[Dkt. Ent. 718, 727]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

ASTRAZENECA LP and ASTRAZENECA AB,

Plaintiffs,

v.

BREATH LIMITED,

Defendant.

ASTRAZENECA LP and ASTRAZENECA AB,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Plaintiffs,

v.

SANDOZ, INC.,

Defendant.

ASTRAZENECA LP and ASTRAZENECA AB,

Plaintiffs,

Consolidated Civil Action
No. 08-1512 (RMB/AMD)

Member cases:
09-1518
09-4115
10-5785
11-3626

MEMORANDUM OPINION

v.

WATSON LABORATORIES, INC.

Defendant.

_____

BUMB, UNITED STATES DISTRICT JUDGE:

On April 2, 2013, the Court issued an Order granting in part and denying in part a motion filed by the plaintiffs, AstraZeneca LP and AstraZeneca AB ("AstraZeneca"), for an injunction pending appeal pursuant to Federal Rule of Civil Procedure 62(c). [Dkt. Ent. 727.] The Court now sets forth the basis for that Order.

Under Rule 62(c), this Court has the authority to grant injunctive relief pending appeal.[1] It considers four factors in determining whether to grant such relief: (1) whether the applicant has a strong likelihood of success on the merits; (2) whether the applicant will be irreparably injured absent the relief; (3) whether issuance of the relief will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. Sanofi-Aventis U.S. LLC v. Sandoz, Inc., No. 07-2762, 2009 WL 1968900, *2 (D.N.J. July 29, 2009) (citing Hilton v. Braunskill, 481 U.S. 770, 776 (1987)).

[1] Rule 62(c) provides in relevant part:

> While an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party's rights. . . .

Likelihood of Success on the Merits

This prong clearly weighs against AstraZeneca for the reasons set forth in this Court's April 1st Opinion. AstraZeneca asserts various arguments in its motion, which the Court briefly addresses now.

First, AstraZeneca argues that the Court "failed to take account of the undisputed fact that in seven years between 1990 . . . and 1997, . . . there was no study even trying nebulized budesonide once daily." AZ's Br. 18. The Court considered this issue at closing arguments. Ultimately the Court was not persuaded by it, since (1) the lack of studies could also suggest that the issue was so obvious that such studies were not necessary, see, e.g., Tr. 2380 (Barnes) ("[I]t was known that once-daily budesonide via other inhaled routes was effective and therefore nebulized budesonide would certainly be as effective. Because once the drug is in the lung it will work in exactly the same way whichever inhaler device you use to deliver the drug to the airways."); (2) the Court would flout the legal standard for obviousness set forth in KSR Int'l. Co. v. Teleflex, Inc., 550 U.S. 398 (2007), if it found that the lack of studies on a patented method rendered the claimed invention non-obvious; indeed, this would effectively render almost every patent non-obvious; and (3) the critical pieces of relevant art were published within only a couple of years of the critical date of the Patent, December 31,

---

Fed. R. Civ. P. 62(c).

1996. See, e.g., C. Möller, et al., Administration of Budesonide via Turbuhaler® (200 µg and 400 µg) Once Daily Is as Effective as when Given Twice Daily in Children with Asthma, 9 Eur. Respiratory J. 115s (Sept. 1996) (DTX 816); William F. Jackson, Nebulised Budesonide Therapy in Asthma – A Scientific and Practical Review 39 (1995) (DTX 826A, 826, PTX 1650); L.M. Campbell, et al., Once Daily Budesonide: Effective Control of Moderately Severe Asthma with 800 µg Once Daily Inhaled via Turb[u]haler When Compared with 400 µg Twice Daily, 7 Eur. J. Clinical Res. 1 (1995) (DTX 1045); T.P. McCarthy, The Use of a Once Daily Inhaled Glucocorticosteroid (Budesonide) in the Management of Childhood Asthma, 4 Brit. J. Clinical Res. 55 (1993) (DTX 815).

Second, AstraZeneca argues that the Court's obviousness analysis is flawed, because the Court credited Dr. Barnes' testimony alleging that he had prescribed nebulized budesonide once daily. AstraZeneca argues that this "uncorroborated testimony, 15 years after the fact is highly suspect." AZ Br. 18. AstraZeneca may not usurp this Court's role in finding facts and making credibility determinations. Further, the Court sees no reason to question its previous finding that Dr. Barnes was very well qualified, credible, and persuasive. The Court also notes that it properly qualified its reliance on Dr. Barnes' prescribing practices because he testified that he generally does not treat children. In fact, while

the Court considered this testimony, it was not critical to the Court's findings.

Third, with respect to the '603 Patent's dependent claims, AstraZeneca again challenges the Court's credibility finding of Dr. Barnes concerning his testimony that "the principles for treating [young children] and for treating older children and adults are the same." Slip op. at 78, Dkt. Ent. 717 (April 1, 2013). AstraZeneca argues, "Dr. Barnes's opinion is not credible, given the Court's acknowledgment that Dr. Barnes 'does not generally treat children.'" AZ Br. 19. The Court disagrees. The fact that Dr. Barnes does not primarily treat children does not impugn his considerable expertise in this area. Indeed, he was clearly well versed in the relevant research. He authored one of the critical pieces of prior art, a scholarly article published in the New England Journal of Medicine, which summarized the relevant articles on asthma treatment using glucocorticosteroids and particularly described the studies pertaining to the treatment of children. Peter J. Barnes, Inhaled Glucocorticoids for Asthma, 332 NEW ENG. J. MED. 868 (1995) (DTX 875). Simply because Dr. Barnes does not frequently treat children does not imply that he is not fully aware of the principles for treating children and adults. Indeed, AstraZeneca never objected to his qualifications as an expert at trial.

Fourth, AstraZeneca argues that "the Court overlooked other evidence proffered at trial that the treatment of children with asthma

using inhaled medication – particularly children under age five as claimed in claim 16 – differs from the treatment of older children and adults." AZ Br. 19. It cites Dr. Chipps' testimony at trial (Tr. 1095:20-1096:7, 1100:15-1102:2, 3941:3-3942:11). The Court did not overlook this testimony. To the extent the Court did not reiterate all of Dr. Chipps' testimony, this was because the Court found it cumulative, unpersuasive, or lacking in probative value, for all of the reasons already set forth in the Court's April 1st Opinion. See, e.g., slip op. at 59-60, 68, 79-81.

Likewise, AstraZeneca argues that the Court overlooked its argument that the 1995 Canadian label for AstraZeneca's PULMICORT TURBUHALER® "exemplifies these differences" between treatment of young children and treatment of older children and adults. AZ Br. 19. AstraZeneca states: "Although the Court noted that the PULMICORT TURBUHALER® label indicated that it was not recommended for children under 6, the Court failed to acknowledge the importance of this fact." AZ Br. 19. AstraZeneca argues that the fact that the TURBUHALER label did not specifically prescribe a once-daily indication for children, despite the prior art, renders the claimed method non-obvious. The Court already considered and rejected this argument, finding that it relies on an improper understanding of the legal standard for obviousness. The fact that this label did not include a once-daily indication for children does not render the claimed method non-obvious under KSR, which requires the Court

to adopt an "expansive and flexible" approach and appreciate that the skilled artisan is also a person of "ordinary creativity". Slip op. at 36, 80-81. Further, the Court found the TURBUHALER comparison inapt, because it was well known that PULMICORT RESPULES was safe and effective for children and was already on the market for a twice-daily indication, slip op. at 38, whereas the TURBUHALER was a dry powder inhaler, which was problematic for young children. Slip op. at 42.

Fifth, AstraZeneca objects to the Court's finding that the '603 Patent is anticipated by the Barnes reference. The Court disagrees. However, since this issue did not resolve the case – in light of the Court's obviousness finding – the Court declines to revisit it, given the strong interest in resolving the pending matter expeditiously.

Sixth, AstraZeneca attacks the Court's finding that the Defendants do not infringe the '834 Patent. AstraZeneca merely rehashes its prior arguments that the independent claims "are product claims, not process claims," and again contends that "the Court committed the 'cardinal sin' of claim construction: importing a limitation from the specification into the claim." Id. The Court has already carefully considered and rejected this argument, however. See Op. 103-25. The Court acknowledged the "exacting" standard for claim disavowal but found that the considerable evidence here established that AstraZeneca had clearly disavowed non-"heat

sterilized" products. Op. 122. Under the circumstances, a contrary finding would constitute the "sin".

AstraZeneca also now attempts to change its proposed construction, arguing that the Court should have construed "micronized powder composition" to mean "finely divided particles." Id. at 24. At the time of claim construction, however, AstraZeneca proposed a different definition: "a powder composition in which the particle size has been mechanically reduced to form particles having a mass median diameter (MMD) of approximately 20µm or less." Op. 104-05 (citing AZ's Resp. Markman Br. 31). Certainly, the time for arguing claim construction has long passed.

Seventh, AstraZeneca argues that the Court's infringement analysis of the '834 Patent is "erroneous". Specifically, AstraZeneca argues that the Court overlooked the testimony of its expert, Dr. Robert O. Williams, with respect to the doctrine of equivalents analysis. AZ Br. 24-25. However, AstraZeneca ignores the fact that the critical limitation in the asserted claims is the "heat sterilized" element, and Dr. Williams testified that he relied upon Dr. James Agallaco for the analysis of this element. Tr. 853:17-854:17, 861:19-862:9, 870:11-871:11, 872:10-16. Thus, the Court properly focused its analysis on Dr. Agallaco's testimony with respect to the dispositive "heat sterilized" element. Once the Court found Dr. Agallaco's testimony flawed, it also necessarily found Dr. Williams' testimony flawed for the same reasons.

Eighth, AstraZeneca argues that the Court's "disclaimer analysis" is erroneous. The Court has already considered and rejected all of these arguments and sees no need to restate them.

For these reasons, AstraZeneca has not given the Court any reason to disturb its April 1st Opinion and therefore has not shown a likelihood of success on the merits.

Irreparable Harm to AstraZeneca

AstraZeneca argues that they will suffer irreparable harm if Apotex and Breath/Watson are permitted to launch. Specifically, they submit a declaration from an AstraZeneca executive, Linda Palczuk, stating that "defendants' premature launch would wreak havoc on AstraZeneca's employees and reputation, could lead to product shortages, and would cause severe, irreparable harm. Even if defendants were eventually removed from the market, their introduction of unlicensed generic [budesonide inhalation suspension] products would forever damage the market that AstraZeneca lawfully created." AZ Br. 30. Breath/Watson responds that such harm is quantifiable (e.g., revenue, sales, and market losses) or speculative. Breath/Watson Br. 29-30. For the reasons set forth in this Court's prior opinion granting a preliminary injunction in this matter, AstraZeneca LP v. Apotex, Inc., 623 F. Supp. 2d 579 (D.N.J. 2009), aff'd, 633 F.3d 1042 (Fed. Cir. 2010), this prong likely weighs in AstraZeneca's favor.

Harm to the Defendants

As an initial matter, the Court notes that Apotex does not oppose the requested injunction so long as AstraZeneca posts an appropriate bond. Breath/Watson does, however, object. The Court agrees that issuing the injunction will substantially injure Breath/Watson, as it will be deprived of the opportunity to launch and distribute its generic drug product, though the posting of a bond may ameliorate that harm. See Sanofi-Aventis, 2009 WL 1968900 at *3.

Breath/Watson contends that its commercial launch has already begun. It submits the declaration of Napoleon Clark, which indicates that:

> (1) Watson launched its generic product on April 1, 2013, following this Court's entry of a decision in its favor;
>
> (2) Watson's product has a shelf life and, if it cannot be sold now, it may not be sellable because customers expect at least 12 months of remaining shelf life;
>
> (3) Watson's long-term relationships with customers may be put in jeopardy as customers would question Watson's reliability if it is forced to withdraw its products from the market; and
>
> (4) Watson has made significant investment in preparing to launch.

Clark Decl. ¶¶ 7-10 [Dkt. Ent. 723]. These facts, however, offer little insight into what concrete steps Watson has taken to launch its product beyond announcing that it is launching and previously taking steps to prepare for its launch. Watson's discussion of shelf life suggests that it has already manufactured its product for distribution and potentially has contracts to supply the product, but it is unclear on the record before the Court whether that is the case. Indeed, since the Court issued its Order enjoining the

Defendants from launching a mere 24 hours after issuing its Opinion and Order, it seems unlikely that Breath/Watson's launch could have progressed very far. Importantly, all of these concerns can be minimized by a short injunction.

Public Interest

At this point in the litigation, having found that Defendants should be entitled to launch their products, the public interest weighs in favor of denying the injunction, as the central purpose of the Hatch-Waxman Act, 21 U.S.C. §§ 355, under which this case arises, is to facilitate generic competition and lower prices for consumers. Sanofi-Aventis, 2009 WL 1968900 at *4.

Conclusion

Balancing these factors, the Court finds that while the equities do not warrant an injunction pending appeal in this Court's view, a limited temporary injunction is warranted in order to permit AstraZeneca a meaningful opportunity to seek the same relief from the Federal Circuit pursuant to Federal Rule of Appellate Procedure 8(a). See Eli Lilly & Co. v. Actavis, Civ. No. 07-3770, slip op. at 2, Dkt. Ent. 674 (D.N.J. Aug. 18, 2010) (granting temporary injunction while plaintiff sought injunctive relief from Federal Circuit, noting that "[a]bsent the limited relief granted herein, the Federal Circuit would not have a meaningful opportunity to consider granting the relief sought by [plaintiff], as the Defendant

generic drug manufacturers will be permitted to enter the market regardless of the ultimate determination made as to the enforceability of the patent-in-issue.") (citation omitted).[2]

s/Renée Marie Bumb
RENÉE MARIE BUMB
United States District Judge

Dated: April 3, 2013

[2] The Court notes that since Sandoz has not received FDA approval to launch its generic drug product, the injunction Order naturally does not apply to Sandoz. Should Sandoz receive FDA approval during the duration of the temporary injunction, however, the Court may revisit the issue.