UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ADAMS RESPIRATORY THERAPEUTICS, INC., ADAMS RESPIRATORY OPERATIONS, INC., ADAMS RESPIRATORY PRODUCTS, INC., and RECKITT BENCKISER, INC.,

Plaintiffs,

v.

Case No. 1:07-CV-993

HON. GORDON J. QUIST

PERRIGO COMPANY, L. PERRIGO COMPANY AND PERRIGO RESEARCH AND DEVELOPMENT COMPANY,

Defendants.
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OPINION

Plaintiffs, Adams Respiratory Therapeutics, Inc., Adams Respiratory Operations, Inc., and Adams Respiratory Products, Inc. (collectively "Adams,"), have sued Defendants, Perrigo Company, L. Perrigo Company, and Perrigo Research and Development Company (collectively "Perrigo"), alleging that Perrigo's guaifenesin product described in its Abbreviated New Drug Application (ANDA), a generic version of Adams' 600 mg Mucinex® product, will infringe claims 24, 26, 33, 34, and 39 of Adams' U.S. Patent No. 6,372,252 (the "'252 patent"). Subsequent to filing this lawsuit, Adams, by merger, became Reckitt Benckiser, Inc. ("Reckitt"). (Dkt. # 404 ¶ 4.) For purposes of consistency in this litigation, the Court will continue to refer to the plaintiff as Adams, even though Reckitt is the surviving corporate entity.

The Court has previously construed the disputed claim terms of the '252 patent, (dkt. ## 176, 187), including: (1) "portions," which means a discrete, physically separate part of the product; (2) "modified release product," which is "a dosage form comprising a sustained release portion and an immediate release portion, and having both immediate and sustained release properties"; and (3)

"first quantity" and "second quantity" as, respectively, "the quantifiable or measurable amount of guaifenesin in the first portion" and "the quantifiable or measurable amount of guaifenesin in the second portion."

Perrigo has now moved for summary judgment of noninfringement based on the Federal Circuit's decision in *Reckitt Benckiser, Inc. v. Watson Laboratories, Inc.–Florida*, 430 F. App'x 871 (Fed. Cir. 2011), which affirmed the Southern District of Florida's finding that Watson's ANDA guaifenesin product does not infringe the '252 patent. The Federal Circuit further concluded that the district court properly determined that during prosecution of the '252 patent, Adams disclaimed "single-formulation [sustained release] guaifenesin tablets, even if those tablets release some guaifenesin immediately upon ingestion." *Id.* at 876. Perrigo contends that its ANDA product cannot infringe as a matter of law because it is a single-formula sustained release tablet that falls within the scope of Adams' disclaimer.

As set forth below, the Court agrees with Perrigo and will grant its motion.

I. BACKGROUND

A. The '252 Patent

The '252 patent describes a modified release guaifenesin product containing an immediate release (IR) portion and a sustained release (SR) portion. Guaifenesin is an expectorant that thins mucous secretions and relieves congestion. The invention disclosed in the '252 patent is directed at the problem of providing a therapeutically-effective blood concentration, or C_{max}, of guaifenesin over an extended period of time, i.e., twelve hours. ('252 patent, col. 1, ll. 12-17.) The '252 patent notes that IR formulations provide a quick burst of guaifenesin resulting in a rapid increase of drug followed by a similar rapid decrease, requiring multiple doses over an extended period of time to maintain the drug's therapeutic effectiveness. (*Id.* col. 1, ll. 26-33.) SR formulations, which combine guaifenesin with sustained release polymers, such as hydrophilic hydrocolloid gelling

polymers, slow the rate of drug release and allow treatment with fewer daily doses and side effects. (*Id.* col. 1, ll. 45-56; col. 1, ll. 66 - col. 2, l.2.) The '252 patent notes that prior SR formulations failed to obtain the same high blood concentration of guaifenesin as IR formulations and failed to maintain their effectiveness over extended periods of time. (*Id.* col. 2, ll. 23-27.) Thus, the patent explains, "none of the prior art has described a sustained release dosage form of guaifenesin which has a C_{max} equivalent to that of an immediate release formulation, appears in the blood stream as quickly as an immediate release formulation, yet sustains therapeutic effect for at least twelve hours." (*Id.* col. 3, ll. 15-19.) The '252 patent overcomes these problems with a modified release, or bilayer, tablet containing discrete IR and SR portions. (*Id.* col. 3, ll. 44-48.)

Claim 24, upon which the other asserted claims in this case depend, recites:

> 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 C_{max} in a human subject equivalent to the C_{max} 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.

(*Id.* col. 22, ll. 17-30.)

Adams markets the bilayer tablets disclosed in the '252 patent under the tradename Mucinex®.

B. Perrigo's ANDA Product

Perrigo's extended-release guaifenesin product is a generic version of Adams' Mucinex® product. Unlike Adams' modified release product, Perrigo's tablet is a single-formulation SR tablet. In its ANDA, Perrigo sought to establish the safety and efficacy of its product by showing that it is bioequivalent to Mucinex®.

C. The *Watson* Litigation

In *Reckitt Benckiser, Inc. v. Watson Laboratories, Inc. - Florida*, No. 09-60609-CIV-DIMITROULEAS (S.D. Fla.), Adams alleged that Watson Laboratories' generic Mucinex® product infringed several claims of the '252 patent (including those asserted in this case). Adams' experts in *Watson*, Drs. Amidon, Sawchuck, and Davies, are also Adams' experts in the instant case. After adopting most of this Court's claim constructions, the Florida district court conducted a bench trial. In its findings of fact and conclusions of law, the court concluded that Watson's products–"non-layered, single-blend polymer matrix tablets " (2/9/11 Slip Op. ¶ 187)–do not literally infringe the '252 patent because they do not possess separate IR and SR portions. (*Id.* ¶¶ 185, 190-192, 197.) The court also concluded that Watson's products do not infringe under the doctrine of equivalents because the "two portions" structural limitation is not present in Watson's products. (*Id.* ¶¶ 228, 229.) As part of its decision, the court also held that:

- the two portions (IR and SR) are structural rather than functional limitations (*id.* ¶ 182);
- because they are structural, the separate IR and SR portions cannot be satisfied by showing that the accused product has immediate release properties (*id.* ¶ 183);
- guaifenesin granules that touch the surface of the accused tablet cannot be considered the claimed "first portion" in an immediate release form because such granules do not constitute "a discrete part of the product"; in other words, "[t]he guaifenesin granules do not themselves constitute a formulation separate from the overall formulation of [the tablet]" (*id.* ¶¶ 200-01);
- during prosecution of the '252 patent, Adams disclaimed products lacking two discrete structural portions (*id.* ¶ 182);
- single-formulation SR guaifenesin products do not have discrete IR and SR portions (*id.* ¶¶ 183-187); and
- SR guaifenesin products made from a single-formulation do not infringe literally or under the doctrine of equivalents (*id.* ¶¶ 214, 226-229, 238).

Adams appealed the district court's noninfringement rulings to the Federal Circuit, which affirmed in all respects. **First**, the Federal Circuit affirmed the district court's construction of

"portion" as "a discrete part of the product." *Watson Labs.*, 430 F. App'x at 876. The court noted that the '252 patent refers to both SR formulation tablets and modified release (containing both IR and SR portions) tablets and never refers to SR formulation tablets as containing "portions." *Id.* The court further observed that the modified release products disclosed in the specification have two portions: an IR portion and an SR portion. *Id.* **Second**, the court held that the district court correctly concluded that "the prosecution history demonstrate[s] a disclaimer of single-formulation SR guaifenesin tablets, even if those tablets release some guaifenesin immediately upon ingestion." *Id.* "The unmistakable effect of that disavowal," the court said, "was to limit the remaining claims to two-portion guaifenesin products." *Id.* **Third**, the court rejected Adams' assertion that granules of guaifenesin on the surface of an SR formulation tablet, such as Watson's, could constitute a discrete IR portion: "As the [district] 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 877. Relatedly, the court said that "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." *Id.* at 878. **Fourth**, the court rejected Adams' assertion that bioequivalence equates to infringement by equivalence, noting that they are "different inquiries." *Id.* **Finally**, the court held that prosecution history estoppel barred Adams from recapturing the accused single-formulation SR tablets it disclaimed in order to obtain the '252 patent, thus foreclosing Adams' reliance on the doctrine of equivalents. *Id.*

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate if there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56. Material facts are facts which are defined by substantive law and are necessary to apply the law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). A dispute is genuine if a reasonable jury could return judgment for the non-moving party. *Id.*

The court must draw all inferences in a light most favorable to the non-moving party, but may grant summary judgment when "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." *Agristor Fin. Corp. v. Van Sickle*, 967 F.2d 233, 236 (6th Cir. 1992) (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 1356 (1986)).

III. DISCUSSION

A. Literal Infringement

As noted above, the Federal Circuit held in *Watson* that Adams disclaimed "single-formulation SR guaifenesin tablets, even if those tablets release some guaifenesin immediately upon ingestion." *Watson Labs.*, 430 F. App'x at 876. According to the court, then, "the remaining claims [are limited] to two-portion guaifenesin products." *Id.* Perrigo has shown that its tablets, like Watson's single-formulation SR tablet and the single-formulation SR tablets disclosed in the '252 patent, is a single-formulation SR tablet. In other words, the entire tablet is made from a single list of ingredients designated only as an SR formulation. (Def.'s Br. Supp. Summ. J. at 8 (setting forth Perrigo's list of ingredients and lists of ingredients of the SR tablets disclosed in the '252 patent).) Adams does not explicitly concede that Perrigo's tablet is a single-formulation tablet, but it offers no evidence to show that Perrigo actually uses separate IR and SR formulations to make discrete portions of its tablet, as is the case with the bilayer tablets disclosed in the '252 patent. (252 patent, col. 14, l. 56 - col. 15, l. 45.) Because Perrigo's tablet is a single-formulation SR tablet, it falls squarely within the scope of the disclaimer defined in *Watson*. Therefore, as a matter of law, Perrigo's tablet cannot infringe the '252 patent.[1]

In spite of the clear language in *Watson* regarding the disclaimer, Adams insists that the Federal Circuit did not really mean what it said. Citing portions of the transcript of oral argument

[1] As the Court indicated at oral argument, because the Federal Circuit's decision addresses claim construction of the '252 patent, the Court need not consider whether the doctrine of collateral estoppel applies in the instant case.

before the Federal Circuit, as well as various references throughout the Federal Circuit's opinion, Adams argues that the Federal Circuit meant that the disclaimer was not of single-formulation SR tablets, but rather of non-layered SR tablets. Adams contends that because the court confirmed that the two-portions limitation is a structural and not a process limitation, it was concerned not with how the tablet is made, but instead with its resulting structure. Adams explains that Watson's tablets fell within the disclaimer because they were non-layered SR tablets: because the amount of polymer was consistent throughout the tablet, it lacked a separate immediate-release layer of guaifenesin on the outside. Adams says that Perrigo's tablet differs from Watson's tablet, and thus falls outside the disclaimer, because Adams' experts have identified a separate layer of guaifenesin, uninhibited by polymer, that forms an IR portion. Thus, Adams contends, Perrigo's tablet has a core-coated structure like that identified in the '252 patent, which the Federal Circuit said was outside the scope of the disclaimer.

This Court disagrees with Adams. The Federal Circuit clearly and concisely outlined the scope of the disclaimer in its opinion: "single-formulation SR guaifenesin tablets." Adams cites no case permitting a district court to displace an appellate court's written decision with questions and comments from oral argument. Although the Federal Circuit referred to non-layered SR tablets throughout its opinion, including with reference to Watson's tablet, there is no indication that the court was mistaken or had something else in mind when it described the scope of the disclaimer. The scope of the disclaimer would be no different, however, even if the Federal Circuit had used the term "non-layered" in referring to the disclaimer. As is evident from the opinion, the court and the parties used the term "non-layered" descriptively to distinguish single-formulation SR tablets–which Adams disclaimed–from the bilayer modified release tablets disclosed in the '252 patent. In fact, the court noted that "the '252 patent's disclosure . . . clearly distinguishes between SR formulation tablets and two-portion modified release products" because the disclosed SR products were made

with a single-formulation, whereas each of the modified release products–including the bilayer tablets with back-to-back IR and SR portions; the bilayer tablets with SR core coated by an IR portion, and the non-layered capsules containing separate IR and SR beads–had separate IR and SR formulations.

Adams' effort to divorce structure from process on the ground that the Federal Circuit said that the two-portion limitation is structural is unavailing. While the claims require separate IR and SR portions, the '252 patent makes clear that each portion is made from a separate formulation. As the Court put it at oral argument, whether a product is made with a single formulation or separate IR and SR formulations is essentially evidence of whether the product falls within or without the disclaimer. Furthermore, the '252 patent shows that each portion of the two-portion modified release tablets within the scope of the claims is separately made and then combined with the other portion to form the tablet. ('252 patent Fig. 3.)

Because the disclaimer encompasses single-formulation SR tablets, Adams' "free guaifenesin-on-the-surface" argument is also unavailing. In spite of its attempts to distinguish *Watson*, Adams made substantially the same argument to the Federal Circuit in *Watson* (including that the guaifenesin on the surface of Watson's tablets was uninhibited by polymer) that it now makes in this case with regard to Perrigo's tablet. The Federal Circuit rejected the argument because immediately-releasing guaifenesin granules on the surface of an accused tablet are irrelevant to the scope of the disclaimer. 430 F. App'x at 876. Thus, regardless of whether Adams is now making the same or a different "free guaifenesin" argument, the result is the same because it cannot change the scope of the disclaimer. For the same reason, Adams' arguments relating to whether Perrigo's tablet is "homogeneous" or "uniform" and whether Perrigo's tablet uses the same formulations or manufacturing processes as Watson's tablet or the SR tablet examples disclosed in the '252 patent have no bearing on whether Perrigo's single-formulation SR tablet falls within the disclaimer. In

other words, infringement is determined by comparing the accused product to the asserted patent claims, *see Allen Eng'g Corp. v . Bartell Indus., Inc.*, 299 F.3d 1336, 1351 (Fed. Cir. 2002), and in this case, Perrigo's product falls within the disclaimer and outside the scope of the claims.

B. Doctrine of Equivalents

Adams contends that an issue of fact remains as to infringement under the doctrine of equivalents. The Court disagrees. Contrary to Adams' argument, Perrigo has not misconstrued the scope of the disclaimer as defined by the Federal Circuit in *Watson*. Moreover, as the Federal Circuit explained, "prosecution history estoppel bars [Adams] from recapturing single-formulation SR guaifenesin tablets like those it disclaimed in obtaining the '252 patent. *Watson*, 430 F. App'x at 878. Therefore, Perrigo is also entitled to summary judgment on the doctrine of equivalents.

IV. CONCLUSION

For the foregoing reasons, the Court concludes that Perrigo is entitled to summary judgment of noninfringement, both literally and under the doctrine of equivalents. Perrigo's motion will thus be granted.[2]

An Order consistent with this Opinion will be entered.

Dated: January 11, 2012

/s/ Gordon J. Quist
GORDON J. QUIST
UNITED STATES DISTRICT JUDGE

[2]In its motion, Perrigo requested that prior to the publication of its Opinion, the Court provide the parties with an opportunity to review it and submit redactions of any party or non-party confidential information contained in the Opinion. The Court has carefully reviewed the instant Opinion and concludes that no such information is contained herein. In fact, in light of the Federal Circuit's ruling, the Court saw no need to include information that may be deemed confidential.