IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER LLC,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 14-1203-LPS
	:	
AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA, INC.,	:	
	:	
Defendants.	:	

MEMORANDUM ORDER

At Wilmington this **16th** day of **October, 2017**:

Having reviewed the parties' briefing and other materials (D.I. 185-86, 191-93, 197, 208-213) related to Defendants Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.'s (collectively, "Aurobindo") motion for attorneys' fees and expenses, **IT IS HEREBY ORDERED** that the motion (D.I. 184) is **DENIED** for the reasons stated below.

1. Plaintiff Reckitt Benckiser sued Aurobindo for infringement of U.S. Patent Nos. 6,955,821 and 7,838,032,[1] which claim controlled-release formulations of the drug guaifenesin containing both immediate-release and sustained-release portions or quantities. Following claim construction, the Court allowed Aurobindo to file a motion for summary judgment of non-infringement. (D.I. 138) After full briefing and a hearing, the Court granted summary judgment in favor of Aurobindo, determining that no reasonable factfinder could find that Aurobindo's proposed ANDA product contains two distinct formulations, as required by the asserted claims.

[1]Reckitt initially asserted U.S. Patent No. 6,372,252 as well. (*See* D.I. 1)

(*See* D.I. 174) Aurobindo now seeks attorneys' fees under 35 U.S.C. § 285, contending that this case is exceptional on the basis of Reckitt's claim construction and infringement theories and in light of the need to deter abusive ANDA litigation. (*See* D.I. 185 at 11)

2. In "exceptional" patent cases, a Court may award "reasonable attorney fees" to the "prevailing party." 35 U.S.C. § 285. Federal Circuit law applies when interpreting and applying § 285. *See Highway Equip. Co. v. FECO, Ltd.*, 469 F.3d 1027, 1032 (Fed. Cir. 2006). "An exceptional case under § 285 is 'simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated.'" *Nova Chems. Corp. (Canada) v. Dow Chem. Co.*, 856 F.3d 1012, 1016 (Fed. Cir. 2017) (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014)). Ultimately, the Court must make a discretionary decision based on the totality of circumstances, which may include factors such as "frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence." *Octane Fitness*, 134 S. Ct. at 1756 & n.6. A party moving for attorneys' fees must demonstrate, by a preponderance of the evidence, that a case is "exceptional." *Id.* at 1758.

3. As a preliminary matter, there is no dispute that Aurobindo is a prevailing party. The Court granted Aurobindo's motion for summary judgment and entered final judgment in favor of Aurobindo and against Reckitt. (*See* D.I. 174, 181) Aurobindo undisputedly "receive[d] at least some relief on the merits, which alters the legal relationship of the parties." *Inland Steel Co. v. LTV Steel Co.*, 364 F.3d 1318, 1320 (Fed. Cir. 2004) (internal quotation marks and

original alterations omitted). Therefore, the focus here is whether this case is exceptional.

4. In one way, this case stands out from others: it is an ANDA case that was resolved on summary judgment, a rare occurrence in this Court, which often does not allow summary judgment motions to be filed in an ANDA case. But this fact alone does not make this case per se "exceptional." That the nature of the narrow dispute presented by the parties turned out to be amenable to summary judgment does not inevitably correlate to an exceptionally weak substantive position or an unreasonable manner of litigation.

5. Nonetheless, there are other circumstances here that could support a finding of exceptionality. In particular, one patent (the '252 patent) initially asserted in this case – but ultimately dropped – was the subject of an appeal at the Federal Circuit. *See Reckitt Benckiser Inc. v. Watson Labs.*, 430 F. App'x 871 (Fed. Cir. 2011) ("*Watson*"). *Watson* concerned the construction of the term "portion" – a term also appearing in some of the asserted claims of the related patents here – and infringement. *See id.* at 874-75. There the Federal Circuit affirmed the district court's construction of "portion" and made clear that the proper construction requires two distinct formulations. *See id.* at 876-77. The Court then affirmed the district court's finding of non-infringement, agreeing that "Watson's products do not have two structural portions" and that bioequivalence was insufficient to demonstrate infringement. *Id.* at 877-88.

6. Although *Watson*, in and of itself, does not necessarily make Reckitt's decision to bring the present action unreasonable or exceptional, the fact that the Federal Circuit had already ruled on a patent in this family is relevant to assessing subsequent actions by Reckitt. Reckitt – the same patentee and plaintiff here as in *Watson* – was surely aware of that case and proceeded here with knowledge of the Federal Circuit's decision on the issues presented there. Accepting

that *Watson* did not, at first, provide sufficient reason for Reckitt to abstain from pressing its claims here, after claim construction that calculus should have changed somewhat. By that point, Reckitt was (reasonably) no longer asserting the '252 patent (the subject of *Watson*). Ultimately, this Court's construction of terms found in the related '821 and '032 patents was entirely consistent with the construction of the Federal Circuit in *Watson*. The Court here, as had occurred in *Watson*, construed all of the asserted claims to require two distinct formulations: an immediate-release formulation and a sustained-release formulation. (*See* D.I. 134 at 5-9)

7. Yet Reckitt maintained its suit and continued to assert an infringement theory focused on performance aspects of the ANDA products, resting on dissolution data and various pharmacokinetic studies without regard to the structure of the formulation. (*See* D.I. 174 at 10) Despite the two-formulations requirement, Reckitt did not have its expert analyze the formulation of the ANDA product or the process by which the product is manufactured (*see id.* at 10-11), and Reckitt's expert admitted that his testing data did not speak to the product's structure (*see* D.I. 141 Ex. E at 179). Further, Reckitt elected not to depose Defendants pursuant to Rule 30(b)(6) to learn more about the manufacturing process; nor did it depose Aurobindo's expert. (*See* Tr. at 39) Reckitt's litigation strategy, thus, was unusual.

8. On the other hand, a number of factors weigh against finding this case to be exceptional within the meaning of § 285. First, although *Watson* undoubtedly had to be considered by Reckitt in deciding whether to file this case, *Watson* was not dispositive of the issues presented here. It was reasonable for Reckitt to have perceived an opportunity to develop a case on which it might succeed on the merits, notwithstanding *Watson*. This case involved a different ANDA product and the assertion of additional patents, making it possible to reach a

different result (i.e., to find infringement) despite the *Watson* precedent. At the start of the case, a reasonable litigant viewing the ANDA might have expected, at minimum, that it would be able to find an expert of the opinion that the only way to achieve the ANDA product's dissolution profile was by having separate, independent immediate- and sustained-release portions. In fact, Aurobindo agrees that, had Reckitt's expert clearly opined that the dissolution profile of the ANDA product necessitates the presence of two distinct formulations, *Watson* would not have been dispositive. (*See* Tr. at 10) Further, Aurobindo's ANDA is not so clear as to preclude a reasonable litigant from making that argument, leaving Reckitt with an adequate basis to bring this lawsuit. *See, e.g.*, *Tyco Healthcare Grp. LP v. Mut. Pharm. Co., Inc.*, 2016 WL 3965201, at *5 (D.N.J. July 22, 2016); *Warner Lambert Co. v. Purepac Pharm. Co.*, 2003 WL 21698310, at *4 (D.N.J. May 22, 2003).

9. Furthermore, Reckitt performed a reasonable investigation on the ANDA product after filing the case, including by performing testing.[2] It is notable that the two-formulations limitation was not the only limitation in dispute during this litigation (although it was the sole focus of the summary judgment motion), meaning that Reckitt reasonably devoted resources to generate evidence regarding other claim limitations as well. (*See* Tr. at 44-45) And when, in the course of its investigations, Reckitt determined that it no longer had a good faith basis to assert

[2]The parties dispute the importance of imaging data that Reckitt cited in some infringement contentions, did not produce, and eventually withdrew all reference to in conjunction with dropping the '252 patent from the case. (*See* D.I. 185 at 17; D.I. 191 at 14; D.I. 208; D.I. 210-12) The Court does not find Reckitt's conduct with respect to these "inconclusive" results to support a finding that this case is exceptional. *See St. Clair Intellectual Prop. Consultants, Inc. v. Toshiba Corp.*, 2015 WL 7451158, at *3 (D. Del. Nov. 23, 2015) ("[C]hang[ing] positions in the course of litigation does not make this case exceptional. Parties should abandon positions or claims when it appears they are unlikely to prove fruitful.").

the '252 patent, Reckitt promptly withdrew that patent from the case. (*See* D.I. 191 at 14)

10. The Court also finds that Reckitt's claim construction arguments were not wholly unreasonable or without merit. While the Court construed the patents consistently with *Watson*, to require two distinct formulations, the Court did not adopt Aurobindo's positions wholesale. (*See* D.I. 134) Instead, as is not entirely unusual, the Court considered each parties' proposed constructions and arguments and then crafted its own construction. (*See id.* at 5) With respect to the term "modified release drug product," the Court adopted Reckitt's proposed construction, although it did not fully accept the meaning Reckitt ascribed to that construction. (*See id.* at 7-9) This confirms that Reckitt did not stake out an unreasonable claim construction position. *Cf. Astrazeneca AB v. Dr. Reddy's Labs., Ltd.*, 2010 WL 1375176, at *8 (S.D.N.Y. Mar. 30, 2010).

11. Nor is this the unusual case that is entirely devoid of an infringement theory. *See Tyco*, 2016 WL 3965201, at *3 (D.N.J. July 22, 2016) ("[W]here a party has set forth some good faith argument in favor of its position, it will generally not be found to have advanced 'exceptionally meritless' claims."); *Astrazeneca*, 2010 WL 1375176, at *5-6. Reckitt performed testing on the ANDA product, retained an expert[3] to provide opinions about the testing, and presented a coherent – although ultimately unsuccessful – theory of infringement.

12. Finally, the Court did not accept all of Aurobindo's arguments at summary judgment. In particular, Aurobindo contended that "Aurobindo's ANDA clearly and unequivocally seeks approval of single-formulation, sustained release products." (D.I. 140 at 5) While the Court agreed that the ANDA's reference to a "single layer" – without explicitly stating

[3]The Court also denied Aurobindo's motion to exclude Reckitt's expert, a further indication that Reckitt's infringement position was not entirely baseless. (*See* D.I. 174 at 4-5)

how many portions or formulations would be in the ANDA product – was helpful evidence, the Court found it was ***not*** dispositive. (*See* D.I. 174 at 10)

13. Aurobindo contends that an exceptionality finding is warranted to deter future litigants from behaving like Reckitt, especially in the context of the Hatch-Waxman Act, with its purpose (among others) to foster timely entry of generic drugs to the market. Aurobindo suggests that due to the statutory, automatic 30-month stay of FDA approval of an ANDA that is triggered by the filing of litigation, the Court should be alert to the incentives branded drug companies like Reckitt have to file frivolous cases, and should perhaps be more willing to find an ANDA case exceptional within the meaning of § 285. While these concerns may merit substantial weight in some other case, here they do not, as Reckitt's litigation position was not frivolous, and as the market here already included generic competitors at the time this suit was filed. The Court finds no basis here to conclude that Reckitt chose to file a frivolous case to delay entry of an additional generic manufacturer.

14. On balance and considering the totality of the circumstances, the Court concludes that the factors weighing against finding this case exceptional outweigh those in favor. Reckitt reasonably filed, maintained, and litigated this lawsuit. While the evidence garnered by Reckitt to support its infringement claims was insufficient to overcome Aurobindo's motion for summary judgment, the Court does not find that this case – whether compared to the full panoply of patent cases with which the Court has been involved or with the more narrow category of ANDA cases it has handled – stands out with respect to the substantive strength of Reckitt's

unsuccessful positions or the manner in which Reckitt litigated the case. *See Octane Fitness*, 134 S. Ct. at 1756. Accordingly, the Court exercises its discretion to deny Aurobindo's request for attorneys' fees.

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE