NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, Plaintiff, v. PAR STERILE PRODUCTS, LLC, and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	Case No: 16-4544 (SDW) (LDW) **OPINION** February 25, 2020

WIGENTON, District Judge.

Before the Court is Plaintiff Fresenius Kabi USA, LLC's ("Fresenius" or "Plaintiff") and Defendants Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc.'s (collectively, "Par" or "Defendants") Motions for Summary Judgment, brought pursuant to Federal Rule of Civil Procedure 56. Jurisdiction is proper pursuant to 28 U.S.C. § 1331. Venue is proper pursuant to 28 U.S.C. § 1391. For the reasons stated below, Plaintiff's motion is **DENIED**, and Defendants' motion is **GRANTED**.

I. BACKGROUND AND PROCEDURAL HISTORY[1]

Vasopressin Injection ("Vasopressin") is a life-saving drug used to raise blood pressure in patients. (D.E. 163 ¶ 31.) Although Vasopressin originally did not require regulatory approval, in 2011, the Food and Drug Administration ("FDA") required Vasopressin manufacturers to seek

[1] Citations to "D.E. 154-1" refer to Par's Statement of Material Facts Not in Dispute and the citations contained therein. Citations to "D.E. 163" refer to Fresenius' Statement of Material Facts Not in Dispute and the citations contained therein. Citations to "D.E. 179" refer to Fresenius' Response to Par's Statement of Material Facts Not in Dispute and Supplemental Statement of Material Facts and the citations contained therein. Citations to "D.E. 185-1" refer to Par's Responsive and Supplemental Statement of Material Facts and the citations contained therein. This Court assumes the parties' familiarity with the facts and will only address those facts relevant to this Opinion.

approval by filing New Drug Applications ("NDA"). (Id. ¶¶ 36-39.) Once the first NDA is approved, new manufacturers may file Abbreviated New Drug Applications ("ANDA") to get approval for a "generic" version of that drug. (D.E. 154-1 ¶ 21.) ANDAs and NDAs require information about the drug's active pharmaceutical ingredient ("API"), which is usually included by reference to the API supplier's Drug Master File ("DMF"). (Id. ¶¶ 24-27.)[2] The NDA/ANDA filer may only reference a DMF if the API supplier gives it a letter of authorization ("LOA"). (Id. ¶¶ 30-31.) As part of the approval process, filers must also manufacture and collect six months of data on "stability batches" using API from the supplier providing the LOA. (D.E. 163 ¶¶ 68-69.)

Around 2011, Fresenius and Par were among the U.S. manufacturers of Vasopressin, and both began preparing Vasopressin NDAs. (Id. ¶¶ 75, 80.) Par filed its NDA in 2012, received FDA approval first, in April 2014, and launched its Vasopressin product, "Vasostrict," in November 2014. (D.E. 154-1 ¶¶ 57, 63-64, 81.) Once Vasostrict was approved, the FDA directed Fresenius to stop selling unapproved Vasopressin. (Id. ¶¶ 142-145.) Fresenius then shifted its focus from filing a Vasopressin NDA to filing an ANDA, and in early 2015, began working with BCN Peptides ("BCN"), an API supplier. (D.E. 163 ¶¶ 192-98.) In April 2015, BCN fulfilled an order of API for Fresenius' ANDA stability batches and Fresenius began testing these batches on October 16, 2015. (Id. ¶¶ 164, 202.) Fresenius planned on filing this ANDA by July 30, 2016 and projected to launch its product by July 2018. (Id. ¶¶ 160-61.)

Between 2014 and 2016, Par was negotiating potentially exclusive supply contracts with the only three API suppliers with DMFs at the time—BCN, Bachem Holdings AG ("Bachem") and PolyPeptide Group ("PolyPeptide"). (See, e.g., D.E. 154-1 ¶¶ 88, 101, 120.) Most relevant

[2] DMFs are technical documents filed with the FDA. (D.E. 154-1 ¶ 27.) For the purposes of this Opinion, "API" will refer specifically to Vasopressin API, unless otherwise noted.

here are Par's negotiations with BCN. Around January 2015, Par approached BCN about an agreement in which BCN would exclusively supply API for Par. (D.E. 163 ¶¶ 217-240.)[3] BCN ultimately agreed, executing an exclusivity agreement on March 1, 2016 in which Par agreed to pay $10 million per year and indemnify BCN for future legal costs arising out of the agreement. (Id. ¶¶ 263-68.) Due to this agreement, BCN could not provide Fresenius a LOA and Fresenius was unable to use its BCN-API based stability batches for its ANDA. (Id. ¶¶ 471-72.)[4] Fresenius maintains that, but for Par's conduct, it would have been able to file this ANDA ("But For ANDA") in July 2016 as planned.

Fresenius was aware that BCN was negotiating exclusivity as early as July 2015, and had discussed, but did not bid for, a semi-exclusive contract with BCN. (See id. ¶¶ 241-43; D.E. 154-1 ¶ 242.) On December 11, 2015, Dr. Marc-Alexander Mahl ("Dr. Mahl"), a Fresenius executive, reported that BCN said that Fresenius "could get Par out of [the BCN] deal, in case [it] would be willing to submit short-term a convincing, competitive offer," however, Fresenius declined to bid ("December Meeting"). (D.E. 170-14; D.E. 154-1 ¶¶ 232-33, 235-36, 242.)

On June 28, 2016, Par obtained its first patent for Vasostrict, and obtained several more the following year. (D.E. 163 ¶ 439; D.E. 154-1 ¶¶ 398-403.) Around October 2017, Fresenius selected Bachem as its new API supplier and filed its Vasopressin ANDA in July 2019. (D.E. 154-1 ¶¶ 357-64; D.E. 232 at 51:14-15.)[5]

Fresenius sued Par on July 27, 2016. (D.E. 1.) This Court denied Par's motion to dismiss on February 10, 2017. (D.E. 41.) Both parties moved for summary judgment on July

[3] BCN was Par's API supplier at the time Par's NDA was approved. (D.E. 154-1 ¶¶ 58, 63, 65.)
[4] Par also negotiated with Bachem and PolyPeptide. Par did not reach written exclusivity agreements with either, but purchased API from both, and both declined to supply other potential Vasopressin manufacturers during this timeframe. (See, e.g., D.E 163 ¶¶ 272-74, 306, 321-41, 359-360, 370-78; D.E. 154-1 ¶¶ 101-07, 120-27.)
[5] On March 23, 2018, Eagle Pharmaceuticals was the first to file an ANDA. (D.E. 154-1 ¶¶ 376-77.) Additionally, Fresenius' 2019 ANDA ultimately differed from what it asserts its But For ANDA would have been. (Id. ¶ 449.)

12, 2019 (D.E. 149, 153), and all briefs were timely filed. (D.E. 180, 185, 195, 199.) Oral argument was held on December 18, 2019. (D.E. 232.)

II. LEGAL STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247–48 (1986) (emphasis in original). A fact is only "material" for purposes of a summary judgment motion if a dispute over that fact "might affect the outcome of the suit under the governing law." Id. at 248. A dispute about a material fact is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. The dispute is not genuine if it merely involves "some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).

The moving party must show that if the evidentiary material of record were reduced to admissible evidence in court, it would be insufficient to permit the nonmoving party to carry its burden of proof. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). Once the moving party meets its initial burden, the burden then shifts to the nonmovant who must set forth specific facts showing a genuine issue for trial and may not rest upon the mere allegations, speculations, unsupported assertions or denials of its pleadings. Shields v. Zuccarini, 254 F.3d 476, 481 (3d Cir. 2001) (citing Rule 56(e)). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in

his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

The nonmoving party "must present more than just 'bare assertions, conclusory allegations or suspicions' to show the existence of a genuine issue." Podobnik v. U.S. Postal Serv., 409 F.3d 584, 594 (3d Cir. 2005) (quoting Celotex Corp., 477 U.S. at 325). Further, the nonmoving party is required to "point to concrete evidence in the record which supports each essential element of its case." Black Car Assistance Corp. v. New Jersey, 351 F. Supp. 2d 284, 286 (D.N.J. 2004). If the nonmoving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which . . . [it has] the burden of proof[,]" then the moving party is entitled to judgment as a matter of law. Celotex Corp., 477 U.S. at 322-23. Furthermore, in deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. The nonmoving party cannot defeat summary judgment simply by asserting that certain evidence submitted by the moving party is not credible. S.E.C. v. Antar, 44 F. App'x 548, 554 (3d Cir. 2002).

III. DISCUSSION

Fresenius raises eleven counts against Par, which can be grouped as follows: Antitrust claims under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2 (Counts One to Five); Antitrust claims under the New Jersey Antitrust Act, N.J. Stat. § 56:9-1 et seq. ("NJAA") (Counts Six to Ten); and a common law claim of tortious interference (Count Eleven). (D.E. 1 ¶¶ 146-237.) Fresenius moves for summary judgment on all counts except for certain antitrust counts (Counts Three, Five, Eight, and Ten). Par moves for summary judgment on all of Fresenius' claims.

The heart of Fresenius' claims is that Par, in violation of state and federal antitrust laws, delayed generic Vasopressin manufacturers' entrance into the market by entering into exclusive agreements with the only three API suppliers with DMFs, foreclosing generic manufacturers' access to them. (See D.E. 164 at 1-2.) Because causation is a necessary element to all of Fresenius' claims, this Court turns first to whether Fresenius can show that Par's conduct caused its alleged injury.[6]

Antitrust Injury and Causation

"In order to maintain an antitrust suit, a plaintiff must establish antitrust standing," which requires a plaintiff show it "suffered an antitrust injury." In re Wellbutrin XL Antitrust Litig. ("Wellbutrin"), 868 F.3d 132, 163-64 (3d Cir. 2017). To establish antitrust injury, a plaintiff must show a "causal connection between the purportedly unlawful conduct and the injury." City of Pittsburgh v. W. Penn. Power Co., 147 F.3d 256, 265 (3d Cir. 1998). Where the alleged antitrust injury stems from delayed market entry, a patent may "break the chain of causation" if it independently "would have prevented market entry." Wellbutrin, 868 F.3d at 165.

Fresenius argues that Par's patents do not break the chain of causation because, but for Par's alleged anticompetitive conduct, Fresenius would have filed the But For ANDA around July 2016, challenged Par's patents in court or via inter partes review ("IPR"), won this challenge on the basis of invalidity or non-infringement, gained regulatory approval, and then launched its product around June 2018. (See D.E. 180 at 44-46.) Thus, in this alternative world, Par's patents would not have delayed Fresenius' market entry.

[6] Without causation, there is no antitrust injury, which is necessary for antitrust claims. See In re Wellbutrin XL Antitrust Litig., 868 F.3d 132, 163-64 (3d Cir. 2017); ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 269 (3d Cir. 2012) (noting both Sherman Act Sections 1 and 2 require showing antitrust injury); see also N.J. Stat. § 56:9-18 (noting NJAA claims run parallel to federal antitrust claims). Causation is also required for the tortious interference claim. Kern v. Med. Protective Co., Inc., Civ. No. 13-02286, 2018 WL 4502187, at *10 (D.N.J. Sept. 20, 2018).

Evaluating this argument would require a jury, amidst an antitrust trial, to predict what the resolution of these hypothetical patent challenges would have been. This task, however, would be unduly speculative and procedurally burdensome. First, there was never an actual patent challenge and, thus, no concrete basis to determine what a hypothetical adjudicator would have found at each stage of such action. Second, Fresenius never submitted the ANDA outlining the Vasopressin product it would have created ("Hypothetical Product"), therefore, evaluating a hypothetical infringement action based on that product is even more speculative.

A. No Underlying Litigation or Challenge to the Patents

Fresenius argues it would have overcome Par's patents by showing: 1) non-infringement or invalidity in federal court; or 2) invalidity via IPR. (D.E. 232 at 30:3-7.) Though no litigation or IPR was ever initiated, Fresenius argues a jury may rely on expert testimony opining that such challenges would have been initiated and that Fresenius would be more likely than not to win them. (D.E. 180 at 39-40.) Here, however, evaluating what would have happened in a purely hypothetical, complex patent proceeding would require too much speculation, particularly when patents are presumed valid. See W. Penn. Power Co., 147 F.3d at 267-68 (finding predicting regulatory body's decision too speculative to establish causation in an antitrust action when there was a lack of supporting facts); see also In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003) (noting patent litigations are "inherently uncertain"); 35 U.S.C. § 282(a).

Litigation in Federal Court

First, Fresenius asks this Court, and ultimately a jury, to determine how a hypothetical court in a hypothetical patent litigation would have ruled on any substantive rulings such as claim construction or summary judgment, and how the Federal Circuit would have ruled on any

final decision. See In re Androgel Antitrust Litig. (No. II) ("Androgel"), Civ. No. 09-955, 2018 WL 2984873 at *12-13 (N.D. Ga. June 14, 2018).[7] However, without any concrete decisions in the underlying patent action to guide a jury in this action, "determining the ultimate outcome of the underlying patent litigation is fundamentally unknowable and procedurally impossible." Id. at *12. Expert testimony attempting to do so is "coming up with probabilities out of whole cloth" and "would be far too speculative to aid a jury in making a reasoned decision." Id. at *12-14. The speculative nature of this inquiry is especially apparent here, where the litigation in question never even started. See id. at *3, 13-14 (finding it too speculative to determine what the result of an actually initiated, underlying patent litigation which had settled, would have been).

Fresenius argues that not resolving the underlying patent litigation would "provide a get-out-of-jail-free card for anticompetitive conduct" which "prevents the ANDA filing that would trigger the patent suit." (D.E. 180 at 43.) This argument is undermined by the facts of this case. First, Fresenius did not need an ANDA to challenge Par's patents—it could have done so via IPR, despite Par's conduct, and did not. (D.E. 152-42 ¶¶ 177, 179, 190; D.E. 185-1 ¶¶ 814-15); 35 U.S.C. §§ 311. Second, Dr. Mahl reported that at the December Meeting, BCN informed him that Fresenius "could get Par out of [the BCN] deal, in case [Fresenius] would be willing to submit short-term a convincing, competitive offer," and wrote, "I guess we are not pursuing this further." (D.E. 170-14.) Fresenius' unwillingness to bid even when explicitly invited to do so undermines its stance that Par prevented Fresenius' "ANDA filing that would trigger the patent suit." (See D.E. 153-1 ¶ 242.)[8]

[7] Assumptions would also have to be made regarding procedural decisions. For example, if the underlying trial is assumed to be a bench trial, a jury would step into a hypothetical judge's shoes. See Androgel, 2018 WL 2984873 at *13 (noting "this means that to survive summary judgment, [plaintiffs] would have to provide enough evidence to show that a reasonable jury could find it more likely than not that a judge would have found it more likely than not that the Generics did not infringe or that the [ ] patent was invalid").

[8] Dr. Mahl at his deposition asserted that Fresenius was unwilling "to get into a bidding war" because this invitation to bid was "a little bit of [a] rhetoric[al] offer" and any bid would have been futile. (D.E. 167-9 at 201:9-202:14.)

Patent Invalidity via IPR

Predicting the outcome of an IPR action would be similarly speculative. A jury would first have to consider whether Fresenius would have actually filed an IPR, if it had been able to file an ANDA, and then determine what the hypothetical IPR would have looked like, what the Patent Trial and Appeal Board ("PTAB") would have decided, and how the Federal Circuit would have determined any appeal. Cf. Androgel, 2018 WL 2984873 at *12; see also St. Jude Med., Cardiology Div., Inc. v. Volcano Corp., 749 F.3d 1373, 1374-75 (Fed. Cir. 2014) (outlining procedures for IPR).[9]

B. No Underlying ANDA to Serve as a Basis for Non-Infringement Claims

As noted above, Fresenius did not file the But For ANDA, making consideration of any hypothetical infringement action even more speculative. When filing an ANDA is the predicate act to an infringement suit, as it would have been in the alternative world Fresenius proposes, that ANDA provides the basis for what a generic product will look like and generally governs the infringement inquiry. See 35 U.S.C. § 271(e)(2)(A); Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1373 (Fed. Cir. 2002). Without the ANDA, a factfinder would have to determine the

---

He additionally testified that he was unwilling to bid for "something which [Fresenius] believe[s] belongs already to [it]," and "[i]t's not in [Fresenius'] culture to do something like that," in part because BCN's action was "illegal, and therefore, no, no bidding war." (Id. at 201:25-202:7.) However, a month after the December Meeting, Fresenius informed BCN that it was "aware of ongoing discussions between BCN and Par, and [Fresenius] would be in position to recognize and respect any type of exclusive arrangements that may be in current dialogue," noting any future API purchases would be strictly for non-U.S. markets. (D.E. 170-15.) Dr. Mahl's testimony appears to go against the record and does not create a material dispute of fact. See Irving v. Chester Water Auth., 439 F. App'x 125, 127 (3d Cir. 2011) (noting that "self-serving deposition testimony is insufficient to raise a genuine issue of material fact" in light of contradictory evidence on the record).

[9] Had Fresenius filed an IPR, which it admits it could have, it likely would have received a PTAB decision on Par's first patent over a year ago. (D.E. 152-42 ¶ 190) (Fresenius' expert noting this decision would likely have been made by September 29, 2018). Fresenius argues that once it could not be the first ANDA filer (giving it certain exclusivity rights), it lacked the incentive to invalidate Par's patent for the "whole world." (D.E. 232 at 32:4-33:22.) However, Fresenius points to no contemporaneous evidence as to its reasoning for filing or not filing an IPR, only citing its patent law expert's opinion on what Fresenius would have done. (See D.E. 164 at 42 n. 19; D.E. 163 ¶ 445; D.E. 152-42 ¶¶ 182-83); see In re Gabapentin Patent Litig., Civ. No. 00-2931, 2011 WL 12516763, at *6–7 (D.N.J. Apr. 8, 2011) (barring a Hatch-Waxman Act expert from "testifying as to actions generic manufacturers would have taken in the 'but for' world"); see also Robertson v. Allied Signal, Inc., 914 F.2d 360, 382 n. 12 (3d Cir. 1990) (noting "inference based upon a speculation or conjecture does not create a material factual dispute sufficient to defeat entry of summary judgment").

Hypothetical Product's formulation, find that Fresenius would have used that formulation for that ANDA, and then use this Hypothetical Product to predict the hypothetical infringement suit's result. See Par Pharm., Inc. v. Luitpold Pharm., Inc., Civ. No. 16-02290, 2017 WL 452003, at *6 (D.N.J. Feb. 2, 2017) (rejecting the argument that the court should consider a product not specified in an ANDA "because it is premised on the mistaken belief that the Court can and should determine patent infringement by looking to drug formulations and ANDAs not yet in existence").

Fresenius argues its experts have provided the basis for how each of these steps would have looked like. Such analysis, however, would ask jurors to cut conclusions from "whole cloth," given the lack of an actual ANDA and all the data that would have been in that ANDA. Androgel, 2018 WL 2984873 at *12, 14. Namely, Fresenius' expert, Dr. Ralph Tarantino ("Dr. Tarantino") based his conclusions as to the formulation of the Hypothetical Product on Fresenius' stability batch records for samples created in September and October 2015. (D.E. 179 ¶ 635; D.E. 172-19 at 174:8-25, 192:11-18; D.E. 184-38 ¶¶ 4, 8.) In turn, Dr. Tarantino stated he did not review a draft ANDA, or other elements which would have been in the But For ANDA, such as the testing specifications for excipients; drug product specifications; quality overall summary of the product; clinical study reports; or documents on bioequivalences to the reference listed drug. (See D.E. 172-19 at 184:6-185:23, 188:25-191:23; see also D.E. 154-1 ¶ 406.)[10]

C. Wellbutrin and Reverse-Payment Settlement Cases

Fresenius argues that under Wellbutrin, this Court (and later, a jury) must consider what the result of an underlying patent litigation would have been, if doing so is necessary to resolving causation in an antitrust matter. (D.E. 180 at 40-41 (citing Wellbutrin, 868 F.3d at 164-167).) It

[10] Fresenius asserts its 2019 ANDA's formulation differs from what the But For ANDA's would have been, and it is thus not indicative of what the But For ANDA would have been. (D.E. 154-1 ¶ 449; D.E. 172-43 ¶ 185.)

may do this by considering evidence, in the form of expert testimony, "from which a reasonable jury could conclude that it is more likely than not" that Fresenius would have prevailed in a patent suit. (D.E. 180 at 39-40.)[11] Fresenius argues that it has provided such evidence, and thus survives summary judgment. (Id. at 44-46; see, e.g., D.E. 179 ¶¶ 657-63 (citing patent law expert John R. Thomas' Report, opining on the likelihood of succeeding in a patent action (D.E. 152-42 ¶¶ 103-160) and his Reply Report on the same (D.E. 183-82 ¶¶ 17-18, 76-102), both relying on Dr. Tarantino's analysis (D.E. 183-41)).)

Wellbutrin, however, critically differs from the instant matter. Unlike here, in Wellbutrin, (1) underlying patent actions actually existed and were litigated past the early stages; and (2) an ANDA underlying the patent challenge had been filed. 868 F.3d at 145-46; In re Wellbutrin XL Antitrust Litig., 133 F.Supp.3d 734, 766-67 (E.D.Pa. 2015) aff'd sub nom. Wellbutrin, 868 F.3d 132 (noting one underlying litigation had claim construction and summary judgment orders; in the other, the expert considered underlying litigation's "briefs, pleadings, [and the] ANDA" in opining on the likelihood of infringement); see also Androgel, 2018 WL 2984873 at *14 (noting importance of concrete decisions in underlying litigation for this inquiry).[12] Wellbutrin's alternative world was much more concrete than the alternative world

[11] Wellbutrin related to whether patent litigation-ending "reverse-payment" settlements between patentee and potentially patent-infringing generic manufacturers delayed the release of generic drugs in violation of antitrust laws. 868 F.3d at 142. There, defendant's expert opined that, had the underlying litigation not settled, there was an 80% chance the patent would be found infringed. Id. at 169. Because the expert was unrebutted, at summary judgment, the court found that "no reasonable jury could conclude that [the infringer] would have been more likely than not to prevail." Id. Thus, the court found the patent would have blocked generic entry, and so the settlements did not cause plaintiff's (consumers of the drug) injury (delayed entry of the drug). Id. at 169-70.

[12] Other cases in which a court considered the underlying patent litigation are similarly distinguishable. See United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, 296 F.Supp.3d 1142, 1156 (N.D.Cal. 2017) (ANDA filed and patent suit went to trial prior to settling); In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 42-43 (1st Cir. 2016) (ANDA filed and patent suits lasting years prior to settling); In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 191, 201 (S.D.N.Y. 2018) (ANDA filed and patent suit had a Markman ruling); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., Civ. No. 14-02503, 2018 WL 563144, at *3 (D. Mass. Jan. 25, 2018) (ANDA filed and underlying patent suit initiated and settled); In re Loestrin 24 Fe Antitrust Litig., Civ. No. 13-2472, 2019 WL 7286764, at *1, 25-27 (D.R.I. Dec. 17, 2019) (ANDA filed and underlying patent litigation suit initiated and settled).

Fresenius proposes considering here, allowing experts a less speculative basis for their opinions.[13]

In short, in the instant matter, there was never an underlying patent challenge or an underlying ANDA from which a jury could make a reasoned decision on how such hypothetical patent action on invalidity or infringement would have been resolved. Without a more concrete basis, expert evidence on how such action would have been resolved would be unduly speculative, and does not create a genuine issue of material fact. Therefore, Par's patents cut off the chain of causation, barring Fresenius' claims. As Fresenius has not established causation or an antitrust injury, no further analysis is required.

IV. CONCLUSION

For the reasons set forth above, Plaintiff's motion is **DENIED**, and Defendants' motion is **GRANTED**. An appropriate Order follows.

s/ Susan D. Wigenton
SUSAN D. WIGENTON
UNITED STATES DISTRICT JUDGE

Orig: Clerk
cc: Leda Dunn Wettre, U.S.M.J.
Parties

[13] At oral argument, Fresenius pointed out that Wellbutrin found a patent challenger would have lost its challenge as to the invalidity of the patent, relying on an argument that "hadn't even been raised in that underlying [patent litigation's] body of work." (D.E. 232 at 40:4-41:17); 868 F.3d at 169, 169 n. 63. This challenge, however, did not require speculation on the merits of the invalidity claim. 868 F.3d at 169. Instead, the court found a patent challenger would have been barred from arguing the patent was invalid due to the doctrine of assignor estoppel. Id.