

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION
(Both Direct and Indirect Cases)

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Civil Action Nos. 1:16-cv-12653-ADB
1:16-cv-12396-ADB

**MEMORANDUM AND ORDER ON SHIRE’S MOTION FOR
LEAVE TO MOVE FOR PARTIAL SUMMARY JUDGMENT**

BURROUGHS, D.J.

This “pay-for-delay” or “reverse settlement” case arises from an alleged anticompetitive agreement between the brand and generic manufacturers of Intuniv, an ADHD medication. Defendants Shire LLC and Shire U.S., Inc. (collectively, “Shire”) manufacture Intuniv, which is the brand-name for extended release guanfacine hydrochloride. Defendants Actavis Elizabeth LLC, Actavis Holdco US, Inc., and Actavis LLC (collectively, “Actavis,” and, together with Shire, “Defendants”) manufacture Intuniv’s generic counterpart. Plaintiffs, who include both Direct Purchaser Plaintiffs (“DPPs”) and Indirect Purchaser Plaintiffs (“IPPs,” and, together with the DPPs, “Plaintiffs”), allege that they were forced to pay inflated prices for Intuniv due to Defendants’ improper agreement to delay competition for both brand Intuniv and generic Intuniv in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1–2. See generally [FWK 140].¹ Currently before the Court is Shire’s motion for leave to move for partial summary

¹ For purposes of this memorandum and order, the Court refers to docket entries in FWK, et al. v. Shire, et al., 16-cv-12653 as “FWK [ECF No.]” and docket entries in Picone, et al. v. Shire, et al., 16-cv-12396 as “Picone [ECF No.]”

judgment, [Picone 346; FWK 528].² For the reasons stated below, Shire’s motion, [Picone 346; FWK 528], is DENIED.

I. BACKGROUND

Because a full recitation of the factual background is unnecessary for resolution of the instant motion, the Court will provide only the pertinent facts here. For a more comprehensive factual background, the Court refers the reader to its summary judgment order. [FWK 523].

In September 2009, the Food and Drug Administration (“FDA”) approved Shire’s New Drug Application for Intuniv. [FWK 523 at 3]. As a result, Shire was entitled to three years of regulatory exclusivity, during which time the FDA could not approve a generic version of Intuniv. [Id.]. In December 2009, Actavis filed an Abbreviated New Drug Application (“ANDA”) for a proposed generic version of Intuniv and asserted that its drug would not infringe on Shire’s patent. [Id. at 4]. As the first filer of an ANDA, Actavis would have been entitled to a 180-day period during which no other generic manufacturer could have manufactured an Intuniv alternative. [Id.].

In May 2010, Shire sued Actavis for patent infringement in the U.S. District Court for the District of Delaware (the “Delaware Court”), which automatically triggered a 30-month stay of the FDA’s approval of Actavis’ ANDA. [FWK 523 at 4]. In February 2012, the Delaware Court held a claim construction hearing and issued an interim decision that made it more difficult for Shire to prevail at trial. [Id. at 4–5]. After denying Actavis’ motion for summary judgment, the Delaware Court held a bench trial in September 2012. [Id. at 5]. While the underlying patent litigation proceeded, Shire and Actavis engaged in settlement negotiations. [Id. at 6–9]. In April

² Shire filed an identical motion on each docket. See [Picone 346; FWK 528]. Hereinafter, in instances where the same document was filed on both dockets, the Court will cite only the FWK docket entry.

2013, before the Delaware Court issued a decision, Shire and Actavis settled the case. [Id. at 9–10]. In broad strokes, Shire and Actavis agreed that (1) Shire would drop the patent suit, (2) Actavis could make and market generic Intuniv beginning in December 2014, (3) Actavis would pay a 25% royalty to Shire for the first 180 days that Actavis’ generic Intuniv was on the market so long as it was the only generic Intuniv on the market, and (4) Shire could not authorize or license a third party to market or sell a generic Intuniv during Actavis’ 180-day exclusivity period but could, itself or via an affiliate, market a generic Intuniv during that time. [Id. at 10].

Plaintiffs argue that this settlement agreement was anticompetitive. See generally [FWK 247; Picone 39]. Essentially, Plaintiffs assert that the market for Intuniv would have become competitive earlier had Shire and Actavis not entered into their settlement because Actavis would have launched a generic Intuniv before December 2014 and Shire would have authorized a third-party to market a generic to compete with Actavis’ generic. [FWK 247 ¶¶ 151–54; Picone 39 ¶¶ 93–107]. They advance a number of theories as to why the allegedly anticompetitive settlement caused their alleged injuries, including their At-Risk Launch Theory and their Alternative Settlement Theory. [FWK 523 at 43]. With their At-Risk Launch Theory, Plaintiffs argue that but for the settlement, Actavis would have launched at risk prior to December 2014.³ [Id.; FWK 247 ¶¶ 153–54]. Under their Alternative Settlement Theory, Plaintiffs argue that but for the settlement, Actavis would have entered into a procompetitive settlement agreement with Shire pursuant to which Actavis would have entered the market prior to December 2014. [FWK 523 at 43].

³ An “at risk” launch refers to a generic company entering the market with a generic drug despite the pendency of a patent infringement case. [FWK 523 at 16].

To support these theories, Plaintiffs put forth various expert witnesses, including John Thomas and Dr. Thomas McGuire. Mr. Thomas would have opined, among other things, that Actavis had a greater than 95% chance of ultimately prevailing in its patent dispute with Shire and that, when Actavis and Shire settled their dispute in April 2013, a final decision from the Delaware Court in the patent litigation was imminent. [FWK 525 at 21]. Dr. McGuire was prepared to testify, among other things, that had Actavis and Shire entered into an alternative, procompetitive settlement, they would have agreed that Actavis could launch its generic between June and October 2013. [Id. at 45].

Defendants moved to exclude these opinions. [FWK 333 (Mr. Thomas); FWK 329 (Dr. McGuire)]. The Court ruled on Defendants' motions in a September 10, 2020 Order (the "Daubert Order"). [FWK 525]. With respect to Mr. Thomas, the Court concluded that he can testify "as to his professional opinion that Shire would not have prevailed in the underlying litigation, but he will not be permitted to provide any specific percentage of likelihood, as he has provided no concrete methodology for how he reached this figure," [id. at 24], and that he cannot testify as to the timing of the Delaware Court's decision in the patent litigation, [id. at 25]. With respect to Dr. McGuire, the Court concluded that he "may not rely on [Mr.] Thomas's 95% statistic in testifying as to possible generic entry dates" but "[i]nsofar as [he] is able, without relying on [Mr.] Thomas's 95% statistic, he may testify as to other reasonable dates for generic entry, but not the specific dates that the parties would have agreed to." [Id. at 46].

On September 21, 2020, the Court ruled on the parties' cross-motions for summary judgment. [FWK 523]. Among other things, the Court denied Defendants' motion for summary

judgment on Plaintiffs’ At-Risk Launch Theory.⁴ [*Id.* at 43–53]. The Court also reiterated its conclusion regarding Mr. Thomas: “[a]lthough the Court has excluded [Mr.] Thomas’ specific statistical finding as to Shire’s likelihood of success, he will be permitted to testify as to Shire’s general likelihood of success on the merits in an underlying patent case” [*Id.* at 53].

On October 15, 2020, Shire filed the instant motion for leave to move for partial summary judgment on Plaintiffs’ Alternative Settlement Theory. [FWK 528]. Plaintiffs opposed, [FWK 533 (DPPs’ opposition); Picone 347 (IPPs’ joinder)], and Shire replied, [FWK 541].

II. DISCUSSION

Shire argues that, in light of the Daubert Order, Plaintiffs cannot prove their Alternative Settlement Theory and that the Court should therefore grant summary judgment in Shire’s favor on that issue. [FWK 528 at 1]. More specifically, Shire asserts that Plaintiffs’ Alternative Settlement Theory is based solely on an economic model presented by Dr. McGuire, that Dr. McGuire’s model requires two inputs provided by Mr. Thomas—Actavis’ percentage likelihood of prevailing in the underlying patent litigation and the date on which the Delaware Court would have rendered a decision had the parties not settled—and that, because of the Daubert Order, Mr. Thomas will not provide those inputs. [*Id.* at 2]. In opposition, Plaintiffs maintain that Shire’s motion is untimely because the Court has already ruled on the parties’ summary judgment motions and in so doing considered how the testimony of Dr. McGuire and Mr. Thomas relates to Plaintiffs’ causation theories. [FWK 533 at 2–4]. They further aver that a favorable ruling on the proposed partial summary judgment motion would not shorten the trial

⁴ Defendants did not move for summary judgment on Plaintiffs’ Alternative Settlement Theory. See generally [FWK 523].

because Dr. McGuire and Mr. Thomas would still both testify anyway.⁵ [Id. at 4–5]. In its reply, Shire responds that its proposed motion is timely because it depends on the Daubert Order, which did not issue until September 10, 2020, and that eliminating one of Plaintiffs’ causation theories would necessarily streamline the trial. [FWK 541 at 1, 3].

With regard to timeliness, the Court is vested with broad discretion to manage its docket, including by enforcing, or excusing noncompliance with, deadlines. Perez-Cordero v. Wal-Mart P.R., 440 F.3d 531, 533 (1st Cir. 2006) (“The district court has significant discretionary authority to set and enforce filing deadlines in accordance with the Federal Rules of Civil Procedure”). The deadline for summary judgment motions was more than a year ago. See [FWK 289 at 1–2]. Although the Court could deny Shire’s motion on that basis alone, see United States v. Tineo-Gonzalez, 893 F.3d 64, 66 (1st Cir. 2018), it will consider the motion on the merits given the Court’s relatively recent Daubert Order.

First, although Shire claims that Dr. McGuire will be unable to render his opinion as to Plaintiffs’ Alternative Settlement Theory without the benefit of the excluded aspects of Mr. Thomas’s opinion, [FWK 541 at 1–2], the Court is not willing to foreclose the possibility that Plaintiffs will find a way to advance their Alternative Settlement Theory while simultaneously adhering to the Daubert Order (and the expert disclosure requirements of Federal Rule of Civil Procedure 26).

Second, as Plaintiffs point out, Dr. McGuire and Mr. Thomas will testify even if the Court were to grant Shire’s proposed motion. [FWK 533 at 5]. The primary purposes of summary judgment are to eliminate unnecessary trials and conserve judicial and party resources.

⁵ Plaintiffs also assert that Shire is impermissibly seeking to benefit from the COVID-19 pandemic. [FWK 533 at 5–6]. The Court declines to ascribe any ill motive to Shire and rejects Plaintiffs’ argument.

See McCarthy v. Nw. Airlines, Inc., 56 F.3d 313, 315 (1st Cir. 1995) (“The device allows courts and litigants to avoid full-blown trials in unwinnable cases, thus conserving the parties’ time and money, and permitting courts to husband scarce judicial resources.”). Here, neither purpose would be served by granting Shire’s motion. First, there is no indication that a ruling on the proposed summary judgment motion would eliminate the need for a trial on the remaining issues. Second, the judicial resources that the Court would expend in ruling on Shire’s proposed motion, as well as the resources that the parties would expend in briefing it, far outweigh the marginal benefit of a slightly streamlined trial that might result were the Court to grant the motion. Moreover, because Plaintiffs may elect not to advance their Alternative Settlement Theory given the restrictions imposed by the Daubert Order, the time and effort that would be spent on a summary judgment motion might prove unnecessary. Alternatively, any issues related to this testimony can be quickly resolved during the course of trial.

III. CONCLUSION

Accordingly, for the reasons noted above, Shire’s motion, [Picone 346; FWK 528], is

DENIED.

SO ORDERED.

November 25, 2020

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE