

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

RECKITT BENCKISER INC.,
Plaintiff-Appellant,

v.

WATSON LABORATORIES, INC. - FLORIDA,
Defendant-Appellee.

2011-1231

Appeal from the United States District Court for the Southern District of Florida in Case No. 09-CV-60609, Judge William P. Dimitrouleas.

Decided: July 7, 2011

DOMINICK A. CONDE, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for the plaintiff-appellant. With him on the brief were JOHN D. CARLIN, NINA SHREVE and TARA A. BYRNE.

B. JEFFERSON BOGGS, Merchant & Gould, of Alexandria Virginia, argued for defendant-appellee. Of counsel on the brief were SUSAN BAKER MANNING, MATTHEW L.

FEDOWITZ and ANDREW B. ELLSWORTH, Bingham McCutchen, LLP, of Washington, DC.

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

LOURIE, *Circuit Judge*.

Reckitt Benckiser Inc. (“Reckitt”) appeals from the judgment of the United States District Court for the Southern District of Florida holding that Watson Laboratories, Inc. - Florida (“Watson”) does not infringe the asserted claims of U.S. Patent 6,372,252 (the “’252 patent”). *Reckitt Benckiser, Inc. v. Watson Labs., Inc. – Florida*, No. 09-cv-60609, slip op. (S.D. Fla. Feb. 18, 2011), ECF No. 339. Because the district court correctly construed the asserted claims of the ’252 patent and determined that Watson’s products do not infringe, we *affirm*.

BACKGROUND

I

At issue in this case are pharmaceutical formulations comprising guaifenesin, an expectorant useful for relieving congestion. Reckitt obtained approval from the Food and Drug Administration (“FDA”) to market its Mucinex® products, bilayer tablets containing guaifenesin in both immediate release (“IR”) and sustained release (“SR”) formulations. Reckitt listed the ’252 patent in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) as covering Mucinex®.

The ’252 patent states that IR formulations of guaifenesin were known in the art. ’252 patent col.3 ll.7-11. The patent also states that although SR formulations, including polymer-based formulations containing a hydrophilic hydrocolloid gelling polymer, were known gen-

erally, *id.* col.1 l.57–col.2 l.14, SR formulations of guaifenesin capable of sustaining therapeutic effectiveness for at least twelve hours were not known as of the patent’s filing date, *id.* col.3 ll.12-14.

The prosecution history of the ’252 patent is relevant to the arguments on appeal. Originally filed claims 1-11 were directed to “[a] sustained release pharmaceutical formulation” and were not limited to a bilayer or two-portion structure. *Reckitt*, slip op. at 22; J.A. 41996-97. Original claims 12-32, in contrast, were directed to modified release products. *Reckitt*, slip op. at 23; J.A. 41997-42000. Claims 12-24 were limited to products with two portions, while claims 25-32 were directed to modified release tablets with a Cmax equivalent to an IR guaifenesin tablet and a twelve-hour therapeutic bioavailability.

As the district court noted, the examiner rejected original claims 1-32 as being unpatentable for obviousness under 35 U.S.C. § 103(a) over two prior art references. *Reckitt*, slip op. at 23; J.A. 42201. In response, the applicants filed an amendment on August 6, 2001, cancelling those claims and adding new claims 33-55, all of which were directed to “[a] modified release tablet having two portions.” *Reckitt*, slip op. at 23; J.A. 42216, 42213-14. In remarks accompanying that amendment, the applicants stated that, to facilitate prosecution, they were relinquishing claims directed to guaifenesin SR formulations:

Claims 1-32 have been cancelled and claims 33-55 have been added. *Original claims 1-11 were directed to a sustained release formulation* and claims 12-32 were directed to a modified release formulation having both immediate and sustained release properties. New claims 33-55 are directed to the modified release formulation of original

claims 12-32, while *the sustained release claims have been cancelled to facilitate prosecution* without prejudice to Applicants' ability to pursue them separately in a continuation application.

Reckitt, slip op. at 23; J.A. 42214, 42208 (emphases added). The applicants also distinguished new claims 33-55 over the two cited prior art references, arguing that the new claims, unlike the prior art, required two portions:

Drost et al. *does not disclose a composition having both an immediate release portion* that is fully bioavailable in the subject's stomach *and a sustained release portion* that provides therapeutically effective bioavailability for at least 12 hours. . . .

Dansereau et al. does not supply the deficiencies of Drost et al. While *Dansereau et al. does disclose two separate guaifenesin portions with different release characteristics*, this disclosure describes a dual-action tablet that includes an outer portion that slowly releases a first dose of the drug and an inner portion that provides a second dose which is delayed until some time after administration, i.e., until the outer portion is dissolved sufficiently to expose the inner portion to gastric fluids. *Such an approach is totally different from that of the claimed invention.* In fact, *Dansereau et al. specifically teaches away from employing any immediate release portion:* "This dual-action tablet is contrasted with repeat-action tablets which give an immediate dose followed by a sustained dose" Moreover, the inner dose of Dansereau et al. is not "fully bioavailable in the subject's stomach" because of the time delay caused by the slow-release outer portion.

Reckitt, slip op. at 23-24 (emphases added).

On November 19, 2001, following an interview with the examiner, the applicants filed a supplemental amendment. *Id.* at 24; J.A. 42302-12. At the examiner's suggestion, this amendment added a further limitation to claims 33, 42-44, 46, and 48 requiring the tablet to demonstrate a particular Cmax. The applicants also introduced new claims 56-88. Those claims all required "[a] modified release product having two portions." J.A. 42303-05. In remarks accompanying the supplemental amendment, the applicants again distinguished the prior art from the pending claims as lacking both an IR portion and an SR portion. *Reckitt*, slip op. at 25-26; J.A. 42306-08.

In a notice of allowance dated December 4, 2001, the examiner indicated that the pending claims "are allowable over the prior art because the prior art does not teach a modified release bi-layer tablet product that provides early Tmax or the higher Cmax achievable with the claimed invention." *Reckitt*, slip op. at 26; J.A. 42317. The claims issued as claims 1-56 of the '252 patent. Claims 57 and 58 were added during ex parte reexamination; those claims are also directed to "[a] modified release product having two portions." J.A. 124.

II

In April 2009, Reckitt sued Watson in the United States District Court for the Southern District of Florida for infringing independent claims 24, 57, and 58 and dependent claims 26-28, 31-34, and 39 of the '252 patent based on Watson's abbreviated new drug application ("ANDA") to market guaifenesin tablet formulations. 35 U.S.C. § 271(e)(2). The claim limitation disputed on appeal appears in each of the asserted independent claims. Claim 24 is illustrative:

24. A *modified release product having two portions*, wherein a *first portion* comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a *second portion* comprises a second quantity of guaifenesin in a sustained release form wherein the ratio of said first quantity to said second quantity provides a Cmax in a human subject equivalent to the Cmax obtained when the first of three doses of a standard immediate release formulation having one third the amount of guaifenesin is dosed every four hours over a 12 hour period and wherein said product also provides therapeutically effective bioavailability for at least twelve hours after a single dose in a human subject according to serum analysis.

'252 patent claim 24 (emphases added).

Watson's accused products are non-layered polymer matrix tablets made from a single guaifenesin formulation.¹ *Reckitt*, slip op. at 47. In its ANDA, Watson sought a determination by the FDA that its products are bioequivalent to the Mucinex® products. *Id.* at 36-37.

In January 2011, the district court issued a claim construction order which, *inter alia*, construed "portion" as "a discrete part of the product." J.A. 5520; *see also Reckitt*, slip op. at 41. Following a 7-day bench trial, the court found that Watson's products do not have separate IR and SR portions and thus do not literally infringe the '252 patent. *Reckitt*, slip op. at 43-51. The court did not view as credible Reckitt's theory that guaifenesin granules on the surface of Watson's product constituted a discrete IR

¹ Detailed information concerning the ingredients, manufacture, and performance of Watson's tablets has been marked as confidential by the parties.

portion. *Id.* at 48-49. The court concluded that during prosecution Reckitt disclaimed products lacking two discrete structural portions. *Id.* at 44-45. Further, the court found no infringement under the doctrine of equivalents, because the “two portions” structural limitation is not present in Watson’s products and because Watson’s tablets achieve bioavailability in a different way from the claimed tablets. *Id.* at 53-57.

The district court entered final judgment of noninfringement on February 9, 2011. Pursuant to 28 U.S.C. § 1295(a)(1), we have jurisdiction over final judgments arising under the patent laws.

DISCUSSION

Reckitt appeals the district court’s claim construction and its findings of noninfringement both literally and under the doctrine of equivalents. According to Reckitt, the court misconstrued the claim term “portion” in the asserted claims. Reckitt contends that the written description of the ’252 patent does not limit the invention to discrete bilayered tablets. Reckitt cites *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001) in support of its argument that the district court erred by failing to apply the ordinary meaning of the term “portion,” which is “a part of any whole.” Reckitt maintains that the doctrine of claim differentiation supports its construction of the term portion. Moreover, Reckitt contends that the prosecution history of the ’252 patent does not limit “portion” to a “discrete part.”

As for infringement, Reckitt contends that the district court ignored its own claim construction and based its finding of noninfringement on new process limitations. Reckitt also alleges that granules of guaifenesin on the surface of Watson’s products constitute a discrete IR portion such that Watson’s products literally infringe the

asserted claims of the '252 patent even under the district court's claim construction. Reckitt further asserts that the district court's finding of noninfringement under the doctrine of equivalents was clearly erroneous because the court merely reiterated its analysis of literal infringement and failed to properly apply the function-way-result test. Finally, Reckitt maintains that it did not disclaim non-layered tablets during prosecution because canceled original claims 1-11 claimed a particular ratio of hydrophilic polymer to water insoluble polymer without regard to Cmax or PK profile.

In response, Watson argues that the court correctly found that its accused products do not infringe the asserted claims, as properly construed by the district court. According to Watson, the specification states that the claimed portions must be discrete. Watson also asserts that Reckitt disclaimed non-layered SR formulations during prosecution, and that the court's claim construction correctly accounts for this disclaimer. Although Watson acknowledges that granules on the surface of its products release guaifenesin upon ingestion, Watson insists these do not constitute a "portion" of the tablet within the meaning of the '252 patent's claims. Thus, Watson contends, the court correctly found that its products do not literally infringe the '252 patent because they are non-layered, single-formulation polymer matrix tablets that do not have two portions as the asserted claims require.

Watson also argues that the court correctly found that its products do not infringe under the doctrine of equivalents. According to Watson, the '252 patent discloses non-layered, single-formulation tablets but does not claim them; therefore, they are dedicated to the public. Watson further asserts that prosecution history estoppel also precludes infringement under the doctrine of equivalents.

Watson alleges that the district court correctly concluded that Reckitt may not use the doctrine of equivalents to read out the “two portions” limitation of the asserted claims.

We agree with Watson that the district court did not err in its claim construction and did not clearly err in its finding of a lack of infringement. A district court’s claim construction is a matter of law that we review *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (en banc). We consider the claim language, specification, prosecution history, and relevant extrinsic evidence in ascertaining the scope and meaning of the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-17 (Fed. Cir. 2005) (en banc). “[A]bsent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis.” *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008). However, “when a patent applicant surrendered claim scope during prosecution before the PTO, the ordinary and customary meaning of a claim term may not apply.” *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007). To narrow the scope of claim language, a prosecution history disclaimer must be “clear and unambiguous.” *Seachange Int’l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1373 (Fed. Cir. 2005).

Infringement is a question of fact that, after a bench trial, we review for clear error. *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006). A factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error. *Id.*

Regarding claim construction, we conclude that the district court did not err by construing the term “portion”

to mean “a discrete part of the product.” The court’s claim construction rested on a proper analysis of the claims and written description of the ’252 patent, as well as its prosecution history. *Reckitt*, slip op. at 7-29. The ’252 patent discloses two general types of guaifenesin formulations—SR formulation tablets and modified release tablets with both IR and SR portions. *Id.* at 7-10. The specification never refers to the SR formulation tablets as containing “portions.” *Id.* at 10. In contrast, the modified release tablets disclosed in the specification include three embodiments: bilayer tablets having an IR portion on one face and an SR portion on the other; bilayer tablets having an SR portion in the center that is coated and surrounded by an IR portion; and guaifenesin capsules containing beads of IR formulation and beads of SR formulation. *Id.* at 22; ’252 patent col.3, ll.57-60; col.9, ll.46-56. The specification explicitly states that the modified release tablets contain “two discrete portions.” ’252 patent col.3, ll.44-48.

In the context of the ’252 patent’s disclosure, which clearly distinguishes between SR formulation tablets and two-portion modified release products, the district court properly considered the prosecution history, including the amendments and remarks made by the applicants during prosecution of the application leading to the ’252 patent. *Reckitt*, slip op. at 22-26. The court correctly concluded that the prosecution history demonstrated a disclaimer of single-formulation SR guaifenesin tablets, even if those tablets release some guaifenesin immediately upon ingestion. *Id.* at 45 (characterizing the prosecution history as a “disclaimer of products with merely immediate release and sustained release properties,” as opposed to products with discrete IR and SR portions). The applicants disavowed claim coverage of sustained release tablets by cancelling original claims 1-11 and remarking to the

examiner that “[o]riginal claims 1-11 were directed to a sustained release formulation [T]he sustained release claims have been cancelled to facilitate prosecution.” *Id.* at 23. The unmistakable effect of that disavowal, evident from the applicants’ remarks distinguishing the prior art, was to limit the remaining claims to two-portion guaifenesin products. For instance, the applicants distinguished one reference by arguing that it “does not disclose a composition having both an immediate release portion that is fully bioavailable in the subject’s stomach and a sustained release portion that provides therapeutically effective bioavailability for at least 12 hours.” *Id.* at 24. The file history thus demonstrates a “clear and unambiguous” prosecution disclaimer. *Seachange*, 413 F.3d at 1373.

The district court’s construction of the “portion” limitation not only accurately encompasses the three embodiments of two-portion tablets and capsules disclosed in the specification, it also excludes single-formulation SR tablets such as those disclosed in the ’252 patent. *Reckitt*, slip op. at 44-51. The district court’s claim construction, therefore, properly accounted for the patent’s disclosure and the applicants’ clear and unmistakable prosecution history disclaimer. *See N. Am. Container, Inc. v. Plasti-pak Packaging, Inc.*, 415 F.3d 1335, 1345 (Fed. Cir. 2005) (concluding that the applicant, through arguments during prosecution, met “the high standard required in order to show a prosecution disclaimer”). Even if, as *Reckitt* argues, the district court’s construction departs from the ordinary meaning of the term “portion,” *cf. Rexnord*, 274 F.3d at 1344, we nevertheless affirm the court’s construction of this term in the context of the ’252 patent. *See Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (“[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the

doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.”).

We also reject Reckitt’s contention that the doctrine of claim differentiation runs contrary to the district court’s claim construction. Under the doctrine of claim differentiation, “the presence of a dependent claim that adds a particular limitation raises a presumption that the limitation in question is not found in the independent claim[,] [a]lthough that presumption can be overcome if the circumstances suggest a different explanation, or if the evidence favoring a different claim construction is strong” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (citations omitted). Reckitt maintains that the district court’s construction of claim 24 is erroneously limited to bilayer tablets and that this construction renders superfluous unasserted dependent claim 36, directed specifically to bilayer tablets. We disagree. As we noted above, the district court’s construction encompasses the three embodiments of two-portion tablets and capsules in the specification; thus, a dependent claim directed only to one particular type of bilayer tablet is fully consistent with the doctrine of claim differentiation. *See* 35 U.S.C. § 112 ¶ 4 (2006).

Reckitt’s additional claim construction arguments are unpersuasive. Accordingly, we affirm the district court’s construction of the term “portion,” the only claim term at issue in this appeal.

Further, we reject Reckitt’s arguments that the court clearly erred in its analysis of literal infringement. Contrary to Reckitt’s assertions, the district court did not ignore its own claim construction and base its finding of noninfringement on new process limitations. As the court correctly found, Watson’s products do not infringe because

they are non-layered, single-formulation polymer matrix tablets that do not contain the claimed “first portion” or “second portion.” *Reckitt*, slip op. at 45-47. Moreover, we reject Reckitt’s contention that Watson’s products do not infringe under a proper application of the district court’s claim construction. The district court correctly concluded that Watson’s products do not have two structural portions and that guaifenesin granules on the surface of Watson’s tablets do not constitute the claimed first portion of guaifenesin in an IR form. *Id.* at 48-51. As the court noted, even though the SR formulations that Reckitt disclaimed during prosecution of the ’252 patent exhibit some IR properties, they do not possess a two-portion structure. *Id.* at 45; *see also* J.A. 43344-45. Likewise, even if Watson’s products exhibit some IR properties (as Reckitt maintains), they do not contain a discrete IR portion as required by the asserted claims. *Reckitt*, slip op. at 45.

Finally, Reckitt contends that the district court clearly erred in its finding of noninfringement under the doctrine of equivalents. Again, we disagree. Reckitt asserts, in essence, that bioequivalence necessitates infringement by equivalence. We have clarified, however, that “bioequivalency and equivalent infringement are different inquiries.” *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009). Indeed, on the facts of this case, prosecution history estoppel bars Reckitt from recapturing single-formulation SR guaifenesin tablets like those it disclaimed in obtaining the ’252 patent. *Reckitt*, slip op. at 55. As the district court correctly noted, Reckitt’s narrowing claim amendments were made for reasons of patentability. *Id.* at 23, 25; *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (“Estoppel arises when an amendment is made to secure the patent and the amendment narrows the

patent's scope.”). When, in response to an examiner's rejection, a patent applicant submits an amended claim set, the applicant's “decision to forgo an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim.” *Id.* at 734. We, like the district court, take Reckitt's unambiguous prosecution disclaimer as a concession that the asserted claims of the '252 patent do not extend to single-formulation SR tablets such as Watson's accused products.² *Reckitt*, slip op. at 55-56.

CONCLUSION

We have considered Reckitt's remaining arguments and find them unpersuasive. Accordingly, for the foregoing reasons, we affirm the district court's finding of noninfringement.

AFFIRMED

² This case also appears to invoke the dedication doctrine, whereby the failure to claim a disclosed embodiment forecloses any right to recapture that embodiment under the doctrine of equivalents. *See Abbott*, 566 F.3d at 1297; *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc). However, because we conclude that prosecution history estoppel limits the application of the doctrine of equivalents in this case, we need not separately address the dedication doctrine.