UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

METACEL PHARMACEUTICALS LLC, Plaintiff/Counterclaim Defendant, v. **RUBICON RESEARCH PRIVATE LIMITED**, Defendant/Counterclaimant.	Civil Action No. 21-cv-19463-EP-JRA **OPINION AND ORDER OF SPECIAL DISCOVERY MASTER**

LINARES, J.

This matter comes before the Special Discovery Master by way of a motion filed by Rubicon Research Private Limited ("Rubicon") for an Order to apply the crime/fraud exception to documents that are being withheld on the basis of attorney client privilege by Metacel Pharmaceuticals, LLC ("Metacel"). Metacel filed opposition and Rubicon filed a reply. Argument was held before the Special Discovery Master on June 9, 2026. For the reasons set forth below, Defendants' Motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

The Special Discovery Master presumes the parties' familiarity with the facts surrounding the underlying action and claims. Accordingly, the Special Discovery Master will only recite the relevant procedural and factual background necessary to dispose of the dispute at hand.

This action relates to the submission of Abbreviated New Drug Application ("ANDA") No. 214445 by Rubicon to the FDA, seeking approval for a generic version of Metacel's Ozobax brand product (5mg/5mL) prior to the expiration of Metacel's method patent (U.

S. Patent No. 10, 610,502 ("the '502 Patent"). Metacel timely brought suit under 35 U.S.C. § 271(e)(2)(A) pursuant to the Hatch-Waxman Act, alleging that the product described in Rubicon's ANDA would infringe the '502 patent, which triggered a 30-month stay on any approval of the Generic so long as the patent litigation remains. See, generally, ECF 137, Opinion dated 7/07/23.[1]

Metacel's Ozobax product requires storage "at from about 2 to about 8°C" (the "Fridge Limitation"). Id at 2. Metacel alleged that Rubicon's proposed container labeling and package insert (collectively, Rubicon's "proposed labeling") would induce downstream users, such as physicians, pharmacists, and patients, to store Rubicon's ANDA product at a temperature from about 2° to 8°C, as claimed. Rubicon contended that, because its proposed labeling instructed room temperature storage, and only optionally mentioned refrigeration, its labeling could not induce infringement of claim 1 as a matter of law.

Summary Judgment granted in favor of Rubicon

The District Court granted Rubicon's motion for summary judgment by Opinion filed 7/07/23, holding that because the '502 Patent requires refrigeration and Defendant's Generic does not, the Generic will not induce infringement. Id., at 2. Rubicon's motion, and the Court's decision, hinged solely upon the Fridge Limitation. Id., at 4, ftnt 6.

In rejecting Metacel's argument that the Court should look to Rubicon's Storage Statement, which instructs storage at 2 to 8 degrees Celsius, or other nonpublic statements to the FDA, the Court held that nothing in the record suggests that the downstream user will ever see the Storage Statement's refrigeration requirement. Id. at 7. The District Court explained:

> The label is what matters, because that is what the downstream users—either a healthcare practitioner or patient—will rely upon. *See HZNP Meds.*, 940 F.3d at 701-02 (reviewing ANDA

[1] The District Court's 7/7/23 Opinion, which granted Rubicon's motion for summary judgment, sets forth the Background of Metacel's '502 Patent and Rubicon's Generic.

> label in relation to the asserted claims of the methods-of-use patents to evaluate infringement). And "[m]erely describing the infringing use, *or knowing of the possibility* of infringement, will not suffice; specific intent and action to induce infringement must be shown." *Takeda Pharms.*, 785 F.3d at 631 (emphasis added). Indeed, even where the label itself describes an infringing use "as an option," but still did not "encourage infringement" or require a claimed step, there is no basis to find infringement. *HZNP Meds.*, 940 F.3d at 702 (no infringement where the label "merely permits applying a second topical agent after the patient waits for the diclofenac sodium to dry"); *see also Grunenthal GmbH v. Alkem Labs Ltd.*, 919 F.3d 1333, 1339-40 (Fed. Cir. 2019) (affirming no inducement where label terminology included but did "not specifically encourage" infringing application); *cf. BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 398 (D.N.J. 2018) ("The only way to follow these labels is to administer abiraterone, together with prednisone, in specified doses, to a mCRPC patient.").

Id., at 7. Rubicon's ANDA label instructs storage at 20 to 25 degrees Celsius with optional refrigeration, i.e., storage at 2 to 8 degrees Celsius. The Court found that because downstream users will read and follow the label, and not the ANDA paperwork, infringement will not occur as a matter of law. Id. at 8.

Metacel filed a Motion for Reconsideration, which the District Court denied by Memorandum Order dated August 31, 2023. Metacel then filed an appeal with the United States Court of Appeals for the Federal Circuit, which affirmed the District Court's decision. See, Zapadka Declaration, Exhibit 22. In a decision dated April 23, 2025, the Federal Circuit held that the "district court properly granted summary judgment of no induced infringement because there is no genuine dispute that Rubicon's proposed ANDA label clearly instructs room temperature storage while only optionally permitting refrigeration." Id. at p. 6.

Counterclaim

Rubicon filed a Counterclaim alleging that Metacel's use of Hatch-Waxman Act litigation is for an improper anti-competitive purpose in violation of U.S. Antitrust Laws and as such is

actionable as sham litigation. Rubicon asserts that Metacel's lawsuit is objectively baseless and maintained in bad faith or for an improper purpose. Rubicon argues that no reasonable litigant could realistically expect to succeed in asserting infringement of the '502 patent against Rubicon's ANDA product, and that Metacel knew that its suit was objectively baseless at least from the time it received Rubicon's ANDA. But for this anticompetitive conduct, Rubicon would have been permitted entry into the relevant market as of March 13, 2023 (the date it received tentative approval). Rubicon asserts that without this baseless litigation, Rubicon's room temperature stable product would have been on the market 7 months before Metacel's product, but because of the baseless litigation, Metacel's product beat Rubicon's product to the market by 14 months. Rubicon alleges that Metacel knew of this, planned it from the beginning and maintained the litigation for this purpose.

II. CURRENT DISCOVERY DISPUTE

Metacel has objected to the production of certain discovery on the grounds of attorney-client privilege and work-product doctrine. Rubicon counters that neither the attorney-client privilege nor the work-product doctrine apply due to the crime-fraud exception, arguing that sham litigation may qualify as a type of fraud or wrongdoing that may support application of the crime-fraud exception.

Rubicon requests that the Special Master issue an Order for the following relief:

1. Full production of responsive documents to Requests for Production 64, 65, 66, 67, 68, 70, 71, 72, 73, 81, and 92 without objection or redactions on the basis of attorney-client privilege or the work product doctrine;

2. Removal of privilege redactions to its productions to date;

3. Following completion of items 1 and 2 above, depositions will be taken of the noticed individuals and the noticed 30(b)(6) deposition of Metacel without objections on the basis of attorney client communication or the work product doctrine, specifically including 30(b)(6) topics 1 – 12, and 19.

Metacel produced an initial privilege log on January 7, 2026, containing 31 entries, from the time period beginning June 2022, and only pertains to Metacel's regulatory submissions. Kratz Cert., Exhibit 23. Metacel then supplemented its log to include 63 entries. Kratz Cert., Ex. 19. Neither log includes any of the communications between Metacel and its internal or outside counsel regarding the underlying Hatch-Waxman litigation, which is the basis for Rubicon's sham litigation allegation.

Rubicon's position:

Rubicon asserts that during the course of written discovery on the counterclaim, Rubicon specifically requested communications between Metacel and its attorneys regarding various topics related to the filing and maintenance of the underlying Hatch-Waxman case, the merits of the underlying case, Metacel's knowledge of the 30-month stay, and certain other activities taken by Metacel which would demonstrate Metacel's bad faith.

Rubicon points to three documents as evidence that Metacel sought enforcement of its patent in this litigation for an anticompetitive purpose:

(i) Kratz Decl. Exhibit 16: internal emails in September 2021 discussing the potential risk that a generic could file and start a 30-month clock

(ii) Kratz Decl. Exhibit 17: internal emails in September 2021 discussing that the faster Metacel can convert to market the second iteration of Ozobax DS(double strength 10 mg/5 ml) the sooner it can weaken the foundation for any generic intrusion

(iii) Kratz Decl. Exhibit 18: monthly charts measuring how long for the court to rule on Rubicon's motion for summary judgment before the 30-month stay ends against how long it would take to get approval of DS product

Rubicon asserts Metacel continued this litigation despite it being objectively baseless in order to frustrate Rubicon's approval for long enough that it could get its new formulation on the market. Ultimately, Metacel obtained approval of its own new formulation on October 12, 2023 and delayed Rubicon's final approval until December 6, 2024, the so-called product hop.

Rubicon relies heavily on the interim expert report of Kurt Kartz, Esq. ("Kartz Report"). Metacel objects to the submission of the Kartz Report on this motion, arguing that it is "unauthorized" and procedurally improper at this stage of the case. Because this Report reads more like a legal brief, the Special Master will give it no more weight than would be given to arguments made by Rubicon's counsel in its brief. The Kartz Report, consistent with the arguments in Rubicon's legal brief, opines that no reasonable litigant could reasonably expect success on the merits with respect to the "Fridge Limitation," which is an essential element of the asserted claims of the '502 patent. Kartz further opines that Metacel's real motive and underlying goal was to delay generic OZOBAX competition so that Metacel could achieve a "product hop" from its limited refrigerated formulation to its own room temperature stable baclofen product, OZOBAX DS, thereby improperly frustrating fair competition.

Metacel response

Metacel argues that Rubicon hasn't made a prima facie case that the crime/fraud exception applies here. Under Third Circuit law, Rubicon must (1) make a *prima facie* showing that Metacel's suit was objectively baseless—meaning "no reasonable litigant could realistically expect success on the merits"; (2) it must demonstrate that Metacel's subjective motivation was not to

succeed on the merits but to use the governmental process itself as an anticompetitive weapon; and (3) it must tie specific attorney-client communications to the "furtherance" of that scheme. In re Abbott Laboratories, 96 F.4th 371, 379-380 (3rd Cir. 2024). Metacel argues Rubicon has not satisfied any of these requirements.

As to the three documents Rubicon points to as evidence that Metacel sought enforcement of its patent in this litigation for an anticompetitive purpose, Metacel argues these communications are run-of-the-mill discussions likely to be held at branded and generic companies on a frequent basis, merely recognizing generic competition in the market, understanding of the relevant Hatch-Waxman framework, and the impact on sales or business strategy.

Metacel also argues that Rubicon overstates In re Abbott Labs., 96 F.4th 371 (3rd Cir. 2024) and that simply alleging a "sham litigation" does not automatically trigger the crime-fraud exception. It further states, correctly, that losing a summary judgment motion does not equate to an objectively baseless legal position.

Metacel argues, as it did in opposition to Rubicon's summary judgment motion, that cases such as *Vanda Pharmaceuticals Inc v. West-Ward Pharmaceuticals Internation Ltd*., 87 F.3d 1117 (Fed Cir. 2018), *Glaxosmithkline LLC v. Teva Pharms. USA, Inc.,* 7 F.4th 1320 (Fed. Cir. 2021), and *AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042 (Fed. Cir. 2010), recognize that inducement can be shown by looking at the *totality* of what the generic communicates to prescribers and pharmacists, including label instructions as understood in real world context, rather than reading isolated label phrases in a vacuum. In support of its position that summary judgment should not be granted and that there were material issues in dispute, Metacel proffered an expert opinion from a pharmacist who explained that he had "never seen a drug label that explicitly lists 'opposite' storage conditions as Rubicon's label does," that pharmacy-practice standards and American

Society of Health-System Pharmacists (ASHP) guidance instruct pharmacists to look to the RLD label when determining storage, and that, faced with Rubicon's dual-storage label, he would "store Rubicon's Product consistent with the RLD's storage instructions, or simply default to refrigeration storage due to the benefits. Metacel relies on this argument in this pending discovery motion as evidence that this lawsuit is not objectively baseless.

III. ANALYSIS

The crime-fraud exception allows piercing the attorney-client privilege where the proponent makes a prima facie showing that (1) the client was engaged in or planning criminal or fraudulent activity when the attorney-client communications were made and (2) the communications were in furtherance of that activity. Abbott, 96 F.4th at 379. The Third Circuit in Abbott recognized that sham litigation may qualify as a type of fraud or wrongdoing that may support application of the crime-fraud exception.

Metacel is correct that simply alleging "sham litigation" does not automatically trigger the crime-fraud exception and pierce the privilege. Rather, only where the proponent has already made a *prima facie* showing that the underlying suit was objectively baseless and pursued for an improper purpose, and then ties particular attorney communications to the furtherance of that scheme, does the exception apply. In re Abbott Labs., 96 F.4th at 371-377 (3rd Cir. 2024); see King Drug Co. of Florence, Inc. v. Abbott Labs., 2023 WL 2646926, 2023 U.S. Dist. LEXIS 51230, at *15 and 19 (E.D. Pa. Mar. 27, 2023) ("Merely making a charge of fraud is not enough to trigger court review.") Even then, the Court does not order a blanket production of all documents asserted to be privileged, as Rubicon urges the court to do here. Instead, the Court will conduct an in camera review to assess whether particular attorney communications further an already-established scheme. In re Abbott Labs, 96 F.4th at 377-82.

Before a court undertakes an *in camera* review to determine whether the exception applies, "the party opposing the privilege . . . must present evidence sufficient to support a reasonable belief that in camera review may yield evidence that establishes the exception's applicability." U.S. v. Zolin, 491 U.S. 554, 574-75 (1989). The decision of the court to review documents is a minimal intrusion into the attorney-client privilege and work product doctrine. The standard for undertaking such a review is much more lenient than for a finding that the privilege no longer applies. Id. at 572.

Abbott and King Drug establish a two-step framework for piercing the privilege. First, the proponent must make a prima facie showing of "sham litigation" meaning that the proponent must show that the underlying suit was both (1) objectively baseless—i.e., "no reasonable litigant could realistically expect success on the merits"—and (2) the litigant's subjective motivation for filing the objectively baseless lawsuit was something besides success on the merits. King Drug, 2023 U.S. Dist. LEXIS, at *6; In re Abbott Labs., 96 F.4th 371, 379 (3rd Cir. 2024). A motive to delay a party's entry into the market is an example of a motivation to assert a patent in good faith. Id., at *6, citing FTC v. AbbVie, Inc., 976 F.3d 327 (3rd. Cir. 2020).

Abbott confirms that in-camera review is appropriate only after a prima facie showing of objective baselessness and improper purpose. A *prima facie* showing does not mean that Rubicon will ultimately prevail on the merits of its counterclaim at trial. Rather, it means that, on the face of it, there is sufficient evidence to support a claim. As the court in King Drug explained: "where there is a reasonable basis to suspect the privilege holder was committing or intending to commit a crime or fraud [here, sham litigation] and that the attorney-client communications were used in further of the alleged [sham litigation], this is enough to break the privilege. Id. at *19, quoting In re Grand Jury, 705 F.3d 133, 153 (3rd Cir. 2012).

Here, there is sufficient evidence to support a reasonable belief that in camera review may yield evidence that establishes the exception's applicability – that is, that the underlying suit was objectively baseless — i.e., "no reasonable litigant could realistically expect success on the merits" — and that the subjective motivation for filing the lawsuit was something besides success on the merits.

As the District Court held and the Federal Circuit affirmed: "**The label is what matters**, because that is what the downstream users—either a healthcare practitioner or patient—will rely upon." *See HZNP Meds. LLC v. Actavis Labs, UT, Inc.*, 940 F.3d 680 at 701-02 (Fed. Cir. 2019). Rubicon's label clearly provided for storage at room temperature, with refrigeration optional. Where a label describes an infringing use "as an option," without a specific intent and action to induce infringement, there is no basis to find infringement. *HZNP Meds.*, 940 F.3d at 702. When asked during argument to point to the evidence that is public information that would lead Metacel to believe that it had a successful case of infringement, counsel pointed to the fact that the branded product was refrigerated and that its own expert opined that Rubicon's label was vague. Based on this record, there is a paucity of any other evidence to defeat a finding that a prima facie case has been made that the underlying lawsuit was objectively baseless.

In addition, there is sufficient evidence, in the internal email discussions described above, to support a claim that Metacel's motive and underlying goal was to delay generic competition so that Metacel could achieve a "product hop" from its limited refrigerated formulation to its own room temperature stable product, thereby improperly frustrating fair competition. As the Court in King Drug explained, a subjective motive to delay a party's entry into the market is an example of a motivation to assert a patent in good faith. Id., at *6, citing FTC v. AbbVie, Inc., 976 F.3d 327 (3rd. Cir. 2020).

Accordingly, the Special Master finds that there has been a prima facie showing that the crime/fraud exception (here, sham litigation) applies and that an in camera review is appropriate to determine whether attorney-client communications were used in furtherance of the alleged sham litigation and ought to be produced.

Again, this does not mean that Rubicon will prevail on the merits of its sham litigation counterclaim at trial. This also does not mean that Metacel must simply produce all privileged documents. Rather, Metacel must first supplement its privilege log to include all documents it claims are privileged, including communications with regulatory and litigation counsel on the underlying lawsuit. Once the number of items on the privilege log is established, the Special Master shall determine how many entries Rubicon may designate for in camera review. Metacel will have the opportunity to provide additional information and context, in camera, on the documents that are selected by Rubicon for review. The Special Master shall then determine, after an in camera review, whether any of those documents should be produced.

IV. ORDER

IT IS on this 29th day of June, 2026,

ORDERED that Rubicon's Motion is granted in part and denied in part; and it is

FURTHER ORDERED that Metacel must supplement its privilege log to include all documents it claims are privileged, including communications with regulatory and litigation counsel on the underlying lawsuit by July 14; and it is further

ORDERED that following production of the supplemental privilege log, Rubicon shall designate specific entries, in an amount to be determined by the Special Master, to be reviewed in camera by the Special Master; and it is further

ORDERED that Metacel shall produce those documents to the Special Master for in camera review and may submit additional information, ex parte, on the designated entries, for consideration by the Special Master during the in camera review.

SO ORDERED.

/s/ *Jose L. Linares*

Hon. Jose L. Linares, U.S.D.J. (Ret.)