UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

GILEAD SCIENCES, INC.,

Plaintiff,

v.

MERCK & CO, INC., et al.,

Defendants.

Case No. 5:13-cv-04057-BLF

ORDER DENYING MOTION TO COMPEL

(Re: Docket No. 156)

Scientist A conducts an experiment. Scientist B recreates that experiment years later, with a protocol provided by Scientist C. In a patent suit over this work, all would seem discoverable, even after the new Federal Rules have renewed awareness of the importance of proportionality.[1] But what if Scientist C also is an attorney for the party that hired Scientist B, and the discovery sought includes work product in his possession that he never communicated to anyone, let alone Scientist B? This motion presents just such a question.

Plaintiff Gilead Sciences, Inc. moves to compel production of work product related to a scientific protocol provided by an attorney-scientist for Idenix Pharmaceuticals, Inc., a subsidiary of Defendant Merck & Co., Inc.[2] Because Gilead has not shown that any work product not

[1] See Fed. R. Civ. P. 26(b)(1) (limiting discovery to non-privileged matter that is "relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit").

[2] See Docket No. 156 at 5 (all references to Docket No. 156 use ECF-generated page numbers, located in the upper right corner of each page).

communicated by that attorney-scientist is at issue in this case or that Gilead has a compelling need for it, Gilead's motion is DENIED.

I.

Gilead markets the drugs Sovaldi® and Harvoni® for treating the hepatitis C virus infection.[3] Both rely on the active ingredient sofosbuvir, which has a specific configuration of atoms at the 2' position of the molecule, namely a fluorine atom oriented down and a methyl group oriented up, or 2'-methyl-up-2'-fluoro-down.[4] In this declaratory judgment suit, Merck asserts that two of its patents, U.S. Patent No. 7,105,499 and U.S. Patent No. 8,481,712, claim use of metabolites of this nucleoside, and that Gilead's sales of its products induce and contribute to the infringement of these patents.[5] Gilead counters that Merck's patent claims are invalid for lack of enablement, i.e., the patents do not enable a person of ordinary skill in the art to make the critical 2'-methyl-up-2'-fluoro-down nucleoside.[6]

Even as this case wears on, Gilead has been embroiled in litigation elsewhere with Idenix, now a Merck subsidiary, but previously a standalone company with its own patents related to the 2'-methyl-up-2'-fluoro-down nucleoside.[7] Before its acquisition by Merck, Idenix had been working on developing its own HCV treatments, including a 2'-methyl-up-2'-fluoro-down nucleoside analog.[8] One Idenix scientist working on this project was Dr. Jean-Francois Griffon, who worked on it in 2003.[9] One of his techniques was to use a fluorinating agent called "Deoxo-

[3] See id. at 8.

[4] See id.

[5] See id.; Docket No. 174 at 2.

[6] See Docket No. 156 at 9.

[7] See id.

[8] See Docket No. 174 at 4.

[9] See id.

Fluor."[10] Each iteration of the Deoxo-Fluor experiment yielded multiple reaction products, but Griffon analyzed only the most abundant reaction product yielded by each experiment, rather than all of the reaction products.[11] The most abundant product did not include 2'-methyl-up-2'-fluoro-down nucleosides, and so Griffon believed that he was unsuccessful in synthesizing the nucleoside.[12] Gilead, naturally, agreed with Griffon, but Idenix did not.[13] To Idenix, it was all a matter of failing to appreciate what was always there.

As part of a lawsuit in the United Kingdom, Idenix hired an outside organization, Albany Molecular Research, Inc., to reproduce Griffon's 2003 experiment and check whether the synthetic reaction did produce the 2'-methyl-up-2'-fluoro-down nucleoside.[14] AMRI informed Idenix that it needed more information to conduct the experiments,[15] and Idenix's attorney, Dr. M. David Weingarten, gave AMRI a detailed protocol for reproducing Griffon's Deoxo-Fluor synthesis and analyzing all of the reaction products.[16] Weingarten has significant experience in pharmaceutical drug development and experiment analysis.[17] He holds a Ph.D. in Organic Chemistry from Emory University, served as a post-doctoral fellow at Columbia University, where "he designed and developed new combinatorial methods for determining enantioselective chemical processes and implemented molecular modeling to analyze complex experimental results" and worked for over a decade as a pharmaceutical chemist engaged in drug discovery.[18]

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[10] See id.

[11] See id.

[12] See id. at 5.

[13] See id.

[14] See id.

[15] See Docket No. 156 at 9.

[16] See Docket No. 174 at 6.

[17] See Docket No. 174 at 10.

[18] Docket No. 174-7 at 1-2.

Dr. Alexander Clemens, an AMRI scientist, reproduced Griffon's synthesis using that protocol, analyzed all the reaction products using techniques known in the art at the time the patents-in-suit were filed and found that he had successfully synthesized the 2'-methyl-up-2'-fluoro-down nucleoside.[19]

Meanwhile, in this case, Merck served three expert reports that rely on Clemens' synthesis of the 2'-methyl-up-2'-fluoro-down nucleoside to argue that Griffon successfully—if unknowingly—synthesized the 2'-methyl-up-2'-fluoro-down nucleoside in 2003 and that fluorinating the 2' position is easy because Clemens did it on his first attempt.[20] Gilead maintains that Clemens was successful only because he was following the particular protocol he received from Weingarten after unknown others had shown that it worked, and so Gilead seeks to compel production of all documents, information or objects related to that protocol.[21] Merck states that it already has produced "everything that Idenix's attorneys conveyed to Dr. Clemens,"[22] as well as Clemens' lab notebooks, the protocol and his experimental data,[23] and contends that what Gilead seeks are Weingarten's mental impressions about the protocol, i.e., opinion attorney work product.[24]

II.

The court has jurisdiction under 28 U.S.C. §§ 1331 and 1338. This matter was referred to the undersigned pursuant to Fed. R. Civ. P. 72(a).

Fed. R. Civ. P. 26(b)(3) creates two tiers of protection for attorney work product, based on

[19] See Docket No. 156 at 10.

[20] See id. at 13.

[21] See id. at 5.

[22] See id. at 1.

[23] See id. at 7.

[24] See id. at 8.

the nature of the work product.[25] "[D]ocuments and tangible things that are prepared in anticipation of litigation" may be discoverable if the party seeking discovery shows that it has "substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means."[26] However, discovery of opinion work product, which is comprised of the "'mental impressions, conclusions, opinions, or legal theories of an attorney'" requires a higher showing.[27] "Rule 26 accords special protection to work product revealing the attorney's mental processes."[28] In the Ninth Circuit, "opinion work product may be discovered and admitted when mental impressions are at issue in a case and the need for the material is compelling."[29]

III.

Applying the above standards, Gilead's motion must be denied. Weingarten's mental impressions are not at issue in this case, and Gilead has not shown that they have a compelling need for the material.

First, what Gilead seeks is plainly opinion work product. Gilead argues that it seeks discovery "only into the scientific facts surrounding the development of the protocol," and not Weingarten's legal opinions, thought processes or legal explanations for his actions regarding the protocol.[30] But the protocol was communicated to Clemens expressly for the purpose of disproving Gilead's assertion in the U.K. litigation that Griffon's experiment failed to create the 2'-methyl-up-2'-fluoro-down nucleoside. Whether Weingarten himself created the protocol or

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[25] See Holmgren v. State Farm Mut. Auto. Ins. Co., 976 F.2d 573, 577 (9th Cir.1992).

[26] Fed. R. Civ. P. 26(b)(3)(A)(ii).

[27] Upjohn Co. v. U.S., 449 U.S. 383, 398, 398 n.7 (1981) (quoting Fed. R. Civ. P. 26(b)(3)); Holmgren, 976 F.2d at 577.

[28] Upjohn, 449 U.S. at 400.

[29] Holmgren, 976 F.2d at 577.

[30] Docket No. 179 at 2.

merely reviewed it,[31] it would be impossible to separate out the work he did as a scientist and the work he did as an attorney. Any adjustments Weingarten made to the protocol would necessarily have been done in consideration of its purpose in countering Gilead's litigation position, and the scientific facts surrounding any differences between the protocol and Griffon's procedures were necessarily motivated by attorney thought processes.

Consider this. Gilead questions the protocol's instruction that "all solvents and reagents should be new and from unopened bottles," which it says was not present in Griffon's lab notebook.[32] This difference between the protocol and Griffon's procedure, says Gilead, is not regular scientific practice.[33] However, as Merck explained at oral argument, this instruction arose from "trying to anticipate the kinds of questions that no scientist would ever ask but which a lawyer with an ax to grind certainly would."[34] That is, while a scientist might not ordinarily start with fresh bottles, a lawyer would do so in order to "eliminate questions that would arise . . . about how do you know that the reagents were what they purported to be."[35] In other words, the scientific instruction necessarily reflects the attorney's strategic thinking about issues likely to arise down the road in litigation. When an attorney with experience in other fields wields that non-legal knowledge in furtherance of litigation goals, the attorney's mental impressions, conclusions or opinions remain protected opinion work product because the non-legal and legal thinking are inextricably intertwined in service of the litigation.

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[31] See id. at 8; Docket No. 194 at 28:10-21 ("THE COURT: Okay. The question I had was is it undisputed that the protocol that Dr. Clemens relied upon was prepared, drafted, identified by Dr. Weingarten. MR. RABINOWITZ: It was provided to him by Dr. Weingarten . . . acting as counsel for -- Idenix was being represented at that time by Jones Day, as well as by Finnegan and Henderson. THE COURT: So as a Finnegan lawyer representing his clients. MR. RABINOWITZ: As a Finnegan lawyer that's what he did.") (emphasis added).

[32] See Docket No. 179 at 4.

[33] See id.

[34] See Docket No. 194 at 29:18-20.

[35] See id. at 29:21-24.

Second, Gilead has not satisfied the higher standard for discovery of opinion work product. In particular, Gilead has not shown that Weingarten's mental impressions are at issue in this case, or that they have a compelling need for the material. The "compelling need" standard "usually equates to an inability to prove his case if the material is not made available."[36] The key question in the enablement defense is whether Merck's patents adequately teach a POSITA to make the critical 2'-methyl-up-2'-fluoro-down nucleoside. However, Griffon's work is unrelated to this issue. Gilead's expert report relies on Griffon's apparent failure to show that "it would take undue experimentation to synthesize 2' C1-4 alkyl-up / 21 fluoro-down nucleosides/nucleotides,"[37] but Griffon's work is irrelevant to the enablement issue, because it is undisputed that he did not use Merck's International (PCT) Application, which later issued as the '499 patent, as a reference.[38] Clemens' reproduction of Griffon's experiment, and the new protocol, thus also are irrelevant.

Furthermore, Gilead does not have a compelling need for the opinion work product surrounding the development of the protocol. Gilead argues that the protocol contains differences from Griffon's procedures, and that it needs to know the source of the differences in order to determine whether they were based on information not available to a POSITA at the time of Griffon's experiments in 2003.[39] However, Idenix and Merck have produced sworn testimony in the U.K. litigation (which also was submitted in the United States District Court for the Northern District of New York) that flatly denied that

> any other party on behalf of [their] clients . . . conducted any experimental investigations into the work of Dr. Griffon when reacting a 3'-5' TIPS-protected 2'-methyl (down) 21-hydroxy (up) nucleoside with Deoxo-Fluor, including investigations in which variations have been made to the reagants, the conditions of

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[36] Korpi v. United States, Case No. C-95-3170, 1996 WL 882598, at *261 (N.D. Cal. Oct. 25, 1996) (applying Holmgren).

[37] Docket No. 174 at 7.

[38] See id. at 4.

[39] See Docket No. 179 at 3-6.

> the reaction, the methods of analysis of the reaction products and the methods of purification of the reaction products, other than those experiments as recorded in pages 1-74 of Alexander Clemens.' lab note book CLE-F.[40]

"Without more specific information triggering some reason for doubt, the Court must take the producing party . . . at its word when it claims to have produced everything it has."[41]

SO ORDERED.

Dated: January 11, 2016

PAUL S. GREWAL
United States Magistrate Judge

[40] Docket No. 174-2 at Ex. B.

[41] Aristocrat Techs. v. Int'l Game Tech., Case No. C 06-03717 RMW (RS), 2009 WL 3573327, at *3 (N.D. Cal. Oct. 30, 2009).