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August 17, 2018

The Honorable Leonard P. Stark
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Bayer HealthCare LLC v. Teva Pharmaceuticals USA, Inc.*,
Civ. A. No. 1:16-01221-LPS (D. Del.) (Consolidated)

Dear Chief Judge Stark:

I write on behalf of Plaintiffs' Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc. ("Bayer") in response to Defendants' August 15, 2018 letter. Bayer has more than satisfied its discovery obligations in this case, producing approximately 100,000 documents constituting 8 million pages, the overwhelming majority of which are research and development documents. Defendants' requests for additional discovery should be denied.

I. Date Limitation for Inventor Emails

Although Defendants downplay the significance of their request, Defendants' proposal to extend email searches for the named inventors on three patents would derail the Court's schedule for this litigation and be highly prejudicial to Bayer. In essence, Defendants would have Bayer undertake a new, burdensome search and review process of email from multiple custodians, just weeks before the close of fact discovery and months after the deadline for substantial completion of document production. That extreme request is unjustified. Bayer informed Defendants of the date limitations it would use for inventor collections in ***January***—seven months ago—when it served Responses to Defendants' Requests for Production. Ex. A, at 13. Bayer then proceeded, at great burden and expense, to search for, review, and produce its documents, and the parties have already begun taking depositions. Yet now, at this last stage of fact discovery, Defendants for the first time raise this issue with the Court. It is far too late in the day to be debating this question, and Defendants, having sat on this issue, have no one to blame but themselves for failing to press it sooner. To be clear, what Defendants are asking for is a major project. Bayer would need to first conduct searches for documents in question, and then re-start its document review process before any productions could begin. That would take a significant amount of time. In the meantime, the Court's schedule will require a substantial modification, imperiling not only the close of fact discovery, but later dates as well. Defendants could have raised this issue long ago. The prejudice caused by Defendants' delay alone warrants denying their request.

Moreover, Defendants' request is not the narrow compromise that they suggest. For two of the asserted patents that derive from U.S. priority documents (the '553 and '124 patents), Bayer applied date limitations based on the filing date of the U.S. or U.S.-PCT application[1]; for a third (the '107 patent), Bayer applied a date limitation for the foreign priority document. For the '834 patent, Bayer reproduced the documents from a prior patent case before this Court involving Bayer's Nexavar® product. As Defendants acknowledge, Bayer did not apply a date limitation in that litigation. However, it is precisely because of Bayer's experience in that case—which resulted in Bayer's production of substantial quantities of unused and irrelevant documents—that Bayer chose to impose reasonable date limitations here. Defendants are asking for one to four more years of inventor emails depending upon the patent at issue—all of which, by definition, post-date the conception of the invention and the filing of the relevant application.[2] And it is not as if the categories of documents Defendants request are already neatly organized somewhere, waiting to be picked up. Bayer would need to review the custodial emails to identify the particular categories of documents that Defendants have requested (many of which will be in German) and then produce them. That is no small task, and highlights the unreasonableness of Defendants' request at this late stage in fact discovery.

Nor are Defendants able to articulate the relevance of these documents beyond a blind search for materials that they hope may be helpful to their written description and enablement defenses. Defendants have not presented any plausible argument that would justify additional custodial email productions, and certainly have not linked their request to any particular written description or enablement issue that they have raised in this case. Indeed, Defendants' only explanation is a boiler-plate recitation of the applicable standards for written description and enablement. *See* D.I. 81, at 2. That is no explanation at all. Moreover, Defendants' letter ignores the information that is actually in the patent applications that were used for the date limitations. For example, for the '553 patent, Defendants' enablement/written description allegations are limited to two claims directed to metabolites of regorafenib; but metabolites of regorafenib are described in the U.S. application. Similarly, Defendants' enablement/written description arguments for the '107 patent focus on methods of detecting certain impurities in regorafenib, but the priority application for the '107 patent provides such methods of detection. What issue Defendants may be thinking of is anyone's guess; it certainly is not in their letter.

Furthermore, Bayer has already produced numerous categories of research and development documents that are not subject to any date limitation, undermining Defendants' suggestion that Bayer's production is somehow inadequate. Those documents include (1) files

[1] Defendants incorrectly suggest that Bayer used the date of the first U.S. provisional application for the '553 patent as a cut-off. *See* D.I. 81, at 2. Rather, Bayer applied the date of the non-provisional U.S. application, which was filed one year later.

[2] The reason the application that led to the '107 patent was filed four years after the relevant priority document (as opposed to one year) is that the '107 patent issued from a continuation of an earlier application. Defendants' suggestion that this additional period of time is somehow relevant to any issue in this case is without basis, and certainly is not justified by their letter.

from Bayer's central archive of research and development reports (the "Pharma Reports"); (2) files from Bayer's former West Haven facility, where regorafenib was first synthesized; (3) documents from Bayer's archive of FDA regulatory materials; and (4) batch records of large-scale syntheses of regorafenib. Contrary to Defendants' assertion, the Pharma Reports and regulatory documents are not "vague narratives that fail to provide key information." D.I. 81, at 2 n.1. They are files that Bayer relies upon outside of litigation to document its research and development efforts. Collectively, the documents that Bayer has produced constitute more than reasonable discovery. Defendants articulate no basis for their assertion that they are missing anything that is relevant to any issue actually in this case; and in any event, they could have raised this issue months ago. Put simply, there is no reason to blow up the schedule merely because Defendants want to go fishing for additional documents.

II. Documents from the Onyx Litigation

Defendants' request for certain transcripts from a prior litigation between Bayer and Onyx (which has since been acquired by Amgen) is also unjustified. The Onyx litigation was not a patent case and is not relevant to this action. It involved Onyx's allegations of breach of contract and fiduciary duty over the terms of the parties' collaboration, and centered on internal research at Bayer that was not public and was known only to Onyx on confidential terms. Nevertheless, despite this irrelevance,[3] Defendants omit from their letter that Bayer has already agreed to produce the vast majority of materials that Defendants have requested from the Onyx case, specifically: (1) deposition transcripts and exhibits for all Bayer fact witnesses; (2) all expert reports and any exhibits to those reports; (3) expert deposition transcripts and exhibits; and (4) all pleadings, so long as those materials do not contain Onyx's confidential information. Documents, pleadings, and testimony in the Onyx case, like this one, are covered by a protective order prohibiting their disclosure. Bayer requested permission from Amgen to produce Onyx's confidential information. With certain very narrow exceptions, that permission was denied. Indeed, Bayer has expended substantial time, effort, and money to attempt to comply with Defendants' requests, in particular to determine whether the materials can be properly disclosed. Following this review, Bayer is withholding only a narrow set of documents from the categories identified above on confidentiality grounds, as Bayer does not have permission to produce them.

Despite the documents that Bayer has agreed to produce, Defendants still insist on obtaining deposition transcripts and exhibits for Onyx fact witnesses. However, Defendants have failed to articulate why the prior testimony of a third-party's employees in an unrelated litigation regarding confidential contractual matters are relevant to any issue in this case. Moreover, at least some of these materials will contain Onyx's confidential information, which Bayer could not produce, even if somehow relevant.

In short, there is no basis for Defendants' position that they have not received enough materials or that the process has been somehow insufficient. The request should be denied.

[3] Bayer disagrees with various statements that Defendants make about sorafenib and regorafenib, but will not provide a detailed response in the limited space available for this discovery dispute.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/bac
Enclosure

cc: Clerk of Court (via hand delivery; w/enclosure)
All Counsel of Record (via electronic mail/ w/enclosure)