Gmail

Max Gottlieb <mgottlieb@hfdrlaw.com>

Re: Regeneron v. Celltrion, No. 1:23-CV-89: Celltrion's Good Faith Deficiency Letter

1 message

Max Gottlieb <mgottlieb@hfdrlaw.com> Mon, Mar 4, 2024 at 3:28 PM
To: "Beazley, Jennalee" <jbeazley@wc.com>
Cc: Rhochelle Krawetz <rkrawetz@wc.com>, David Pogue <drpogue@cdkrlaw.com>, Steve Ruby <sruby@cdkrlaw.com>, Eylea <Eylea@wc.com>, Eylea Biosimilars <Eylea.Biosimilars@weil.com>, REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>, "Michael W. Johnson" <mjohnson1@willkie.com>, Mike Cottler <mcottler@geminilaw.com>, Robert Cerwinski <rcerwinski@geminilaw.com>, Matthew Freimuth <mfreimuth@willkie.com>, Aviv Zalcenstein <azalcenstein@geminilaw.com>, DG-Aflibercept <DG-Aflibercept@netorg8512690.onmicrosoft.com>, Andrew Robey <arobey@hfdrlaw.com>, Michael Hissam <mhissam@hfdrlaw.com>, "WFG-aflibercept@willkie.com" <WFG-aflibercept@willkie.com>, Carl Shaffer <cshaffer@hfdrlaw.com>, Kimberly Thomas <kthomas@hfdrlaw.com>, Teagan Gregory <TGregory@wc.com>

Jennalee,

I appreciate the response. As an initial matter, I see that Regeneron has adopted the tactical approach of responding to the deficiencies in its own discovery responses by continually reverting back its belief about what Celltrion did or didn't do in response to Regeneron's discovery requests. However, that approach is neither productive nor apt. And certainly the Court is not going to want to deal with finger pointing like that. Regeneron has never raised any of those issues in writing prior to yesterday's email and letter. To my knowledge, the first time any of those issues were raised was on our February 29 meet and confer call that was specifically and solely for the purpose of attempting to work through Regeneron's deficient discovery responses. Therefore, Regeneron has waived its right to pursue a motion to compel. That said, Celltrion can make itself available for a meet and confer the week of March 11 to discuss Regeneron's letter.

As for your positions with respect to the Regeneron deficiencies we discussed during the meet and confer, I will take up each one in order. On the *Mylan* materials, given that your team indicated that it "wanted" to produce the *Mylan* materials, I am disappointed to hear that Regeneron does not want to join in seeking the Court's assistance in making those available. To be clear, it is Regeneron's responsibility — not Celltrion's — to take the necessary action to produce the responsive materials. But it appears that Regeneron has opted not to take the necessary action to fulfill that responsibility. Given that, according to Regeneron, Mylan has refused to cooperate in a way that Regeneron believes it can produce the *Mylan* materials, it is Regeneron's obligation to seek relief from the Court on that front. As such, Regeneron's deficient responses and failure to produce the *Mylan* materials will be addressed in our forthcoming motion to compel. Also, contrary to Regeneron's position, the trial exhibits from *Mylan* are responsive to Celltrion's discovery requests, specifically, at the very least, RFPs 2, 4, and 7. That too will be addressed.

I am glad to hear that Regeneron has now abandoned its prior refusal to produce any privilege log. As we discussed, I certainly disagree that the Court's scheduling order did not contemplate providing privilege information. Indeed, as I have mentioned multiple times, the local rules require it. Regardless, in the interest of good faith cooperation, Celltrion is willing to agree to a 10 day extension of the motion to compel deadline for this issue to permit the parties time to see if a resolution can be reached. Given your email, ***if we do not hear otherwise by 6:00pmEST today***, we will assume Regeneron has agreed to that extension. We can get an agreed stipulation over to you tomorrow.

With respect to Regeneron's boilerplate objections, I believe Regeneron is mistaken about being made aware of the boilerplate objections. First, the repeated general and boilerplate objections should be, and are, clear from the face of Regeneron's responses. Second, on our meet and confer, we mentioned how the responses generally rely on the repeated boilerplate objections, such as unduly burdensome, not proportional, overly broad, and irrelevance. Of the 32 requests, Regeneron relied on substantially similar, if not nearly identical, language asserting those objections in response to 29 requests. Thus, Regeneron's assertion that it "can't reasonably guess" as to our concern about boilerplate objections falls flat.

However, given that Regeneron has indicated a willingness to discuss producing some Board materials, Celltrion is willing to agree to a 10 day extension of the motion to compel deadline for this issue to permit the parties time to see if a resolution can be reached. Given your email, ***if we do not hear otherwise by 6:00pmEST today***, we will assume Regeneron has agreed to that extension. That extension can be covered in the proposed stipulation noted earlier.

Finally, with respect to the packaging documents, specifically the LUCENTIS® materials/information, as we have repeated, RFPs 5 and 24 clearly cover those materials to the extent Regeneron or its agents had knowledge or possession of such information. Again, as we explained contemporaneously with service of RFPs 33 and 34, they were an effort by Celltrion to help provide a more targeted search in the interest of good faith cooperation. I am glad to hear that Regeneron is going conducting a review for the materials/information. Given that effort, Celltrion is willing to agree to a 10 day extension of the motion to compel deadline to permit Regeneron gather, identify, and produce those materials/information. Given your email, ***if we do not hear otherwise by 6:00pmEST today***, we will assume Regeneron has agreed to that extension. That extension can be covered in the proposed stipulation noted earlier.

As explained, it is clear that there remains some disagreement as to Regeneron's responses and production. Therefore, we will file the appropriate motion today with respect to those issues. With respect to the matters for which the parties will continue to try to work things out, Celltrion will prepare a proposed stipulation giving Regeneron 10 days to provide the necessary responses/materials **unless we hear otherwise by *6:00pmEST* today.**

Max C. Gottlieb
Lawyer

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On Mar 3, 2024, at 11:18AM, Beazley, Jennalee <jbeazley@wc.com> wrote:

Max,

Thank you for your note and for our call on Thursday.

I'll begin by reiterating an overarching concern we expressed on the call, namely that Celltrion itself has failed to produce (and seemingly has failed even to search for, collect, or review) the materials it agreed to produce in response to Regeneron's Requests for Production. The parties' requests were directed to a number of overlapping subjects, including issues relating to the irreparable harm inquiry and issues relating to patent validity and infringement. Yet, outside of the BLA Celltrion was required to produce by statute, Celltrion has produced only about 150 total documents. This stands in stark contrast to the nearly 67,000 documents produced by Regeneron to date. It is apparent that Celltrion has failed to perform the reasonable searches and productions promised in its own discovery responses and now seeks to leverage the resulting asymmetry of the productions to this point for strategic advantage. Regeneron will further outline its concerns in separate correspondence today, and we request that Celltrion make itself available to meet and confer no later than Monday.

With respect to the Mylan Litigation Written Discovery, the Mylan Litigation Trial Demonstratives, the Mylan Litigation Deposition Materials, and the Mylan Litigation Expert Reports, as defined in Regeneron's Responses and Objections to Celltrion's First Set of RFPs, we have explained that Regeneron is not in a position to unilaterally produce these materials given its Protective Order obligations in the Mylan litigation and Mylan's/Biocon's ("Mylan's") confidentiality assertions to date. We have been in contact with Mylan regarding these materials and have made multiple requests for Mylan to either confirm the absence of its confidential information or provide appropriately redacted versions. We have indicated to Mylan which of the documents we believe do contain Mylan confidential information and require their redactions and which we believe do not contain Mylan confidential information and for which we only request a confirmation of the same. Despite repeated efforts, Mylan has prohibited us from producing even documents in the latter category until they provide express authorization. In any event, we note certain of the documents falling within the Mylan Litigation Written Discovery, the Mylan Litigation Trial Demonstratives, the Mylan Litigation Deposition Materials, and the Mylan Litigation Expert Reports definitions are available and accessible by Celltrion on the public docket: e.g., Regeneron's First Set of Interrogatories to Mylan Pharmaceuticals Inc. (Nos. 1-2) (Aug. 31, 2022) Dkt. 299-11; Mylan Pharmaceuticals Inc. Answers and Objections to Regeneron's First Set of Interrogatories (Nos. 1-2) (Sept. 30, 2022) Dkt. 299-13; Mylan Pharmaceuticals Inc.'s Second Set of Interrogatories to Regeneron Pharmaceuticals, Inc. (Nos. 18-24) (Dec. 19, 2022) Dkt 252-19. To the extent Celltrion wishes to seek the involvement of the Court to further expedite this process, Regeneron does not object, but it also does not wish to burden the Court with yet another filing in this matter and declines to join your motion. With respect to your separate inquiry on our call regarding the trial exhibits from the Mylan litigation, these materials were not sought in Celltrion's First Set of RFPs.

With respect to your request that Regeneron produce privilege logs, I reiterate that the Court's scheduling order for this initial, preliminary injunction phase of the litigation does not contemplate the service of privilege logs. ECF 61 at 3. Celltrion apparently shared this view until quite recently, as Celltrion itself has not produced any privilege logs. Indeed none of the parties in these BPCIA actions that were the subject of the Court's January 9 scheduling order have served such logs. Respectfully, your "commit[ment] to produc[e] a privilege log by early to mid next week" "in the interest of cooperation and reciprocity" rings hollow. Having shared until now an understanding that the schedule does not include privilege logging—an understanding that makes good sense given the expedited nature of these proceedings—Celltrion now seeks to reverse course and demand an immediate exchange of logs. Celltrion's gamesmanship is apparent—that exchange would be "reciproc[al]" in name only, as Celltrion seeks to use the deficiency of its own production to shield itself from burden while using the Regeneron's good faith production efforts to impose an exponentially greater burden on its adversary. Nevertheless, Regeneron has begun working to prepare privilege logs for the materials relevant in these PI proceedings and will seek to serve those logs on a rolling basis over the coming days and weeks. As we note in our separate correspondence, we expect that Celltrion's commitment to produce a privilege log next week extends not just to the privileged material withheld or redacted during Celltrion's deficient searches and productions to date but will also

With respect to Regeneron's objections to Celltrion's First Set of RFPs, we explained the basis for each of the objections you wished to discuss on our call. Your email below does not identify the "boilerplate" to which you now object, and you did not clarify during our meet and confer. Nor can we reasonably guess as to the source of your concern—Celltrion's own general and specific objections are recited with less particularity than Regeneron's. With respect to Board of Director materials, which we did discuss, Regeneron believes its objections are entirely proper given the marginal relevance of these documents, their duplicative nature, their sensitivity, and the privilege issues presented. With that said, Regeneron is willing to discuss a compromise that would result in the production of Board materials from targeted time periods or as otherwise appropriate, assuming Celltrion will commit to conducting an appropriate search and production of its own Board materials. Your response that you "do not view this as something that must be reciprocal" is again revealing of Celltrion's troubling asymmetric view of discovery in this matter, and your attempt to shield Celltrion from equitable discovery based on the timing of its responses is not well taken. The immediate issue here is not Celltrion's responses (though those too are concerning)—it is Celltrion's failure to search for and produce documents consistent with even those responses. To put it simply, Regeneron should not be punished for conducting appropriate searches and making clear the limited categories of materials it is withholding from production while Celltrion is rewarded for conducting deficient searches and obfuscating the scope of its efforts. I note even now you have not confirmed whether Celltrion searched for or reviewed relevant Board materials.

With regard to Celltrion's additional RFPs 33 and 34, it has been over one month since the Court-mandated deadline to serve any requests for production for purposes of the preliminary injunction proceedings. That deadline was January 11, 2024. Under the Court's scheduling order, we have no obligation to serve additional documents responsive to belated requests. Celltrion's attempt to mask the additional requests as "clarifying" is a rather transparent attempt to seek additional information that Celltrion should have requested at the appropriate time, or otherwise sought via subpoena, and the service of a new set of RFPs serves as an implicit acknowledgement that your original set of RFPs did not cover this topic. None of the RFPs that Celltrion served by the deadline cover RFP Nos. 33 and 34, and Celltrion citing to RFP No. 5 ("All records concerning the alleged invention of the subject matter described or covered by the Identified Patents including, without limitation, laboratory notebooks, invention disclosure forms, and invention records") or RFP No. 24 ("All documents and things concerning the conception, reduction to practice, whether actual or constructive, and diligence from the date of conception to the reduction to practice of the subject matter recited in any claim of the Identified Patents, including without limitation laboratory notebooks, invention disclosures, presentations, and meeting minutes") for support is inapt. The language of RFP Nos. 5 and 24 clearly does not cover documents and things relating to the LUCENTIS® blister packaging —a product which has never been developed by Regeneron or used in developing Regeneron's products. Regardless of the total lack of justification for these additional requests from Celltrion, we can confirm that our previous collections and productions related to the 926 patent did not exclude mentions of ranibizumab or LUCENTIS® PFS. While an entirely new search covering your belated requests is not warranted, we nevertheless are reviewing the documents originally collected for any that are responsive to your new RFPs, and we will get back to you regarding what, if anything, we identify as relevant.

Regards,
Jennalee

Jennalee Beazley
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*Admitted only in Pennsylvania; practice supervised by D.C. Bar members.

From: Max Gottlieb <mgottlieb@hfdrlaw.com>
Sent: Thursday, February 29, 2024 1:40 PM
To: Gregory, Teagan <TGregory@wc.com>
Cc: Krawetz, Rhochelle <rkrawetz@wc.com>; David Pogue <drpogue@cdkrlaw.com>; Steve Ruby <sruby@cdkrlaw.com>; Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>; REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>; Michael W. Johnson <mjohnson1@willkie.com>; Mike Cottler <mcottler@geminilaw.com>; Robert Cerwinski <rcerwinski@geminilaw.com>; Matthew Freimuth <mfreimuth@willkie.com>; Aviv Zalcenstein <azalcenstein@geminilaw.com>; DG-Aflibercept <DG-Aflibercept@netorg8512690.onmicrosoft.com>; Andrew Robey <arobey@hfdrlaw.com>; Michael Hissam <mhissam@hfdrlaw.com>; WFG-aflibercept@willkie.com; Carl Shaffer <cshaffer@hfdrlaw.com>; Kimberly Thomas <kthomas@hfdrlaw.com>
Subject: Re: Regeneron v. Celltrion, No. 1:23-CV-89: Celltrion's Good Faith Deficiency Letter

Teagan,

Thanks to you and your team for the productive meet and confer today. I write to memorialize the topics of discussion and deliverables.

- Mylan documents

- As we discussed, it would be helpful to finalize a determination, even if by category, of documents that (i) Regeneron has produced regarding the Mylan action; (ii) documents that Regeneron desires to produce but believes it can't do to the outstanding issues with Mylan confidentiality assertions; and (iii) documents that Regeneron does not intend to produce. That list will help to understand the universe of outstanding documents, and will help the Court in the event that we (jointly or individually) are forced to seek its assistance in obtaining production on the Mylan action.
  - We asked for production of the Mylan trial exhibits. You stated that you had not agreed to produce these but that you would take it back and see if this was something you could commit to producing.
  - We also expressed the urgency of having Mylan litigation documents relating to Dr. Trout, as his deposition is in less than two weeks.

· Privilege logs
  - I appreciate you confirming that Regeneron withheld documents based upon the assertion of privilege. We reiterated our request, as set forth in Max's February 19 letter, for the required privilege logs/information. You said you would take the request to provide privilege logs back to your team. Please let us know your position before Monday. In the interest of cooperation and reciprocity, we can commit to producing a privilege log by early to mid next week. We hope and expect that Regeneron will be able to do the same.
  - Notwithstanding your general objection to producing a privilege log, we understand that you will by tomorrow provide a copy of the redacted document you recently clawed back on the basis of privilege, along with a privilege log entry related to the redacted information.

· Documents withheld on the basis of general, boilerplate objections
  - As noted during the call, in this jurisdiction, withholding documents on the basis of boilerplate general objections as you have done is improper. Please let confirm whether you will continue to stand on those repeated boilerplate objections.
  - Although you refuse to produce documents regarding board of direct meetings, including presentations, you do not dispute the relevance of such documents. Rather, you claim those documents are duplicative of other documents you produced and the review and production of them would be burdensome. To help us better understand your objection, we asked you to identify how many documents are being withheld on the basis of this objection, and to identify documents representative of those that are withheld. Please let us know your position on this before Monday. As a compromise, however, would Regeneron be amenable to producing board of director meetings, including presentations, from the 2004-2006 timeframe related to the development of the EYLEA formulation, and from the 2015-2019 timeframe related to the development of the blister packaging for the PFS?
  - You asked if Celltrion withheld board of director-related documents, but we do not view this as something that must be reciprocal. For over a month now, you have had Celltrion's objections and responses to Regeneron's first set of requests, along with Celltrion's PI document production, and the scope of what Celltrion agreed to produce, and did produce, was clear.

· Documents concerning Lucentis packaging
  - As we mentioned on the call, documents concerning Lucentis packaging are covered by, for example, Celltrion's RFP No. 5, which requests "All records concerning the alleged invention of the subject matter described or covered by the Identified Patents including, without limitation, laboratory notebooks, invention disclosure forms, and invention records." Likewise, as we discussed, those Lucentis documents are responsive to RFP No. 24. Such documents would have been undisputedly relevant and in the possession of the inventors at the time of the invention. You stated that you had made a document collection from both of the named inventors of the '926 patent. You also represented that your team is going back and look to see if documents concerning Lucentis were collected in your document collection but not produced. Please let us know the results of that search, including whether you used key word searches to limit the scope of documents collected from the named inventors' files.

I appreciate your efforts to resolve these issues, especially in light of the fact that we need to resolve them, prior to Monday's motion to compel deadline. Of course, please feel free to reach out to discuss further.

Kindly,
Max

Max C. Gottlieb
Lawyer

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Thanks, Max - will plan to join at 9:10.

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From: Max Gottlieb <mgottlieb@hfdrlaw.com>
Sent: Thursday, February 29, 2024 8:54 AM
To: Krawetz, Rhochelle <rkrawetz@wc.com>
Cc: Gregory, Teagan <TGregory@wc.com>; David Pogue <drpogue@cdkrlaw.com>; Steve Ruby <sruby@cdkrlaw.com>; Eylea <Eylea@wc.com>; Eylea Biosimilars <Eylea.Biosimilars@weil.com>; REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>; Michael W. Johnson <mjohnson1@willkie.com>; Mike Cottler <mcottler@geminilaw.com>; Robert Cerwinski <rcerwinski@geminilaw.com>; Matthew Freimuth <mfreimuth@willkie.com>; Aviv Zalcenstein <azalcenstein@geminilaw.com>; DG-Aflibercept <DG-Aflibercept@netorg8512690.onmicrosoft.com>; Andrew Robey <arobey@hfdrlaw.com>; Michael Hissam <mhissam@hfdrlaw.com>; WFG-aflibercept@willkie.com; Carl Shaffer <cshaffer@hfdrlaw.com>; Kimberly Thomas <kthomas@hfdrlaw.com>
Subject: Re: Regeneron v. Celltrion, No. 1:23-CV-89: Celltrion's Good Faith Deficiency Letter

Hi Rhochelle,

Just FYI, having a call bleed over. We will likely start about 9:10 if that works for you all.

Thanks,
Max

Max C. Gottlieb
Lawyer

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> On Feb 28, 2024, at 11:00 PM, Krawetz, Rhochelle <rkrawetz@wc.com> wrote:
>
> Max,
>
> Please see the attached correspondence.
>
> Best,
> Rhochelle
>
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>
> **From:** Gregory, Teagan <TGregory@wc.com>
> **Sent:** Wednesday, February 28, 2024 1:07 PM

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