

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

ASTELLAS US LLC, ASTELLAS)	
PHARMA US, INC., and GILEAD)	
SCIENCES, INC.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 18-1675-CFC-CJB
)	
APOTEX INC., et al.,)	(CONSOLIDATED)
)	
Defendants.)	

MEMORANDUM ORDER

Plaintiffs Astellas US LLC, Astellas Pharma US, Inc. and Gilead Sciences, Inc. (“Plaintiffs”) have moved for relief against Defendants Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, Inc. (“DRL” or “Defendants”) regarding this discovery dispute (“Motion”). (D.I. 525) The Court¹ has considered the parties’ letter briefs, (D.I. 508; D.I. 518), heard argument on October 26, 2020 and conducted an *in camera* review of certain disputed documents.

This pharmaceutical patent suit involves asserted patents that are directed to regadenoson monohydrate and related compositions and methods. With their Motion, Plaintiffs request that Defendants produce unredacted versions of certain documents (“the documents-at-issue”) that Defendants have either withheld entirely or have partially redacted. (D.I. 508 at 1) The documents-at-issue relate to Defendants’ communications with Euticals Inc. (“Euticals”), and Euticals’ parent company, Albany Molecular Research Inc. (“AMRI”). (*Id.*) Euticals

¹ This case has been referred to the Court to resolve all disputes relating to discovery and the protective order. (D.I. 186)

manufactures the regadenoson active pharmaceutical ingredient (“API”) that will be used by Defendants to make their generic regadenoson product. (*Id.*)

Defendants have withheld or redacted the documents-at-issue on the basis that their content is protected by the common interest doctrine. (D.I. 518 at 1-3 (Defendants addressing only the common interest doctrine in explaining why the documents-at-issue are protected from disclosure))² The common interest doctrine is an exception to the general rule that an applicable privilege will be deemed waived if the relevant materials are disclosed to a third party. *INVISTA N. Am. S.a.r.l. v. M&G USA Corp.*, Civil Action No. 11-1007-SLR-CJB, 2013 WL 12171721, at *5 (D. Del. June 25, 2013); *Corning Inc. v. SRU Biosystems, LLC*, 223 F.R.D. 189, 190 (D. Del. 2004). To prove that the common interest doctrine protects certain materials from discovery, the party asserting the doctrine bears the burden to show that an underlying privilege has been established, and that: (1) the communications-at-issue are made by separate parties in the course of a matter of common legal interest; (2) the communications are designed to further that common legal interest; and (3) the privilege has not been waived. *INVISTA*, 2013 WL 12171721, at *5 (citing cases). With regard to establishing that a common legal interest in fact existed, the party with the burden must show that this interest was identical (or at least substantially similar) in nature, and that it was legal, not solely commercial. *Id.* at *7 & n.7; *Corning Inc.*, 223 F.R.D. at 190. And the key time period at issue in assessing this doctrine’s applicability is the time when the communications-at-issue were actually made. *See In re Maxus Energy Corp.*, 617 B.R. 806, 823 (Bankr. D. Del. 2020) (assessing the applicability of the doctrine “at the time of the communications” that were at issue); *Corning Inc.*, 223 F.R.D. at 190

² There is no dispute (at least before the Court) that the documents-at-issue contain material relevant to this case.

(assessing the applicability of the doctrine “at the time of the[] negotiations” between defendant and a third party during which the communications-at-issue were made).

Defendants provided the Court with four sets of documents (which Defendants refer to as “Tab 1,” “Tab 2,” “Tab 3” and “Tab 4”) for the Court’s *in camera* review; these four sets of documents are purportedly representative of all of the documents-at-issue. (D.I. 518 at 1; Transcript of October 26, 2020 oral argument (hereafter “Tr.”) at 5, 12) They are as follows:

- **Tab 1:** This is a “Patent Status” memorandum (attached to an accompanying e-mail string, dated April 20, 2015), which was prepared by Euticals’ “IP and Scientific Director” Dr. Grisenti Paride on January 8, 2014. In the e-mail string, a DRL employee mentions Euticals’ patent application for its “non-infringing polymorph” and asks if Euticals could share information about its API; in response, a Euticals employee attached the Patent Status memorandum. Defendants contend the entire Patent Status memorandum is protected from disclosure. (D.I. 518 at 2; Tab 1)
- **Tab 2:** This is an e-mail string dating from December 2015 through January 2016. Defendants seek to maintain redactions to just three portions of the string. The first portion amounts to most of the content of a December 9, 2015 e-mail from DRL employee Bhaskar Ganguly, in which Mr. Ganguly conveys that DRL’s Intellectual Property Management (or “IPM”) team is requesting that Euticals send information about Euticals’ API as it relates to certain published patent applications and issued patents. Dr. Paride noted in response to Mr. Ganguly’s e-mail that the requested data would have to be transferred from “legal-IP dept to legal-IP dept” because it is “privileged.” Thereafter, on January 7 and 8, 2016, e-mails (which include contents that amount to the second and third redacted portions at issue) were sent, respectively, from Dr. Paride to DRL and then from DRL employee (and member of the IPM team) M Lokeswara Rao back to Dr. Paride/Euticals. In these e-mails, the parties discuss whether the requested content had been sent from Euticals to DRL. (D.I. 518 at 3; Tab 2)
- **Tab 3:** This is another “Patent Status” memorandum (with attachments); it was written by Dr. Paride, and though it seems to be dated January 7, 2015, the memorandum also contains content that appears to have been added as late as December

2015. The memorandum and attachments relate to the patent status regarding regadenoson, including information about Euticals' own patent application. This content, the entirety of which Defendants contend is protected from disclosure, was sent in a series of January 8, 2016 e-mails from Dr. Paride to DRL (in response to DRL's above-referenced December 9, 2015 request for information). (D.I. 518 at 3; Tab 3)

- **Tab 4:** This is an August 2017 e-mail string. Defendants seek to maintain a redaction to only one portion of the string, which amounts to the content of an August 23, 2017 e-mail between Mario Laderas, an AMRI employee and European Patent Attorney who works in AMRI's Intellectual Property Department in Spain, and DRL's Mr. Ganguly. (Verner Miller, who is "Senior Counsel, Intellectual Property" at AMRI, is also copied on the e-mail.). In the e-mail, which followed a teleconference between Mr. Ganguly and AMRI attorneys/representatives, Mr. Laderas is making reference to the content of certain material that appears to have been discussed during that teleconference. (D.I. 518 at 3; Tab 4)

In explaining why the common interest doctrine applies here, Defendants argue that the documents-at-issue "reflect the obvious and long-standing common legal interest between DRL and Euticals—preparing to defend against Plaintiffs' infringement allegations." (D.I. 518 at 1) More specifically, Defendants argue that: (1) Plaintiffs' infringement contentions are based, in part, on the premise that Euticals' "patented 'Form G' drug substance could contain some unidentified amount of [the claimed] 'Form A'"; and (2) if DRL were to receive regulatory approval to manufacture an ANDA product using Euticals' Form G drug substance, there "could be evidence that both Euticals and DRL would infringe" the asserted patents. (*Id.* (emphasis omitted)) The implication is that with regard to the documents-at-issue, Euticals and DRL had a common legal interest in avoiding such a lawsuit and that their communications furthered that interest.

Defendants' argument has some initial, superficial appeal. While attorneys are not directly participating in most of the four sets of communications in dispute, each of the disputed

portions of Tabs 1-4 seems to involve a discussion of some arguably *legal* issue with regard to the Euticals API. That is, in each of Tabs 1-4, DRL and Euticals employees appear to be discussing whether Euticals' API is patent protected and/or whether it is vulnerable to a challenge in light of certain prior art. And in most of the four document sets, all or portions of the communications are accompanied by various legal buzzwords, such as notations that the content is "privileged" or "protected from discovery" or "confidential[,] " or that it should be shared only between the parties' legal departments. (D.I. 518 at 2-3) So it is fair to say that the subject of these communications is in some sense *legal* in nature—even if the discussions are undoubtedly taking place at a time in which one party (Euticals) is trying to convince another party (DRL) to engage in a *commercial* transaction (i.e., to convince DRL to purchase the API from Euticals).

But in the Court's view, when one contextualizes the communications with regard to what was happening in the relevant time period, Defendants have not met their burden to demonstrate that DRL and Euticals *then* shared a common legal interest. After all, the communications in Tabs 1-4 all occurred between April 2015 and August 2017. And yet DRL: (1) did not select Euticals to be its API supplier until October 2018; (2) did not submit its paragraph IV certification until March 2019; and (3) was not sued by Plaintiffs until June 2019. (D.I. 508 at 2 & n.4; Tr. at 8, 16) Indeed, even as of 2017, not only was DRL still over a year away from agreeing to enter into any type of commercial relationship with Euticals, but DRL was then still apparently considering *five* different potential regadenoson API suppliers. (D.I. 508 at 2; *id.*, ex. D at 73-74)

Now, to be sure, even back in 2015 to 2017, it was theoretically possible that if a number of eventualities came to pass, DRL and Euticals might later find themselves in the same legal

boat. That is, *if* DRL eventually picked Euticals to be its API supplier (instead of one of those other four competing entities, or some other entity) and *if* a third party later threatened to or did assert their patent rights against DRL and/or Euticals with regard to the manufacture of the drug product at issue, *then* DRL and Euticals would likely find themselves aligned from a legal perspective. But in the Court’s view, in that 2015-2017 time frame, the prospect of DRL and Euticals sharing a common legal interest was too remote, contingent and uncertain to allow for invocation of the common interest doctrine here. (Tr. at 14-15, 20)³

Indeed, for similar reasons, courts have indicated that in order to demonstrate the existence of a common legal interest, the party with the burden should either point to evidence of an existing written agreement between it and the third party that relates to the disclosure, or failing that, at least cite to some other evidence indicating that a common legal interest had been solidified at the relevant time.⁴ And in the absence of that type of evidence, various courts

³ Of course, parties not need to be actually involved in litigation to share a common legal interest. *See MobileMedia Ideas LLC v. Apple Inc.*, 890 F. Supp. 2d 508, 515 (D. Del. 2012). But such litigation does at least then need to be firmly “anticipated.” *Id.* (citation omitted). And in the Court’s view, it is a bridge too far to conclude that in 2015-2017, Defendants and Euticals sufficiently and concretely anticipated that they would be involved in litigation regarding the API—*when they would not even agree to go into business together until years later*. Taken to the extreme, Defendants’ position could lead to a conclusion that Defendants had a common legal interest in that time frame with as many as five different potential API suppliers—four of which never actually entered into a business relationship with Defendants.

⁴ *See, e.g., Xerox Corp. v. Google Inc.*, 801 F. Supp. 2d 293, 303-04 (D. Del. 2011) (concluding that the plaintiff and a non-party patent licensing company shared a common legal interest at the relevant time, but where at that time plaintiff had retained the third party to assist with licensing strategy and patent enforcement, including litigation, such that it was clear that the two companies had “an allied, uniform, agency relationship”); *cf. Am. Mgmt. Servs., LLC v. Dept. of the Army*, 703 F.3d 724, 733 (4th Cir. 2013) (“The common interest doctrine does not require a written agreement, . . . nor does it require that both parties to the communications at issue be co-parties in litigation However, there must be an agreement or a meeting of the minds. . . . [M]ere indicia of joint strategy as of a particular point

(including this Court) have repeatedly concluded that no common legal interest had been formed between such parties. *See, e.g., Acceleration Bay LLC v. Activision Blizzard, Inc.*, Civil Action No. 16-453-RGA, 2018 WL 798731, at *1, *3 (D. Del. Feb. 9, 2018) (concluding that communications between the plaintiff and a third party made during negotiation of a litigation financing agreement were not protected by the common interest doctrine, because at the relevant time, the parties had no “written agreement [] to have a legally common interest[,]” and because the communications occurred before any agreement was reached and before any litigation was filed—such that the parties were not then “allied in a common legal cause”) (internal quotation marks and citations omitted); *Thought, Inc. v. Oracle Corp.*, Case No. 12-cv-05601-WHO (MEJ), 2014 WL 3940294, at *1, *3 (N.D. Cal. Aug. 11, 2014) (assessing communications between the plaintiff and third-party non-practicing entities, which were made at a time when the third parties were considering whether to acquire the plaintiff’s patents, and concluding that they did not evidence a common legal interest, where the third parties ultimately declined to acquire the patents and because “even if the correspondence had potential relevance to a hypothetical litigation[,] such interest is secondary to the immediate business decision of whether to purchase the patents”); *Leader Techs., Inc. v. Facebook, Inc.*, 719 F. Supp. 2d 373, 375–77 (D. Del. 2010) (overruling objections to an Order that found no common legal interest regarding communications between a patentee and litigation financing companies, “because a deal was not consummated between” those entities); *Corning Inc.*, 223 F.R.D. at 190-91 (concluding that the defendant did not share a common legal interest with a third party at a time when the third party was evaluating plaintiff’s patents, because the defendant had not sufficiently proven that “at the

in time are insufficient to demonstrate that a common interest agreement has been formed.”) (internal quotation marks and citations omitted).

time of their negotiations” it and the third party “shared identical legal interests”; instead, the disclosures “were made not in an effort to formulate a joint defense but rather to persuade [the third party] to invest in [the defendant]”). For the reasons set out above, the record here similarly fails to evidence the existence of a concrete common legal interest between DRL and Euticals in the April 2015 to August 2017 time period.⁵

Therefore, the Court hereby ORDERS that because Defendants have not met their burden to show the applicability of the common interest doctrine, the Motion is GRANTED.

Because this Memorandum Order may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the document. Any such redacted version shall be submitted by no later than **April 13, 2021** for review by the Court, along with a motion for redaction 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.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Order.

⁵ As noted above, to invoke the common interest doctrine, the party with the burden must first demonstrate that an “underlying privilege has been established.” *INVISTA*, 2013 WL 12171721, at *5. To the extent that Defendants are arguing that the underlying privilege that applies here is the attorney-work-product doctrine, (D.I. 508 at 3; D.I. 518, ex. 2), that would require a showing that the documents-at-issue were prepared by or on behalf of attorneys in anticipation of litigation, *see INVISTA*, 2013 WL 12171721, at *4. And for the reasons set out above, the Court concludes that Defendants have not demonstrated that the primary purpose of the documents’ creation was related to an “anticipation of litigation.” *Cf. TC Tech. LLC v. Sprint Corp.*, No. 16-cv-153-RGA, 2018 WL 6584122, at *3 (D. Del. Dec. 13, 2018) (noting that courts “look to the documents’ primary purpose to determine whether attorney client privilege applies”); (Tr. at 9). Instead, at most, the primary purpose of the documents (and the transmission of those documents) was to further the prospect of a future commercial transaction.

Dated: April 8, 2021

Christopher J. Burke

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE