble polymer or a mixture of water soluble and water insoluble polymers to form an extended release coated drug particle (ER beads)"). The same is true for Example 2, which describes spraying an extended release polymer membrane "onto the IR beads for a weight gain of approximately 10%." *Id.* at col. 8 ll. 39–43; *see id.* at col. 8 l. 62 – col. 9 l. 13 (discussing Example 3's application of extended release coating onto immediate release beads until a certain weight gain is reached).

These disclosures would have taught a person of ordinary skill that the extended release coating is an outer coating of polymer relative to the active-containing core.[4] And the specification's frequent references to applying the extended release coating "onto" the active-containing core comports with our understanding of the spatial orientation required by the claims. *See, e.g.*, *id.* at col. 3 ll. 64–67, col. 4 ll. 15–17, col. 8 ll. 39–43, col. 8 ll. 62–66.

Second, the specification demonstrates the inventors' ability to describe a *non*-continuous coating when they so desired. The specification's background of the invention

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[4] The specification's disclosure of an extended release matrix formulation does give us pause. *See id.* at col. 6 ll. 23–33 (describing an embodiment where the rate-controlling polymer is blended together with the active drug and compressed into beads, as opposed to spraying the rate controlling polymer onto an active-containing core). But while a construction that excludes a preferred embodiment "is rarely, if ever, correct," *Vitronics Corp.*, 90 F.3d at 1583, "[t]his does not mean . . . that each and every claim ought to be interpreted to cover each and every embodiment," *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 755 (Fed. Cir. 2016). We note that the specification describes the steps in this embodiment as "blend[ing]," "granulat[ing]," "extrud[ing]," and "spheroniz[ing]." *Id.* at col. 6 ll. 26–30. The other embodiments and the claims, however, require a "coating"; and, in any event, nothing in the specification forbids the application of an extended release coating onto this matrix embodiment. *See* Oral Arg. at 28:44–30:29, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-1344.mp3. Thus, this does not alter our conclusion that the specification, when read as a whole, would have taught an ordinarily skilled artisan that an "extended release coating" requires a continuous outer film.

section referred to a prior art reference that disclosed the application of a water impermeable coating onto a core followed by the creation of apertures in the coating. The inventors of the asserted patents described the coating in this prior art reference as "ha[ving] apertures exposing between about 5–75% of the core surface." *Id.* at col. 2 ll. 30–31. By contrast, the asserted claims require the coating to "surround[] said core." The inventors' decision to claim a coating that surrounds the core instead of claiming a coating with a certain percentage of exposed core surface would have informed a person of ordinary skill in the art that the claims require a continuous coating.

The prosecution history offers additional support for construing "extended release coating" to require a continuous outer film. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc) ("To construe claim language, the court should also consider the patent's prosecution history, if it is in evidence."). During prosecution of the '199 patent, the applicants submitted a declaration from Dr. James W. McGinity. The Declaration summarizes Dr. McGinity's interview with the examiner during the prosecution of a related patent application that shares the same specification as the asserted patents. According to Dr. McGinity, the process taught by the shared specification results in the formation of a continuous film:

> If the liquid medium used in the coating process contains the polymer suspended as an aqueous dispersion, the polymer is initially deposited onto the core as discrete polymer spheres, *which must then coalesce to form a continuous film*. In such cases, a plasticizer may be added to the liquid medium to facilitate the coalescence process. On the other hand, if the liquid medium contains the polymer dissolved as a solution in an organic

> solvent, *a continuous film forms directly upon evaporation of the solvent*.

J.A. 1140–41, ¶ 9(c) (emphases added). A person of ordinary skill reading this Declaration would have understood that the extended release coatings of the invention were continuous films. And an ordinarily skilled artisan would have understood the film to be an outer layer relative to the core because the coating is "deposited onto" the cores.

We are not persuaded by Aptalis' arguments in defense of the district court's contrary construction. Aptalis first argues that the "applied onto the surface of the active-containing core" and "outer" requirements would exclude preferred embodiments. In Example 2, for instance, a seal coat is applied onto the active-containing core before the extended release coating, and an additional coating layer is added after the extended release coating. *See* '199 patent col. 8 ll. 23–46. Because there is a seal coat between the extended release coating and the active-containing core, Aptalis argues that the extended release coating was applied onto the seal coat, not "onto the surface of the active-containing core." Similarly, Aptalis interprets "outer" to mean "outermost" and points out that there is a coating layer applied onto the extended release coating in Example 2.

Neither argument is persuasive. The specification refers to seal-coated active-containing cores as "core[s]," *id.* at col. 7 ll. 4–14, so the presence of a seal coat does not mean that the extended release coating is not applied "onto the surface of the active-containing core." And although Aptalis is correct that there is no basis for requiring the extended release coating to be the "outermost" coating, our construction imposes no such requirement. The extended release coating need only be an outer coating relative to the active-containing core, which is consistent with Example 2's teachings.

Aptalis next asserts that the word "continuous" does not appear in the asserted patents and that a "continuous" extended release coating would not be functional because the coating must be permeable to gastrointestinal fluids. Aptalis conflates continuity with permeability, as demonstrated by Dr. McGinity's Declaration:

> Extended release drug products may be made by coating water-insoluble polymers (e.g., the water-insoluble polymers claimed by Applicants) onto a core containing the active drug. In general, the applied polymer coatings do not dissolve when the drug product is ingested; *instead, the coatings are semi-permeable such that water can enter and exit the core*, thereby releasing the dissolved drug at a controlled rate.

J.A. 1140, ¶ 9(a) (emphasis added). It follows that a continuous film covering the surface of the active-containing core would not defeat the extended release functionality because the polymer coatings described by the invention are semi-permeable to water.

Finally, Aptalis contends that the prosecution history is irrelevant to the claim construction question here because there is no clear and unmistakable disavowal of claim scope. Our precedent does not support this proposition. We have stated that "[a]ny explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to 'capture the scope of the actual invention' that is disclosed, described, and patented." *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015) (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011)). Although the prosecution history may lack the clarity imbued by the specification, it "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited

the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. Accordingly, even in the absence of a clear and unmistakable disavowal, we conclude that the prosecution history can be evaluated to determine how a person of ordinary skill would understand a given claim term.

III.

We have considered the parties' remaining claim construction arguments and find them unpersuasive. Because we conclude that the district court erred in construing the claims, we vacate and remand the district court's infringement finding for further proceedings consistent with our claim construction.

VACATED AND REMANDED

COSTS

Costs to Appellants.