IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AbbVie Inc. *et al.*,

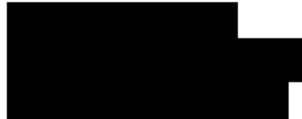
Plaintiffs/Counterclaim-Defendants,

v.

Boehringer Ingelheim International GmbH *et al.*,

Defendants/Counterclaim-Plaintiffs.

C.A. No. 17-1065-MSG-RL



BOEHRINGER'S OPPOSITION TO ABBVIE'S OBJECTIONS TO MAGISTRATE JUDGE LLORET'S ORDER COMPELLING PRODUCTION OF UNREDACTED HUMIRA® PRESENTATION

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I. INTRODUCTION

Boehringer Ingelheim International GmbH *et al*. submit this opposition to AbbVie Inc. *et al*.'s Objections to United States Magistrate Judge Lloret's June 14, 2018 Order (D.I. 127 ("Op.")) requiring AbbVie to produce additional unredacted portions of the document referred to as "the Humira® Presentation." In its Objections, AbbVie does not, and cannot, challenge Judge Lloret's factual determinations. AbbVie instead makes scattershot arguments that the Order is contrary to law. AbbVie is wrong. Judge Lloret, who has been closely managing this case, including through resolving numerous discovery disputes over the past several months, performed an *in camera* review of the Humira® Presentation and applied the correct legal standard in his detailed and carefully reasoned opinion finding that AbbVie improperly redacted pages that it should not have. AbbVie failed to prove privilege before Judge Lloret and does not come close to carrying its even heavier burden of demonstrating that Judge Lloret's non-dispositive discovery ruling is clearly erroneous or contrary to law.

II. BACKGROUND

A. <u>Discovery to Date</u>

This patent suit involves Boehringer's Cyltezo®, an FDA-approved adalimumab drug product that Boehringer seeks to market. On November 1, 2017, Your Honor set forth a case schedule and designated Judge Lloret to manage discovery. (D.I. 29 at 1.) The parties began exchanging discovery requests later that month. (*E.g.*, D.I. 33, 34.) Seven months later, and on the eve of the May 18, 2018 document production deadline, AbbVie had still refused to produce documents relevant to many of Boehringer's claims and defenses.

Aided by the parties' extensive briefings and argument, Judge Lloret has become thoroughly familiar with the case and has ruled on these disputes. (*See, e.g.*, D.I. 100 (involving third-party discovery); D.I. 110 (concerning Humira® supply, distribution, and manufacturing

agreements); D.I. 119 (relating to research and development documents); D.I. 127 (analyzing search terms); D.I. 112 (ordering AbbVie to produce documents concerning unclean hands).) Judge Lloret has also received regular status reports from the parties (D.I. 32) and held telephone conferences concerning discovery disputes and case management (*e.g.*, D.I. 91, 92, 129).

B. The Present Dispute

The Humira® Presentation—the document at issue here—was originally produced by AbbVie in unredacted form on February 9, 2018. Boehringer then cited that presentation, with other documents, in a May 3, 2018 interrogatory response detailing Boehringer's unclean hands defense. That defense alleges, *inter alia*, that AbbVie engaged in a multifaceted, unlawful scheme to [REDACTED][1] A day after receiving Boehringer's interrogatory response, AbbVie sent a letter seeking to claw back documents relating to unclean hands, including the Humira® Presentation, under a claim of privilege.

The Humira® Presentation, however, is a business document, developed with the help of [REDACTED], that details one aspect of AbbVie's comprehensive biosimilar strategy. By way of example, the Humira® Presentation sets forth AbbVie's efforts to [REDACTED]

[1] AbbVie is not a stranger to using the litigation process as a means to delay competition. *FTC v. AbbVie Inc.*, No. 14-5151, 2018 U.S. Dist. LEXIS 109628, at *55 (E.D. Pa. June 29, 2018) (finding that AbbVie used the litigation process itself "to impose expense and delay on [generics] so as to block their entry into the . . . market with lower price generics and to delay [AbbVie's] impending loss of hundreds of millions of dollars in . . . sales and profits," and that AbbVie "had no expectation of prevailing in the lawsuits").

[REDACTED]. The incentive for delay is massive: each ***day*** AbbVie delays competition in the United States is currently worth roughly $32 million. (D.I. 71 at 3.)[2] AbbVie produced a redacted version of the Humira® Presentation that included its self-selections of what it wished to disclose. (D.I. 73, Ex. 3.)[3]

Boehringer moved to compel an unredacted version of the Humira® Presentation. (D.I. 73.) Judge Lloret received briefing and conducted an *in camera* review, and, in a detailed Memorandum and Order, ruled that AbbVie had redacted certain non-privileged information. (Op. at 10.) Among other things, AbbVie improperly redacted a copy of a publicly available document within the Humira® Presentation, a diagram designating various programs with AbbVie's assessment of their value, and information about a widely attended 2010 "brainstorm meeting" designed to broaden AbbVie's patent coverage in response to the threat posed from biosimilars. (*Id*. at 7-8.) Judge Lloret found that AbbVie failed to carry its burden of proving legal issues predominate the document, and ordered production of the unredacted version of the presentation with the exception of two slides. (*Id.* at 5-10.) AbbVie then waited a full two weeks to file its Objections.

III. LEGAL STANDARDS

A. <u>Objections under Fed. R. Civ. P. 72(a)</u>

"In discovery matters, decisions of the magistrate judge are given great deference and will be reversed only for an abuse of discretion." *Norguard Ins. Co. v. Serveons Inc.*, No.

[2] The patent claiming the invention of adalimumab, formulations thereof, and its use to treat inflammatory diseases expired in December 2016. (D.I. 71, Ex. 2 at 16; D.I. 20 at 42, ¶ 12.)

[3] After producing the Humira® Presentation wholly unredacted, then clawing it back after Boehringer cited it as supporting unclean hands, and eventually producing a redacted copy, AbbVie now suggests in a footnote that the entire document is privileged. (D.I. 130 at 4 n.1.) This unsupported assertion is factually wrong, was soundly rejected by Judge Lloret (Op. at 5), and does not support reversal. The frenetic fluidity of AbbVie's privilege claims only serves to highlight their lack of merit.

08-900, 2011 WL 344076, at *2 (D. Del. Jan. 28, 2011). In reviewing a nondispositive order by a magistrate judge, the district court judge may only modify or vacate the order if it was "clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a). The objecting party bears the burden of demonstrating that the magistrate judge's decision should be overruled. *See, e.g., Przybylska v. Nine West Holdings, Inc.*, No. 16-637, 2017 WL 626776, at *2 (D.N.J. Feb. 15, 2017).

Under a "clearly erroneous" standard, the Court will set aside factual findings only when it is "left with the definite and firm conviction that a mistake has been committed." *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, No. 15-819, 2018 WL 2551053, at *1 (D. Del. May 8, 2018) (further citation omitted). It is "the responsibility of an appellate court to accept the ultimate factual determination . . . unless that determination either (1) is completely devoid of minimum evidentiary support displaying some hue of credibility, or (2) bears no rational relationship to the supportive evidentiary data." *Id.* A Magistrate Judge's order is contrary to law only "when the magistrate judge has misinterpreted or misapplied the applicable law." *Becker v. Cont'l Motors, Inc.*, No. 15-675, 2018 WL 582112, at *3 (D. Del. Jan. 29, 2018).

B. <u>Attorney-Client Privilege</u>

The attorney-client privilege protects only communications between a client and an attorney related to the purpose of securing legal advice. *Immersion Corp. v. HTC Corp.*, No. 12-259, 2014 WL 3948021, at *1 (D. Del. Aug. 7, 2014). The burden is on the party asserting privilege to prove: "(1) a communication (2) made between privileged persons (3) in confidence (4) for the purpose of obtaining or providing legal assistance for the client." *In re Grand Jury*, 705 F.3d 133, 160 (3d Cir. 2012). If the communications relate primarily to business concerns, it is not within the scope of attorney-client privilege, even if between attorneys and non-legal

personnel. *Immersion*, 2014 WL 3948021, at *1. Privilege does not apply simply because an attorney is involved. *Hercules, Inc. v. Exxon Corp.*, 434 F. Supp. 136, 144 (D. Del. 1977).

IV. JUDGE LLORET APPLIED THE CORRECT LEGAL STANDARD AND THE ORDER IS NOT CLEARLY ERRONEOUS

A. AbbVie Fails to Prove Judge Lloret's Application of the "Primary Purpose" Standard Is Contrary to Law

Recognizing that "business and legal advice may often be inextricably interwoven," "courts look to the documents' ***primary purpose*** to determine whether attorney client privilege applies." *Immersion*, 2014 WL 3948021, at *1; *In re Diagnostics Sys. Corp.*, 328 F. App'x 621, 622-23 (Fed. Cir. 2008) (upholding rejection of privilege "where [patent owner] has failed to make a clear showing that the primary purpose of the communication was securing legal advice").[4] Here, Judge Lloret observed that the "mix of business and legal concerns in the [Humira® Presentation] is obvious." (Op. at 4.) AbbVie therefore bore the burden to demonstrate that the portions of the Humira® Presentation it sought to withhold from discovery were "directed to issues which are primarily or predominately legal in nature." (*Id.*; *see also id.* at 3 ("When the communication between an attorney and non-legal personnel primarily relates to business concerns, the communication is not within the scope of attorney-client privilege.") (quoting *Immersion*, 2014 WL 3948021, at *1).) AbbVie fails to carry its burden to prove Judge Lloret's application of this standard was contrary to law.

AbbVie alleges that Judge Lloret "d[id] not consistently find that patentability advice is privileged." (D.I. 130 at 3.) The underlying assumption for this proposition is incorrect: the Humira® Presentation was ***not*** a request about the patentability of various inventions. (Op. at 5-6.) Rather, Judge Lloret correctly found that the Humira® Presentation summarized business

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[4] Unless otherwise noted, all emphasis has been added.

initiatives widely known and disseminated within AbbVie. (*Id.*; *see also* D.I. 117 at 5.) AbbVie had every opportunity to develop the factual record before Judge Lloret and prove its privilege claim if there was a basis to do so, but did not put forth any evidence that the presentation served to "inform or provide a legal opinion or service" (Op. at 5), let alone constituted a request for an assessment on the patentability of certain inventions.[5] *See, e.g.*, *Powerweb Energy, Inc. v. Hubbell Lighting, Inc.*, No. 12-220, 2013 WL 4504304, at *2 (D. Conn. Aug. 22, 2013) (rejecting privilege claim over patent-related emails where there was no evidence they were intended to be "for the purpose of securing legal advice").[6]

AbbVie further objects to Judge Lloret's analysis of slides 4, 5, 8, and 19 on the basis that each allegedly addresses patentability. Judge Lloret found otherwise: slide 4 merely references a publicly available document with no legal advice; slide 5, a diagram designating classes of projects within AbbVie, "has nothing to say about a legal issue"; slide 8 summarizes the results of a 2010 meeting attended by [REDACTED] AbbVie employees [REDACTED]; and slide 19 discusses examples without context as to purpose or audience. (Op. at 7-10.) AbbVie's broadside attacks on Judge Lloret's understanding of privilege cannot meet its burden of demonstrating that Judge Lloret's thorough analysis was clearly erroneous or contrary to law.

AbbVie also objects to Judge Lloret's decision to order production of the "Objectives" column on slides 10, 11, and 17. AbbVie reasons that, because the patentability scores were found to be privileged, the accompanying descriptions of "objectives" and "proposals" must be

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[5] *See Diagnostic Sys. Corp. v. Symantec Corp.*, No. 06-1211, 2008 WL 9396387, at *6 (C.D. Cal. Aug. 12, 2008) (finding that presentation concerning "how to assess value and how to develop an assertion plan" addressed business functions and was not subject to "sweeping assertions of privileges" simply because the author was a lawyer).

[6] AbbVie's reliance on *In re Spalding Sports Worldwide*, 203 F.3d 800 (Fed. Cir. 2000), is misplaced. Unlike that case, the Humira® Presentation was not found to, and does not, concern information provided by an inventor to a patent prosecutor for the filing of a patent application.

as well. But AbbVie ignores that it left the "Project Name" and "Technical Success Score" columns ***unredacted*** in the Humira® Presentation, both of which involved non-legal aspects of the proposals. (*See, e.g.*, D.I. 73, Ex. 3 at *10.) Thus, AbbVie has already conceded by its actions that the technical information associated with the "projects" and "proposals" is ***not*** privileged. Judge Lloret applied the correct legal standard,[7] and engaged in a detailed analysis of whether legal issues were the "primary purpose" of the information at issue in the Humira® Presentation.

B. <u>AbbVie Mischaracterizes Attorney-Client Privilege</u>

In its second argument, AbbVie attacks Judge Lloret's privilege analysis of slides 2 and 3 on the theory that the Order allegedly ignores clear law that, "[e]ven if a business decision is reached, if it was reached only after securing legal advice, then the discussions leading to that decision are privileged." (D.I. 130 at 7-8.) This misstates the law and incorrectly suggests even a modicum of subsidiary legal analysis somewhere in a document cloaks all related documents with privilege, no matter how attenuated they are from the legal advice. *See Kickflip, Inc. v. Facebook, Inc.*, No. 12-1369, 2015 WL 13446263, at *2 (D. Del. Jan. 21, 2015) ("because the attorney-client privilege obstructs the truth-finding process, it is construed narrowly"); *see also Union Pac. Res. Grp., Inc. v. Pennzoil Co.*, No. 97-064, 1997 U.S. Dist. LEXIS 24216, at *19-22 (D. Del. Sept. 2, 1997) (rejecting argument that "obtaining tax relief is a core activity of tax attorneys [which] should be protected even though it addresses business conduct").

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[7] AbbVie suggests a "but for" test to assess privilege. (D.I. 130 at 7-8 (citing *Louisiana Mun. Police Employees Ret. Sys. v. Sealed Air Corp.*, 253 F.R.D. 300, 306 (D.N.J. 2008) (designed "to prevent corporate attorneys from abusing . . . privilege").) Yet AbbVie has not shown—and did not even seek to prove before Judge Lloret—that "but for" legal advice, any portion of the slides, including the objectives column, would not have been included in the presentation.

Given that "business and legal advice may often be inextricably interwoven . . . courts look to the documents' ***primary purpose*** to determine whether attorney client privilege applies." *Immersion*, 2014 WL 3948021, at *1. AbbVie's argument undercuts the careful balance courts have struck regarding the privilege status of information involving in-house attorneys who, as in this case, are involved with business affairs. *See, e.g.*, *FTC v. AbbVie, Inc.*, No. 14-5151, 2015 U.S. Dist. LEXIS 166723, at *17, *29-32 (E.D. Pa. Dec. 14, 2015) (information concerning use of the legal process to thwart generic competition not privileged "despite making reference to legal matters [as it] primarily, if not exclusively, [was] concerned with providing business advice").

AbbVie ignores the legal standard for establishing privilege where legal considerations inform business strategy. In those instances, "a claimant should specifically identify a disclosure made specifically to a lawyer for the purpose of assisting in rendering legal service." *Union Pac.*, 1997 U.S. Dist. LEXIS 24216, at *20-21. In short, the claim AbbVie makes requires AbbVie to establish a specific factual foundation. Instead, AbbVie makes only broad proclamations of privilege, and did not demonstrate a specific disclosure made to any AbbVie in-house lawyer for legal services. (Op. at 5; *see In re Diagnostics Sys.*, 328 F. App'x at 623.) AbbVie's reliance on [REDACTED] conclusory declaration failed to meet this burden with respect to the portions of the document found by Judge Lloret to be subject to production.[8]

Judge Lloret carefully considered the content of slide 2's pie chart, considered [REDACTED] declaration, and determined AbbVie failed to carry its burden to prove privilege. (Op. at

[8] *Cf. FTC v. AbbVie*, No. 14-5151, 2016 WL 4478803, at *6-7 (E.D. Pa. Aug. 25, 2016) (opining that testimony by Perry Siatis concerning work-product doctrine amounted merely to "after-the-fact testimony and argument by an interested party that is [not only] contradicted by contemporaneous evidence," but also failed to explain involvement of relevant individuals).

4-5.) Judge Lloret also considered redacted information from the "Executive Summary" slide and reasoned a heading relating to "patenting" did not mention legal issues, but only "business opportunities" and "competitive advantages" that AbbVie sought to advance through its scheme. (Op. at 6-7.) These factual determinations of privilege are given "great deference." *Norguard*, 2011 WL 344076, at *2. AbbVie has failed to prove grounds for reversal of Judge Lloret's decision as to slides 2 and 3.

C. AbbVie Misstates the Order to Create Straw Man Holdings

AbbVie's final two arguments, couched in hedging language, are a transparent attempt to manufacture an "appealable" issue that does not exist. (D.I. 130 at 9, 10 ("to the extent the Order . . .").)

1. The Order Does Not Hold That Non-Lawyer Involvement *Per Se* Negates Privilege

AbbVie asserts: "***to the extent the Order*** finds slide 2 not privileged because it was prepared by a scientist, discussed amongst non-lawyers, and touched on activities that may require input from non-attorneys, such a finding is contrary to law and must be reversed." (D.I. 130 at 9.) No such ruling was made. Instead, Judge Lloret found AbbVie had not provided "a clear account of how the 'communication' in the slide served to either inform or provide a legal opinion or service." (Op. at 5.) AbbVie bore the burden to establish that the Humira® Presentation was made between privileged persons in confidence for the purpose of obtaining or providing legal assistance for AbbVie. *See FTC v. AbbVie*, No. 14-5151, 2016 WL 4478803, at *3. Yet AbbVie failed to address the respective roles of the attendees, whether there were other attendees besides the six presenters listed on the cover slide, and with whom the document was shared. Judge Lloret's conclusion that privilege did not apply was buttressed by the fact that [REDACTED], a non-lawyer, took the lead in arranging the meeting and preparing the slides. (Op. at 5.)

In short, in apparent recognition of the lack of evidence supporting its privilege claim, AbbVie now tries to refashion Judge Lloret's explanation of AbbVie's failures to create a false "issue" before Your Honor. The Order does not hold the involvement of a non-lawyer is sufficient *per se* to negate privilege. The Order merely describes AbbVie's failure to prove its claim of privilege.[9]

2. The Order Does Not Hold That There Is No Privilege Solely Because AbbVie Inadequately Described Allegedly Privileged Sections

AbbVie also asserts: "***[t]o the extent the Order*** concludes slide 2 is not privileged because AbbVie failed to adequately describe the privileged portions," then such a ruling is contrary to law. (D.I. 130 at 9-10.) AbbVie complains that the Order's citation to Chief Judge Stark's decision in *Idenix Pharmaceuticals, Inc. v. Gilead Sciences, Inc.*, 195 F. Supp. 3d 639 (D. Del. 2016) improperly required AbbVie to disclose privileged information through its privilege log description. The Order says no such thing. Judge Lloret cites *Idenix* for the proposition that, "given the nature" of the document forwarded to an attorney in *Idenix*—which concerned marketing and business development and patent issues concerning a medical treatment—it was not privileged. (Op. at 6.) Simply put, Judge Lloret did not make a privilege ruling based on AbbVie's privilege log description. He reviewed slide 2 and the parties' briefing, and referenced the description of an analogous business document in *Idenix*. (Op. at 6.)

V. CONCLUSION

For the reasons set forth above, Boehringer respectfully requests that the Court deny AbbVie's motion seeking to reverse Magistrate Judge Lloret's June 14, 2018 Order.

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[9] Judge Lloret was amply aided by a full set of briefings and a sur-reply, and determined no "additional *in camera* submissions" were needed. (D.I. 130 at 10.)

Dated: July 12, 2018

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CERTIFICATE OF SERVICE

I, Selena E. Molina, Esquire, hereby certify that on the 12th day of July, 2018, a copy of Defendants' Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim Fremont, Inc.'s ***Opposition to AbbVie's Objections to Magistrate Judge Lloret's Order Compelling Production of Unredacted Humira Presentation*** was caused to be served via e-mail on the following counsel of record:

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