NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, JANSSEN RESEARCH AND DEVELOPMENT, LLC, and CILAG GMBH INTERNATIONAL, Plaintiffs, v. SANDOZ INC. and ZYDUS PHARMACEUTICALS (USA) INC., Defendants.	Civ. Action No. 17-5319 (FLW)(DEA) (consolidated) **OPINION**

WOLFSON, Chief Judge:

Presently before the Court are two motions *in limine* by Defendant Zydus Pharmaceuticals Inc. In its first motion, Zydus seeks to preclude testimony of three of Plaintiffs' experts related to patent nonobviousness "secondary considerations." In its second motion, Zydus seeks to preclude Plaintiffs from asserting an invention date derived from documents in its Local Patent Rules 3.2(b) disclosures that is earlier than the "priority date" Plaintiffs expressly disclosed in its Local Patent Rule 3.1(f) disclosures. For the reasons set forth below, Zydus' Motion *In Limine* No. 1 is **GRANTED IN PART AND DENIED IN PART**. All of Dr. Gavin's challenged testimony is admissible as expert opinion except for Dr. Gavin's testimony regarding the impact of late-night commercials and Dr. Sims's testimony which is derived from Dr. Gavin's inadmissible opinion. Zydus' Motion *In Limine* No. 2 is **DENIED**. Plaintiffs may assert an invention date of October

13, 2003 derived from their timely Local Patent Rule 3.2(b) document disclosures.

I. BACKGROUND

In July 2017, Plaintiffs Mitsubishi Tanabe Pharma Corp. ("MTPC"), Janssen Pharmaceuticals, Inc. ("JPI"), Janssen Pharmaceutica NV ("JNV"), Janssen Research and Development, LLC ("JRD"), and Cilag GmbH International ("Cilag") (collectively, "Plaintiffs") filed suit against Sandoz Inc. ("Sandoz") and Zydus Pharmaceuticals Inc. ("Zydus") (collectively, "Defendants") for infringement of U.S. Patent Nos. 7,943,788 ("the '788 patent), 8,222,219 ("the '219 patent), and 8,785,403 ("the '403 patent") (collectively, "the patents-in-suit"). Compl. at ¶ 10. The patents-in-suit are held by MTPC and are exclusively licensed or sublicensed to JPI, JRD, JNC, and Cilag. Compl. at ¶¶ 19-27. The patents-in-suit are related to canagliflozin, the active pharmaceutical ingredient in two related drug products marketed in the U.S. as Invokana and Invokamet. Def.'s Mot. In Lim. No. 1 at 1. Canagliflozin is in a class of compounds known as SGLT-2 inhibitors which are used in the treatment of type 2 diabetes. *Id.*

In response to Plaintiffs' allegations, Zydus alleges that MTPC's asserted patents are invalid because, among other reasons, they are obvious over prior art. In defending Defendants' prima facie showing of obviousness at trial, Plaintiffs have produced testimony from Dr. Gavin, Dr. Davies, and Mr. Sims regarding "secondary considerations" which seek to demonstrate that the patents were nonobvious. In its first motion *in limine*, Zydus argues that six opinions of Dr. Gavin should be excluded under Rule 702 and *Daubert*. Zydus claims that three of the opinions are factually unsupported, and three are speculative and unreliable. Zydus further argues that expert opinions by Dr. Davies and Mr. Sims derived from Dr. Gavin's allegedly inadmissible opinions should likewise be excluded.

On June 15, 2018, pursuant to the Court's Letter Order and Local Patent Rule 3.1, Plaintiffs

timely served their Infringement Contentions on Zydus. *See* Ex. F, Pls.' Infringement Contentions. Pursuant to Rule 3.1(f), Plaintiffs disclosed that their patents were "entitled to a priority date of no later than July 30, 2004" and "reserve[d] the right to establish an earlier date of invention based on documents being produced contemporaneously." *Id.* at 9. Along with their Rule 3.1 disclosures and consistent with Local Patent Rule 3.2(b), Plaintiffs produced certain documents to Zydus that they claim evidenced a conception date predating the Rule 3.1(f) priority date that they had identified. Def.'s Mot. In Lim. No. 2 at 2. Specifically, a laboratory notebook titled "E0894" indicated that the conception date of the patented chemical compound, "canagliflozin," allegedly occurred as early as October 29, 2003. Pls. Opp'n Mot. In Lim. No. 2 at 3. However, when these documents were produced, Plaintiffs did not expressly inform Zydus that the documents demonstrated a conception and reduction to practice date (i.e. invention date), which predated the previously disclosed priority date, or that Plaintiffs would assert the earlier invention date found within them. Def.'s Mot. In Lim. No. 2 at 2. In its second motion *in limine*, Zydus moves to preclude Plaintiffs from asserting an invention date earlier than July 30, 2004—that is, the "priority date" stated in Plaintiffs' Rule 3.1(f) disclosures. *Id.* at 1. Zydus contends Plaintiffs were required to disclose earlier invention dates they planned to assert with their Infringement Contentions. The parties' dispute centers on the invention date disclosure requirements required by Local Patent rules 3.1(f) and 3.2(b).

II. STANDARD OF REVIEW

A. Federal Rule of Evidence 702

Federal Rule of Evidence 702 governs the admissibility of testimony by an expert witness. Pursuant to Rule 702, a witness, who qualifies as an expert, may provide testimony if "(a) the expert's scientific, technical, or 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 Third Circuit has found "that Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir.2003) (citation omitted). The qualification restriction requires that the witness possess specialized expertise. *Id.* This restriction has been interpreted liberally, and the Third Circuit has held "a broad range of knowledge, skills, and training qualify an expert." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). The reliability restriction requires "the expert's opinion . . . 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 or her belief." *Id.* at 742 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993)). As *Daubert* notes, "[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 594. Finally, the expert's opinion must "fit the issues in the case" and help the trier of fact. *Schneider*, 320 F.3d at 404. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591–92.

"[T]he 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*, 320 F.3d at 404. The party offering the expert testimony bears the burden of establishing the existence of each matter by a preponderance of the evidence. *See In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir.1999. Rule 702, however, "has a liberal policy of admissibility." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir.1997). "If the expert meets [the] liberal minimum qualifications, then the level of the expert's expertise goes to credibility and weight, not admissibility." *Id.* at 809.

B. Local Patent Rules

Pursuant to the Local Patent Rules for the District of New Jersey, a party asserting patent infringement must serve on all parties a "Disclosure of Asserted Claims and Infringement Contentions" no later than 14 days after the initial Scheduling Conference. *See* L. Pat. R. 3.1. Among the necessary disclosures, Patent Rule 3.1(f) specifically requires that the infringement contentions disclose, "[f]or any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled." L. Pat. R. 3.1(f).

Local Patent Rule 3.2 governs document production that must accompany Rule 3.1 disclosures. Rule 3.2(b) requires that the party asserting patent infringement produce "[a]ll documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the patent in suit or the priority date identified pursuant to L. Pat. R. 3.1(f), whichever is earlier." L. Pat. R. 3.2(b).

The Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *TFH Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 365 (D.N.J. 2010) (quoting *Comput. Acceleration Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)). "The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *TFH Publications*, 705 F. Supp. 2d at 365-66 (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)). Courts may impose any just sanction for failure to comply with the Patent Local Rules, including "refusing to allow the disobedient party to support or oppose designated claims or defenses, or prohibiting that party from introducing designated matters in evidence." *O2 Micro*

Int'l Ltd. v. Monolithic Power Sys., 467 F.3d 1355, 1363 (Fed. Cir. 2006) (citing Fed. R. Civ. P. 16(f); Fed. R. Civ. P. 37(b)(2)(B)).

III. DISCUSSION

A. Whether Plaintiffs' Experts Opinions Are Excluded

Zydus claims three of Dr. Gavin's expert opinions are factually unsupported and should therefore be excluded under *Daubert*. First, Zydus argues Dr. Gavin failed to provide any factual support for his opinion that Invokana provided an important, novel tool in the comprehensive management of type 2 diabetes when it was approved by the FDA on March 29, 2013. Zydus contends that SGLT-2 inhibitors were known in the scientific community since the early 1980s and Dr. Gavin's proposed testimony is contrary to the case record since Dr. Garvin himself admitted that Farxiga was the first SGLT-2 inhibitor clinically used in Europe. Zydus, however, misstates Dr. Gavin's opinion. Dr. Gavin opines only that Invokana "was the first SGLT-2 inhibitor approved in the U.S." and to "reach [the U.S.] market." Ex. C, Gavin Report, at ¶ 68. Moreover, Dr. Gavin provides extensive support for his opinion by explaining the shortcomings of the type 2 diabetes treatments available in the U.S. before the approval of Invokana, as well as how Invokana served as a vital new treatment in management of type 2 diabetes in the U.S. since it was approved. *See id.* at ¶¶ 45-53, 74-80. Dr. Gavin provides citation to scientific literature, medical guidelines, and FDA-approved prescribing information which confirms his firsthand observations of the impact of the drug. *See id.* at ¶¶ 74-80; *see also Pfizer Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006) (finding an expert's opinions on the history and development of drug appropriate and admissible when based on many years of training and experience in the field, as well as reference to several academic medical journals"). Therefore, Dr. Gavin's opinion as to the importance and novelty of Invokana is admissible because it is not based

on "subjective belief or unsupported speculation" as contended by Zydus. *Ruggiero v. Yamaha Motor Corp., U.S.A.*, 778 F. App'x 88, 93 (3d Cir. 2019).

Second, Zydus argues Dr. Gavin's opinion that Invokana has a unique mechanism of action "is a sweeping conclusion" and has no factual support. Here, again, Zydus misstates Dr. Gavin's opinion. Dr. Gavin's opinion states that Invokana's mechanism to treat type 2 diabetes is unique when compared to FDA-approved drugs prior to 2003, none of which acted as SGLT-2 inhibitors. Ex. C, Gavin Report, at ¶ 68. Dr. Gavin's opinion details the mechanisms of other type 2 diabetes treatments that had been approved by the FDA prior to 2003 and provides factual support for his opinion with citation to scientific literature and medical guidelines. *Id.* at ¶¶ 69-73, 45-52. As such, Dr. Gavin's opinion regarding Invokana's unique mechanism of action compared to prior FDA-approved type 2 diabetes treatments is admissible.

Third, Zydus argues Dr. Gavin's opinion that Invokana "has been shown to have superior efficacy when compared to other SGLT-2 inhibitors" is not factually supported. Specifically, Zydus argues Dr. Gavin's opinion is not supported by any head-to-head trials that are required by the FDA in order to market a drug as "superior" in its class. However, there is no requirement that scientific studies must comply with FDA marketing standards to be admissible, nor is Zydus able to cite any case law supporting such a proposition. Indeed, as Plaintiffs note, Zydus's argument "confuses the requirements under the law for obtaining a patent with the requirements for obtaining [FDA] approval." *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995). Dr. Gavin provides ample citation to studies detailing Invokana's superiority to other SGLT-2 inhibitors. Because Zydus at no point challenges the reliability or methods used in those studies, Dr. Gavin's opinion regarding the superiority of Invokana compared to other SGLT-2 inhibitors is admissible.

Zydus also claims that three of Dr. Gavin's expert opinions should be excluded under

Daubert because they are speculative and unreliable. Zydus first argues that Dr. Gavin's opinion that "[the] new cardiac and renal indications further evidence the transformational impact of [Invokana]" for type 2 diabetes patients should be excluded. Ex. C, Gavin Report, ¶ 78. Zydus contends Dr. Gavin's opinion is speculative and unreliable because Dr. Gavin himself admitted that Jardiance, another diabetes drug, was the first SGLT-2 inhibitor to receive a new cardiovascular indication, and the impact of Invokana's renal indications had not been measured at the time of Dr. Gavin's opinion. I find that Dr. Gavin's opinion regarding the transformational impact of cardiac and renal indications is admissible. Dr. Gavin's opinion was based on numerous medical guidelines and scientific literature, as well as the Invokana Prescribing Information, which served as the basis for the FDA's approval of the indications. *Id.* at ¶¶ 31, 34, 76-79, 87-91. Although Jardiance may have been the first SGLT-2 inhibitor to receive a cardiovascular indication, that drug was not known in the prior art. Additionally, Dr. Gavin specifically opines that Invokana has "the *broadest* cardiac indication of any SGLT-2 inhibitor on the market," as provided on the approved FDA label for Invokana. Ex. C, Gavin Report, at ¶ 76 (emphasis added). Thus, there is scientific support for the transformational impact of the cardiovascular indication of Invokana. With regard to the renal indication, Dr. Gavin was unable to rely on clinical studies to inform his opinion, because there was simply no reliable methodology to study the impact for a recently approved indication. However, Dr. Gavin's opinion is informed by the fact that Invokana is the first and only type 2 diabetes drug that has been approved by the FDA for renal protection, and Invokana has received industry praise for its renal indication. Ex. 2, National Kidney Foundation Award, at 1-2. Such reliance on Dr. Gavin's part is permissible. Accordingly, because there is reliable support for Dr. Gavin's opinion on the transformational impact of the cardiac and renal indications, the opinion is admissible.

Second, Zydus contends Dr. Gavin's opinions regarding the supposed impact of late-night commercials are inadmissible because they are speculative and unreliable. Specifically, Zydus argues that the exclusion of Dr. Gavin's opinion that clinicians' decisions to not prescribe Invokana were influenced by patients who "made requests after watching late-night commercials from product liability attorneys alleging that patients who take Invokana would lose a limb" and "deliberate falsehoods by late-night advertisements [] [are] preventing some patients from being prescribed beneficial new therapies like Invokana." Ex. C, Gavin Report, ¶¶ 92-93. After review, I find that Dr. Gavin's opinion in that respect is inadmissible as expert opinion.

"Where a doctor's conclusion is based upon subjective experience and perceptions, it is not of the type that can be tested by other doctors in order to determine its validity." *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 786 (D.N.J. 1996). "The statements constituting a scientific explanation must be capable of empirical testing." *Daubert*, 509 U.S. at 593, 113 S. Ct. at 2797. Here, Dr. Gavin's – personal rather than expert – opinion in this context cannot be tested by others, and is therefore inadmissible as expert opinion. Critically, Plaintiffs admit that Dr. Gavin is "discussing confirmed facts" based on "his own experience and interactions with physicians" and Dr. Gavin states that his opinion is not based on any empirical data. Pls.' Opp'n Mot. In Lim. No. 1 at 15.; Ex. B, Gavin Tr. at 339:7-339:19. Accordingly, I find inadmissible Dr. Gavin's opinion regrading the impact of late-night commercials.

Third, Zydus argues that Dr. Gavin's opinion that SGLT-2 inhibitor research was met with skepticism by the research community between 2003–2004 should be inadmissible because it is unreliable and speculative. Zydus claims that Dr. Gavin was unable to provide any scientific support or specify the source of information for this opinion, and argues the opinion was based on discussions with unidentified industry opinion leaders. I disagree, and find this particular opinion

admissible. Dr. Gavin's opinion is supported by citation to numerous scientific articles, and confirmed by his own firsthand experience. Dr. Gavin elaborates that SGLT-2 research was met with skepticism because of "the unusual mechanism of action employed by SGLT-2 inhibitors," which some in the industry found to be counterproductive because it "could signal to patients that their diabetes was poorly controlled or worsening." Ex. C, Gavin Report, at ¶¶ 62–63. In support of these opinions, Dr. Gavin cites at least ten peer-reviewed scientific journals to demonstrate that because of the skepticism regarding the risk and efficacy of SGLT-2 inhibitors, the focus of research, during the relevant 2003–2004 period, was instead on (1) α-glucosidase inhibitors, (2) thiazolidinediones, and (3) meglitinides, which "target[ed] mechanisms of action that corresponded to already approved FDA type-2 diabetes drugs," as opposed to the more unusual mechanism employed by SGLT-2 inhibitors. *Id.* at ¶ 54. In that regard, Dr. Gavin cites to one publication that specifically discusses physicians' skepticism regarding SGLT-2 inhibitors and their potential side effects; Dr. Gavin opines that this reported "skepticism" confirms his own firsthand experience. *Id.* at ¶ 66 n.125 (citing Cortez, *J&J Diabetes Drug Seen Challenging Merck's Market Leader*, Bloomberg News Enterprise (June 8, 2012)). Indeed, the Cortez article supports Dr. Gavin's recollection that researchers in the 2003–2004 timeframe were skeptical "that increased glucose in the urine [caused by SGLT-2 inhibitors] might lead to a significant rise of urinary tract infections and genital infections." *See id.* at ¶ 66; *see also* Cortez, *supra*. Having reviewed the articles and publications cited by Dr. Gavin, I find that his opinion regarding the industry's skepticism of SGLT-2 inhibitors during the relevant period is admissible.

Finally, Zydus argues that the opinions of Dr. Davies and Mr. Sims are inadmissible as they are derived from Dr. Gavin's inadmissible proposed testimony. With respect to Dr. Davies, this argument is moot. Dr. Davies does not rely on the portion of Dr. Gavin's testimony that the

Court excludes—the impact of the late-night television commercials. Mr. Sims, however, relies on Dr. Gavin's assessment of the late-night commercials as part of his evaluation of Invokana's commercial success. *See* Ex. E, Sims Report, at 21–22. That portion of Dr. Sims's expert report will be similarly excluded as derivative of Dr. Gavin's inadmissible opinion.

B. Whether Plaintiffs May Assert an Earlier Invention Date

The principal dispute between the parties is whether Plaintiffs complied with disclosure requirements set forth in the Local Patent Rules. Zydus contends that the "priority date" disclosure required by Local Patent Rule 3.1(f) requires Plaintiffs to assert the date of priority relative to an earlier application and, if applicable, the date of an earlier conception and reduction to practice (i.e. the invention date). Zydus cites several cases from the Northern District of California in support of this proposition. *See Harvatek Corp. v. Cree, Inc.*, No. C 14-0353 WHA, 2015 WL 4396379, at *2 (N.D. Cal. July 17, 2015) ("Patent L.R. 3-1(f) particularly requires a patent holder to assert a specific date of conception, not a date range, and Patent L.R. 3-2(b) requires the proactive and expedient production of evidence of that conception date."); *see also Thought, Inc. v. Oracle Corp.*, No. 12-5601, 2015 WL 5834064 (N.D. Cal. Oct. 7, 2015) (requiring patent holder to assert specific date of conception in Rule 3-1(f) disclosure); *OpenTV, Inc. v. Apple Inc.*, No. 15-2008, 2016 WL 3196643 (N.D. Cal. June 9, 2016) ("The Court agrees with Judge Orrick's reasoning in *Thought* that [the plaintiff] had an obligation to disclose its conception date and the relevant documents to support the conception date under the Patent Local Rules."). The Northern District of California adopted this interpretation of its local patent rules because "[t]he purpose of the local rules to crystallize the parties' theories early in litigation would be frustrated if Patent Local Rule 3-1 and 3-2 were read to allow a plaintiff to avoid specifying a conception date or provide any documents that support[ing that] date." *Thought Inc.*, 2015 WL 5834064, at *5. Zydus

contends these cases are applicable to the instant case since this Court's Local Patent Rules have previously been "informed by districts with analogous local patent rules, such as the Northern District of California and the Eastern District of Texas." *Merck Sharp & Dohme Corp. v. Sandoz. Inc.*, 2014 WL 997532, at *3 n. 2 (D.N.J. Jan 6, 2014), *aff'd*, 2014 WL 14945952 (D.N.J. Apr. 16, 2014).

In response, Plaintiffs argue that "invention date" and "priority date" have distinct meanings in patent law, and that they have therefore complied with the plain language of both Local Patent Rule 3.1(f) and 3.2(b).[1] Specifically, in their June 2018 Infringement Contentions, Plaintiffs identified a priority date (thereby satisfying 3.1(f)) and produced documents evidencing an invention date that occurred "before" that priority date (thereby satisfying 3.2(b)). Moreover, Plaintiffs argue that they provided all disclosures required by their discovery agreement with Zydus – namely, they provided the "documents evidencing the date of conception and reduction to practice for each patent asserted in this case . . . when required by L. Pat. R. 3.2 . . . ." Ex. 9, Joint Disc. Plan at 14. Finally, Plaintiffs contend that Zydus' own actions demonstrate its knowledge of the invention date, and therefore, Zydus has not been unduly prejudiced. In support, Plaintiffs point to Zydus' depositions of the inventors of the patents-in-suit regarding the invention date, as well as elicited testimony which confirmed an earlier invention date. They also argue Zydus had possession of the documents evidencing the earlier invention date for nearly two years, and Dr. Davies' expert report clearly identified the earlier invention date. I agree with Plaintiffs on this issue.

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[1] The dates when the inventor conceived the invention and reduced it to practice inform the "invention date." *See, e.g., Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). In contrast, the "priority date" is the filing date is the filing date of the earliest patent application to which the patents-in-suit are entitled. *See, e.g., In re NTP, Inc.*, 654 F.3d 1268, 1277 (Fed. Cir. 2011).

Although this Court recognizes that the Northern District of California's rule requiring a plaintiff to assert an earlier invention date in its 3.1(f) and 3.2(b) disclosures supports the overarching goal of the Local Patent Rules, the cases cited by Zydus are factually distinguishable from the case at bar.[2] Importantly, in *Thought, Inc.*, the court granted a defendant's motion to strike plaintiff's earlier invention date only after plaintiffs "failed to provide any evidence as required by Patent Local Rules 3-1 and 3-2 of an invention date prior to the filing date of the patent at issue." *Thought, Inc.*, 2015 WL 5834064 at *1, 5. Likewise, in *Harvatek*, the plaintiffs "did not produce any documents evidencing a conception date" with their disclosures and productions required by the local patent rules. *Harvatek*, 2015 WL 4396379, at *1. In the instant case, however, Plaintiffs complied with plain language of Local Patent Rule 3.2(b)—as well as the Joint Discovery Plan—by timely producing documents sufficient to establish the earlier invention date.

Zydus' reliance on *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, 2018 WL 2411602, at *5 (D.N.J. May 29, 2018), is similarly unavailing, since the plaintiffs in that case also did not timely produce the documents they needed to support an earlier invention date pursuant to L. Pat. R. 3.2(b). *Id.* at *4-6. The court, however, declined to strike later inventions date which were derived from documents that had been timely produced, such as the inventor's notebooks. *Eagle View Techs., Inc. v. Xactware Sols., Inc.*, No. 15-7025, 2017 WL 5886004, at *13 (D.N.J. Nov. 29, 2017). The plaintiffs in *Eagle View* also failed to properly respond to an interrogatory from defendants requesting the invention date. In the instant case, however, Zydus never served an interrogatory seeking an invention date from Plaintiffs.

Rather, I find *Gamevice, Inc. v. Nintendo Co., Ltd.*, 18-CV-01942-RS, 2019 WL 3533078

[2] The Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases." *TFH Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 365 (D.N.J. 2010).

(N.D. Cal. Aug. 2, 2019), more on point. The plaintiff there, like here, timely disclosed a priority date and documents purportedly evidencing an earlier invention date in their infringement contentions. *Id.* at *1. The court concluded that although the plaintiff was obliged to provide a clear statement disclosing the earlier invention date in its infringement contentions, the plaintiff would not be barred from asserting an invention date derived from its Patent L.R. 3-2(b) disclosures due to the ambiguity in the local rules. *Id.* at *3. Since the New Jersey Local Patent Rules present similar ambiguity, Plaintiffs in the instant case are not be barred from asserting an invention date derived from its 3.2(b) disclosures.

Finally, it is clear that, at the very least, by the time of Dr. Davies' expert report in October of 2019, Zydus should have been on inquiry notice that Plaintiffs planned to assert an earlier invention date. Zydus had specifically deposed inventor Dr. Eiji Kawanishi on May 23, 2019, regarding when he "came up with" the patented compound, to which he answered "autumn of 2003." Ex. 13, Kawanishi Tr., at 69:23-25, 72:24. Dr. Sugama also confirmed in his deposition on June 11, 2019, that Dr. Kawanishi provided him with the instructions to make the patented compound on October 29, 2003, as reflected in the Laboratory Notebook titled "E0894." Ex. 14, Sugama Tr., at 56:19-59:25; 82:22-83:24. Additionally, the Davies expert report clearly asserted the earlier invention date by specifically calling attention to the "time of the invention" and the footnote discussing the invention date. Ex. D, Davies Report, at ¶¶ 32, 32 n.7, 128 n.87. Yet, despite being on inquiry notice, Zydus did not question the invention date, nor request additional discovery on this issue. Instead, without explanation, Zydus waited until the eve of trial to file its motion to preclude Plaintiffs from asserting an earlier invention date. To the extent that Zydus waited to file this motion, any prejudice is the result of its own neglect.

IV. CONCLUSION

For the above reasons, Zydus' Motion *In Limine* No. 1 is **GRANTED IN PART AND DENIED IN PART**. All of Dr. Gavin's challenged testimony is admissible as expert opinion except for Dr. Gavin's testimony regarding the impact of late-night commercials and Dr. Sims's testimony which is derived from Dr. Gavin's inadmissible opinion. Zydus' Motion *In Limine* No. 2 is **DENIED**. Plaintiffs may assert an invention date of October 13, 2003 derived from their timely Local Patent Rule 3.2(b) document disclosures.

DATED: June 15, 2020

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson
U.S. Chief District Judge