**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| EXELIXIS, INC. | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | Civil Action No. 19-2017-RGA-SRF |
| | ) | (Consolidated) |
| MSN LABORATORIES PRIVATE LIMITED and | ) | |
| MSN PHARMACEUTICALS INC., | ) | |
| | ) | |
| Defendants. | ) | |

**MEMORANDUM OPINION**[1]

Presently before the court in this patent infringement action is the motion to exclude the obviousness opinions of Jonathan Steed and Salvatore Lepore filed by plaintiff Exelixis, Inc. ("Plaintiff").[2] (D.I. 257) For the following reasons, Plaintiff's motion is GRANTED-IN-PART. Specifically, the motion to exclude is GRANTED with respect to portions of Dr. Lepore's obviousness opinion that rely on the inventors' internal documents and testimony. The motion is DENIED in all other respects.

## I. BACKGROUND

In October 2019 and May 2020, Plaintiff brought these consolidated Hatch-Waxman suits against defendants MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (together, "Defendants") for alleged infringement of U.S. Patent Nos. 7,579,473 ("the '473 patent"), 8,497,284 ("the '284 patent"), and 8,877,776 ("the '776 patent;" collectively, the "patents-in-

[1] A *Daubert* motion to exclude testimony presents a non-dispositive matter, and a magistrate judge's ruling on a non-dispositive motion is subject to the "clearly erroneous and contrary to law" standard of review under 28 U.S.C. § 636(b)(1)(A) and Fed. R. Civ. P. 72(a). *See Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 388 (D. Del. 2014).

[2] The briefing and filings related to Plaintiff's pending motion are found at D.I. 258, D.I. 259, D.I. 263, and D.I. 265.

suit") based on Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 213878 to the Food and Drug Administration ("FDA") for approval to make and sell a generic version of Cabometyx®. (D.I. 1; C.A. No. 20-633-RGA, D.I. 1) Cabometyx® is a tyrosine kinase inhibitor used to treat patients with kidney and liver cancer. (D.I. 1) The active chemical compound in Cabometyx® is called cabozantinib, and the asserted claims of the '776 patent cover a particular crystalline form of cabozantinib called the N-2 form. (*Id.* at ¶ 18) The asserted claims of the '473 patent cover compounds for modulating or inhibiting kinase activity, with a particular focus on the modulation of c-Met tyrosine kinase, and the '284 patent claims a method of treating cancers with a therapeutically effective amount of the compounds.[3] (C.A. No. 20-633-RGA, D.I. 1, Exs. A-B)

Dr. Salvatore Lepore and Dr. Jonathan Steed issued their opening expert reports in October 2021, and they were deposed in March 2022 regarding their opinions on the invalidity of the patents-in-suit. (D.I. 259, Exs. A, D, E, I) The opinions proffered by Drs. Lepore and Steed are the subject of Plaintiff's pending motion to exclude. (D.I. 257) Defendants have since agreed to withdraw their validity challenges to the '284 and '776 patents. (D.I. 270 at ¶ 5) Because Dr. Steed's obviousness opinion was limited to discussion of the '776 patent, Plaintiff's challenge to Dr. Steed's opinion is moot. (D.I. 269 at 4)

In his opening expert report, Dr. Lepore opined that the asserted claims of the '473 patent are invalid as obvious in view of the prior art. (D.I. 259, Ex. A; D.I. 263, Ex. C) Specifically,

[3] The '473 and '284 patents define c-Met as a kinase that is "the prototypic member of a subfamily of heterodimeric receptor tyrosine kinases (RTKs)," which is expressed "in a wide variety of cell types including epithelial, endothelial and mesenchymal cells where activation of the receptor induces cell migration, invasion, proliferation and other biological activities associated with 'invasive cell growth.' As such, signal transduction through c-Met receptor activation is responsible for many of the characteristics of tumor cells." ('284 patent, col. 2:53-62)

Dr. Lepore opined that the prior art would have motivated a person of ordinary skill to select Example 5 from WO 03/000660 (the "Kirin Publication") as a lead compound and modify it to prepare cabozantinib, with a reasonable expectation of success in obtaining a c-Met tyrosine kinase inhibitor. (D.I. 259, Ex. A at 2)

A bench trial is currently scheduled to begin on May 16, 2022. (D.I. 46 at 11) Fact discovery closed in September 2021 and expert discovery concluded in March 2022. (D.I. 46 at 2; D.I. 234) The 30-month stay expires on November 5, 2022. (C.A. No. 20-633-RGA, D.I. 3)

## II. LEGAL STANDARD

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The trial court has the "task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 594, 597 (1993).

The Third Circuit has explained:

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that "a broad range of knowledge, skills, and training qualify an expert." Secondly, the testimony must be reliable; it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation;' the expert must have 'good grounds' for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In

> other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."
>
> By means of a so-called "*Daubert* hearing," the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury.

*Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404-05 (3d Cir. 2003) (footnote and internal citations omitted).[4] "But the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court." *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. Consistent with "a strong preference for admitting any evidence that may assist the trier of fact" under the Federal Rules of Evidence, "Rule 702 . . . has a liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (internal citations and quotation marks omitted). Nonetheless, the party offering expert testimony bears the burden of showing that it meets the standards for admissibility. *Id.*

## III. ANALYSIS

For the reasons set forth below, Plaintiff's motion to exclude the obviousness opinions of Dr. Lepore is granted-in-part. Guiding the court's analysis is the overarching principle that "[i]t is simply less critical to pre-screen expert testimony in the bench trial setting, since the court can simply disregard expert evidence that it regards as unreliable, irrelevant, or unhelpful." *APEX*

[4] The Court of Appeals wrote under an earlier version of Rule 702, but the subsequent amendments to it were not intended to make any substantive change.

*Fin. Options, LLC v. Gilbertson*, C.A. No. 19-46-WCB-SRF, 2022 WL 613347, at *3 (D. Del. Mar. 1, 2022).

**A. Identification of Specific Prior Art Combinations**

Plaintiff challenges the reliability of Dr. Lepore's expert opinions on obviousness, arguing that he applied a flawed methodology due to his failure to identify specific prior art combinations. (D.I. 258 at 1, 5-8) As a result, Plaintiff contends that its rebuttal experts have been left to guess from among the millions of possible obviousness combinations in preparing their own opinions and testimony. (*Id.* at 10) To cure this prejudice, Plaintiff asks the court to exclude Dr. Lepore's obviousness opinion and preclude him from offering testimony at trial regarding specific prior art combinations that were not addressed in the expert report.[5] (*Id.* at 10-11)

Defendants respond that Dr. Lepore properly based his obviousness opinion on the related teachings of multiple specific prior art references, and a person of ordinary skill in the art would be familiar with the relevant, publicly available prior art. (D.I. 263 at 7-12) Defendants suggest that the level of detail in the rebuttal report of Plaintiff's expert is a testament to the fact that Dr. Lepore's obviousness opinion was clearly disclosed and readily understood. (*Id.* at 8-12)

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[5] Defendants confirm that "neither Dr. Lepore nor Dr. Steed will present at trial any opinions that were not disclosed in their reports (thus mooting Exelixis' request to preclude them from providing testimony 'not discussed in their expert reports.')." (D.I. 263 at 7) Therefore, the court denies Plaintiff's motion to preclude Dr. Lepore from offering testimony at trial regarding specific combinations not discussed in their reports as unduly speculative. Plaintiff also submits that the obviousness opinions of Dr. Anthony Mega should be excluded, to the extent that those opinions are based on Dr. Lepore's obviousness analysis. (D.I. 258 at 7) Having determined that Dr. Lepore's obviousness opinion should not be excluded for his alleged failure to identify specific prior art combinations, the court concludes that no basis exists to exclude the portions of Dr. Mega's obviousness opinion that rely on Dr. Lepore's opinion. (D.I. 259, Ex. B at ¶¶ 187-94)

"The reliability of an expert's conclusions and opinions hinges on the reliability of the expert's methodology." *Wood v. Showers*, 822 F. App'x 122, 124 (3d Cir. 2020). Here, Defendants have adequately established the reliability of Dr. Lepore's methodology. Although his identification of prior art references opens the door to many possible permutations,[6] Plaintiff has not shown that this methodology is unacceptable under Rule 702. Indeed, the Supreme Court has "set forth an expansive and flexible approach" to the obviousness inquiry in recognition of the fact that "it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the . . . community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401, 415 (2007).

In his opening expert report, Dr. Lepore opined that the cabozantinib element of the '473 patent would have been obvious in view of the Kirin Publication as the lead compound in combination with one or more references from three categories of specific prior art references. (D.I. 263, Ex. C at ¶ 204; *see also* D.I. 259, Ex. E at 11:18-13:2) The three categories of prior art references address: (1) c-Met's role in various cancers; (2) prior art related to selecting a lead compound; and (3) prior art related to modifying the lead compound. (*Id.*) Dr. Lepore's approach is consistent with Federal Circuit authority stating that "a prima facie case of

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[6] Generally, parties address concerns about the number of asserted prior art references and combinations through case narrowing proposals made earlier in the case. *See, e.g.*, *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, 918 F. Supp. 2d 277, 285-86 (D. Del. 2013) (citing cases). In this case, Defendants served their initial invalidity contentions in the summer of 2020 and served amended invalidity contentions in September 2021. (D.I. 37; D.I. 53, D.I. 196; D.I. 197) Defendants represent that the combinations disclosed in Dr. Lepore's expert report were previously disclosed in their amended invalidity contentions, and Plaintiff does not refute Defendants' representation. (D.I. 263 at 5; D.I. 265) There is no indication on the present record that Plaintiff sought to limit the number of asserted prior art references and/or combinations prior to filing the pending motion.

obviousness for a chemical compound . . . begins with the reasoned identification of a lead compound" in the prior art. *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008). After identifying the lead compound and the basis for its selection, Dr. Lepore's opening expert report addresses a category of prior art related to modifying the lead compound in keeping with Federal Circuit precedent, which provides that "the requisite motivation [to modify] can come from any number of sources." (D.I. 263, Ex. C at ¶ 204); *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 995 (Fed. Cir. 2009) (quoting *Eisai*, 533 F.3d at 1357). To this end, the motivation to modify a lead compound can be derived from "the totality of the prior art" and "need not necessarily be explicit in the art." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 973 (Fed. Cir. 2014). Dr. Lepore's obviousness opinion based on the Kirin Publication and other prior art references divided into three categories is consistent with these principles.

Plaintiff argues that Dr. Lepore's failure to identify specific combinations of prior art references has prevented Plaintiff's expert from providing a meaningful response to Dr. Lepore's prior art arguments. (D.I. 258 at 10) But the rebuttal report of Dr. David MacMillan shows that he discussed the prior art references with precision and was able to refute Dr. Lepore's obviousness opinions based on his understanding of Dr. Lepore's positions. (D.I. 263, Ex. E at ¶¶ 373-80) In keeping with Dr. Lepore's analysis, Dr. MacMillan discussed the prior art references collectively in his rebuttal. (*See, e.g.*, D.I. 263, Ex. E at ¶ 380) ("None of the cyclopropyl-containing compounds Dr. Lepore presents is even remotely structurally similar to the compounds in Kirin[.]"). Because Dr. MacMillan was able to "respond in proportion to Dr. Lepore's explanation," exclusion of Dr. Lepore's opinion is not warranted on this record. (D.I. 259, Ex. F at ¶ 319)

To the extent that Plaintiff challenges Dr. Lepore's obviousness opinion due to his reliance on a number of prior art references across several categories, Plaintiff's position goes to the weight of the opinion, and not its admissibility. It is ultimately Defendants' burden to show "by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer*, 480 F.3d at 1361 (citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)). The failure to adequately identify specific obviousness combinations goes to this ultimate burden of proof under 35 U.S.C. § 103, and not to the admissibility of an expert opinion, as demonstrated by the fact that a majority of the cases relied on by Plaintiff did not arise in the context of a *Daubert* motion to exclude the opinion of an expert witness. *See ProBatterSports, LLC v. Sports Tutor, Inc.*, 680 F. App'x 972, 975 (Fed. Cir. 2017) (concluding that patents were not invalid as obvious on a motion for summary judgment because the defendant's reliance on "a slew of references in ten separate obviousness combinations" did not satisfy the § 103 standard); *Motorola Mobility, LLC v. Int'l Trade Comm'n*, 737 F.3d 1345, 1350 (Fed. Cir. 2013) (holding that Motorola failed to present clear and convincing evidence of obviousness where it "did not clearly identify the scope and content of the prior art" and did not "provide any argument that certain prior art references render a specific claim obvious."); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) (finding evidence was insufficient to support an obviousness determination on JMOL where expert's testimony bore "no relation to any specific combination of prior art elements."); *Intendis GmbH v. Glenmark Pharms. Ltd.*, 117 F. Supp. 3d 549, 590-91 (D. Del. 2015) (holding after a bench trial on the merits that defendants had not met their ultimate burden under § 103).

Plaintiff's cited cases that do touch on the exclusion of an expert's opinion are distinguishable from the facts before the court in this case. In *Oxford Gene Tech. Ltd. v. Mergen Ltd.*, 345 F. Supp. 2d 431, 441 (D. Del. 2004), the court determined that an expert's obviousness opinion was unreliable and therefore inadmissible under Rule 702. Nonetheless, the case is distinguishable in several ways. First, the case was tried to a jury. *Id.* at 438-39. Second, the expert relied on "common knowledge in the art" for a particular claim limitation without providing any underlying factual support for that assertion beyond "[j]ust my knowledge of the field." *Id.* at 438. In contrast, Dr. Lepore provided extensive explanation and support for each reference identified in the expert report, and Plaintiff's complaints are directed more broadly to the format of the prior art combinations in the report, as opposed to their factual underpinnings. The same is true of *Asahi Glass Co., Ltd. v. Guardian Indus. Corp.*, C.A. No. 09-515-SLR, 2011 WL 4459606, at *1-2 (D. Del. Sept. 26, 2011), in which the court excluded an expert opinion on obviousness in a case to be tried to a jury after determining that the expert did not describe the state or skill in the art.

In *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373 (Fed. Cir. 2008), the Federal Circuit upheld the district court's exclusion of an expert's obviousness opinion under Rule 26 after finding that the expert report "merely lists a number of prior art references and then concludes with the stock phrase 'to one skilled in the art it would have been obvious to perform'" the claimed method. In contrast, Dr. Lepore's expert opinion provides factual details regarding each prior art reference and methodically evaluates the motivation to combine and reasonable expectation of success factors in view of those references. (D.I. 263, Ex. C) Critically, the *Innogenetics* court highlighted the fact that it would not be credible to expect a lay jury to examine the prior art references and perform the obviousness analysis on its own.

*Innogenetics*, 512 F.3d at 1373. The degree of evidentiary support in the expert reports and the fact that the case will not be tried to a jury distinguish this case from *Innogenetics*.

**B. Motivation to Combine and Reasonable Expectation of Success**

Plaintiff submits that Dr. Lepore offered only conclusory statements without identifying any reasons why a person of ordinary skill would have been motivated to combine the prior art references with a reasonable expectation of success. (D.I. 258 at 9-10) But a review of Dr. Lepore's opinions and the applicable case authorities establishes that he adequately addressed why a person of ordinary skill in the art would be motivated to combine prior art references, and why they would have a reasonable expectation of success in doing so. (D.I. 263, Exs. C-D) Dr. Lepore's opinion goes beyond conclusory statements, and it is grounded in acceptable sources, including the prior art references themselves. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1362 (Fed. Cir. 2007) (explaining that the motivation to combine relevant prior art teachings can be found "in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself."). *Cf. TQ Delta, LLC v. CISCO Sys.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (explaining that "a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine").

For example, Dr. Lepore explains that a person of ordinary skill would recognize the need for sufficient oral bioavailability in drug development, which would lead to the selection of Example 5 in the Kirin Publication as the lead compound because it is more orally active and has a suitable number of H-bond receptors. (D.I. 263, Ex. C at ¶¶ 206, 227-29) Dr. Lepore then represents that a person of ordinary skill would have been motivated to modify Example 5 of the Kirin Publication by incorporating a spiro-cyclopropyl ring into the malonamide group to arrive at cabozantinib because it would be more metabolically stable without adding new H-bond

receptors or increasing the molecular weight of the compound, among other reasons. (*Id.* at ¶¶ 206, 234-38, 257) In support of these allegations, Dr. Lepore discusses the asserted prior art references as well as other references that would be known to a person of ordinary skill. (*See, e.g.*, *id.* at ¶¶ 217, 238, 255-56) In particular, Dr. Lepore discusses Lipinski's "rule of 5" factors to assess bioavailability, which is an accepted analysis to establish a known motivation to combine. (D.I. 263, Ex. C at ¶¶ 82-84, 227-28, 238); *see Amerigen Pharms. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076, 1086-87 (Fed. Cir. 2019) (accepting opinion of defendant's expert applying Lipinski's "rule of 5" to determine that the lead compound in that case did not have a bioavailability problem requiring modification, while recognizing that a motivation to modify could exist in some cases despite the absence of a specific bioavailability problem).

Dr. Lepore's obviousness opinion also adequately identifies a reasonable expectation of success in achieving the claimed inventions. For instance, Dr. Lepore represents that cyclopropane-bearing compounds were widely known to have antibiotic, antiviral, and antitumor properties and were useful for inhibiting the activity of tyrosine kinases, and a person of ordinary skill would have reasonably expected that incorporating a spiro-cyclopropyl ring into the lead compound "could create an irreversible c-Met inhibitor." (D.I. 263, Ex. C at ¶¶ 241-49, 255-59) These explanations are sufficient to overcome Plaintiff's position that the opinions should be excluded. *See Pfizer*, 480 F.3d at 1364 ("[T]he expectation of success need only be reasonable, not absolute.").

**C. Testimony Concerning the Inventors' Path**

In the event that the court declines to preclude Dr. Lepore's opinion in its entirety, Plaintiff asks the court to exclude the portions of his opinion addressing the path taken by the inventors. (D.I. 258 at 11) In response, Defendants argue that Dr. Lepore's discussion of

inventor testimony and Plaintiff's development path permissibly show the level of ordinary skill in the art relevant to the claimed invention. (D.I. 263 at 18-19)

Plaintiff's motion to exclude is granted with respect to the limited portions of the expert opinion that are based on internal documents and testimony from Plaintiff's witnesses. (D.I. 263, Ex. C at ¶¶ 300-11; Ex. D at ¶¶ 266-97) The Federal Circuit has stated that "[t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art." *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1367 (Fed. Cir. 2017) (quoting *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012)). Dr. Lepore clarifies that he did not rely on discovery and testimony from Plaintiff's witnesses in forming his opinions, but he nonetheless cites portions of the inventors' internal documents and testimony which allegedly support his opinion. (D.I. 263, Ex. C at ¶ 300) As discussed at § III.A-B, *supra*, Dr. Lepore addresses the bases for his obviousness opinion by relying on prior art and other permissible references, and the final paragraphs of his opinion discussing documents and testimony from Plaintiff's witnesses are not necessary to those analyses.

Defendants' suggestion that these portions of the expert reports address the level of ordinary skill in the art is not compelling. A review of the challenged paragraphs confirms that Dr. Lepore included a discussion of Plaintiff's internal documents and witness testimony to confirm the veracity of his own opinions. (D.I. 263, Ex. C at ¶¶ 300-11) The Federal Circuit has cautioned against "us[ing] the template provided by the inventor, to render the inventor's contribution obvious." *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018) (citing *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985)). By discussing the internal documents and testimony of the inventors, Dr. Lepore blurs the line

between the inventor's work and the prior art, and also the person of ordinary skill and the inventor of exceptional skill in the art. "The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time. The invention must be evaluated not through the eyes of the inventor, who may have been of exceptional skill, but as by one of 'ordinary skill.'" *Interconnect Planning*, 774 F.2d at 1138.

Defendants have not shown that the internal documents and witness testimony discussed in the expert opinions are limited to "routine testing" used to verify characteristics of a pharmaceutical composition, as opposed to "the trial and error procedures often employed to *discover* a new compound[.]" *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364, 1367 (Fed. Cir. 2007). While consideration of the former may be permissible "on the *particularized facts*" of a particular case, the Federal Circuit does not permit consideration of the latter. *Id.*

**D. Commercial Motivation**

Plaintiff also argues that portions of Dr. Lepore's obviousness opinion run afoul of Federal Circuit authority by relying on commercial motivations, even where scientific motivations pointed in the opposite direction. (D.I. 258 at 12) Notably, Plaintiff does not actually cite any Federal Circuit authority addressing this issue in either its opening or reply brief. (*Id.* at 12-13; D.I. 265 at 9) In response, Defendants argue that reliance on commercial motivations in an obviousness opinion is properly considered under the Supreme Court's decision in *KSR*, which recognizes that "market forces can prompt variations" of a design. (D.I. 263 at 20) (quoting *KSR*, 550 U.S. at 418, 421).

Plaintiff's motion to exclude portions of Dr. Lepore's obviousness opinion that discuss commercial motivations is denied. By Plaintiff's own count, Dr. Lepore's discussion of freedom to operate and commercial motivation is limited to discrete portions of three paragraphs in his

opening report. (D.I. 259, Ex. A at ¶¶ 224, 235, 241) Plaintiff has not shown that maintaining the content of these paragraphs will result in any prejudice, particularly in the context of a bench trial. *See APEX Fin. Options, LLC v. Gilbertson*, C.A. No. 19-46-WCB-SRF, 2022 WL 613347, at *3 (D. Del. Mar. 1, 2022) (observing that "the court can simply disregard expert evidence that it regards as unreliable, irrelevant, or unhelpful."). Moreover, Federal Circuit authority suggests that this is an issue that goes to the weight of an opinion, not its admissibility. *See Amerigen Pharms. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076, 1089 (Fed. Cir. 2019) (concluding that, even if a commercial motivation could be shown, "such motivation would not be sufficient to prove that the claimed compounds would have been obvious.").

## IV. CONCLUSION

For the reasons set forth above, Plaintiff's motion is GRANTED-IN-PART. (D.I. 257) Specifically, the motion to exclude is GRANTED with respect to portions of Dr. Lepore's obviousness opinion that rely on the inventors' internal documents and testimony. (D.I. 259, Ex. A at ¶¶ 300-11) The motion is DENIED in all other respects. An Order consistent with this Memorandum Opinion shall issue.

Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Opinion under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Opinion should be redacted, the parties shall jointly submit a proposed redacted version by no later than **April 27, 2022**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (quoting

*Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation marks omitted)). If the parties do not file a proposed redacted version and corresponding motion, or if the court determines the motion lacks a meritorious basis, the documents will be unsealed within thirty (30) days of the date the Memorandum Opinion issued.

This Memorandum Opinion is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Opinion. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to five (5) pages each.

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: April 20, 2022

Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE