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August 15, 2018

**BY HAND DELIVERY**
The Honorable Leonard P. Stark
United States District Court
844 North King Street
Wilmington, DE 19801

Re: *Bayer Healthcare LLC, et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 16-1221-LPS

Dear Chief Judge Stark:

We represent Teva Pharmaceuticals USA, Inc. ("Teva") in the above-referenced matter. We write on behalf of Apotex Inc., Apotex Corp. (collectively, "Apotex"), and Teva (collectively, "Defendants") to request that the Court compel Bayer HealthCare LLC and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") to produce documents concerning (1) the research and development of the alleged invention after certain cutoff dates and (2) documents from previous litigations involving one of the patents asserted in this case and/or the development of the invention claimed therein. This information is material to the depositions of the inventors of the patent-in-suit. Despite numerous meet and confers spanning months, Bayer has maintained its refusal to produce this relevant information.

## I. Brief Factual Background

This is a patent infringement case in which Bayer alleges that Teva's ANDA product infringes U.S. Patent Nos. 7,351,834 ("the '834 patent"), 8,637,553 ("the '553 patent"), 8,680,124 ("the '124 patent"), and 9,458,107 ("the '107 patent"). Bayer alleges that Apotex infringes the '553 and '107 patents. The '834 and '553 patents are directed to compounds used to treat cancer, including the molecule at issue, regorafenib. The '124 patent is directed to a method of treating certain cancers using regorafenib, and the '107 patent is directed to regorafenib compositions containing certain levels of impurities.

Defendants contend, *inter alia*, that each asserted claim of the '834, '553, '124, and '107 patents is invalid for anticipation and/or obviousness, and, for certain claims, failure to satisfy the written description and enablement requirements under 35 U.S.C. § 112. In response to Defendants' obviousness defenses, Bayer asserts secondary indicia of nonobviousness, including unexpected properties, commercial success, long-felt need, failure of others, regulatory approval, industry recognition/acceptance, skepticism, copying, and praise.

## II. Bayer Has a Duty to Produce Research and Development Documents

Defendants served document requests seeking information concerning the research and development ("R&D") of the alleged inventions. Bayer refuses to produce custodial R&D documents created after different cutoff dates for each of the asserted patents unless Defendants

reimburse Bayer's costs associated with review and production.[1] Specifically, Bayer has unilaterally cut off its custodial document collection from the named inventors as follows: '553 patent – filing date of provisional application; '124 patent – filing date of PCT application; '107 patent – filing date of foreign application to which priority is claimed. The cutoff date for the '107 patent precedes the U.S. filing date by *four years*.[2]

During the meet-and-confer process, Defendants significantly narrowed their requests to an extension of searches of custodial emails for PowerPoint presentations, meeting minutes, memoranda, and reports relating to R&D of regorafenib to one year after the U.S. filing dates for the patent(s) on which the custodian is a named inventor to accommodate Bayer's unsupported protestations of undue burden. Bayer still refused to produce these documents.

The routine R&D discovery that Defendants seek is relevant to, *inter alia*, Defendants' written description and enablement defenses. For example, Defendants allege that the patent applications lack sufficient information to show that the inventors were in possession of the alleged invention when they filed their application and that persons of skill would have had to engage in undue experimentation to determine whether the invention actually worked as described. The type and extent of tests Bayer performed after the filing date directly informs this inquiry. *E.g.*, *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1375 (Fed. Cir. 2017) (holding that exclusion of post-patent-filing evidence was error and remanding for new trial on written description and enablement); *Plant Genetic Sys. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1343-44 (Fed. Cir. 2003) (finding that district court properly considered post-filing-date research efforts in its non-enablement determination).

Bayer has argued that the production of the requested documents would be unduly burdensome. But, despite Defendants' repeated requests, Bayer has failed to demonstrate that this burden is *undue* or that this burden is not proportional to the importance and relevance of the requested documents. Costs associated with Bayer's production of narrow categories of highly relevant, routine R&D documents should not be shifted to Defendants. *See, e.g.*, *Juster Acquisition Co., LLC v. N. Hudson Sewerage Auth.*, 12-3427 (JLL), 2013 U.S. Dist. LEXIS 18372, at *8-12 (D.N.J. Feb. 11, 2013) (citing *Zubulake v. UBS Warburg LLC*, 216 F.R.D. 280, 283-84, 287 (S.D.N.Y. 2003) and *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309, 318-321 (S.D.N.Y. 2003)).

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[1] Bayer has agreed to produce only regulatory filings and "Pharma Reports" after these cutoff dates. Unlike the requested custodial documents (i.e., emails and attachments), these regulatory documents and Pharma Reports are vague narratives that fail to provide key information, including when various activities were performed, why Bayer chose to perform them, how they fit into Bayer's R&D efforts, how long they took to perform, and who was involved in performing them.

[2] Bayer previously produced documents concerning the research and development of the '834 patent in another matter in this district and did not adopt a unilateral cutoff date. As a result, this dispute only pertains to the '553, '124, and '107 patents. Bayer's new approach in this case stands in stark contrast to its past practices (and defense counsels' experience with ANDA litigation in this district).

Bayer should be required to provide Defendants discovery relating to its R&D efforts during the critical, narrowly limited, post-filing timeframe. Indeed, Bayer's invention story at trial will not stop with the filing of its provisional applications, and Defendants are entitled to the discovery necessary to test such testimony. For the foregoing reasons, Defendants respectfully submit that the Court should order Bayer to produce the custodial emails and attachments relating to research and development of regorafenib through the period ending one year after the U.S. filing dates for the patent(s) on which the custodian is a named inventor.

**III. Defendants Are Entitled to Certain Documents from Previous Litigations**

Bayer also refuses to produce certain documents from a previous litigation involving a dispute related to development of the claimed invention. In that litigation Bayer was sued by Onyx, a company with whom Bayer partnered to develop a drug known as sorafenib. Sorafenib, like the regorafenib compound at issue in this case, is covered by the asserted '834 patent. The sorafenib and regorafenib compounds are nearly identical, and so Onyx sued Bayer for breach of their joint development agreement, arguing that regorafenib was a collaboration compound under the agreement entitling Onyx to share in the profits. While the Onyx litigation was a breach of contract action, the disputed issues centered on the development of sorafenib and regorafenib. Notably, sorafenib is not only an embodiment of the '834 patent, it is also the closest prior art to the asserted claims of the '553 patent, making it relevant to the issues of unexpected results and commercial success.[3] In fact, there appears to be evidence that regorafenib may have been conceived during the development of sorafenib. As such, sorafenib is a focus of Defendants' obviousness and anticipation defenses to the '553 patent.

Naturally, Defendants requested production of documents from the Onyx litigation concerning the R&D of sorafenib, comparisons of regorafenib and sorafenib, and the marketing and sales of sorafenib. Bayer has withheld transcripts and corresponding exhibits from certain, unidentified, Onyx fact witness addressing these topics on the basis that they are not relevant and likely contain Onyx confidential information.[4] While Bayer has confirmed that Onyx objected to the production of other materials (*see* n.4), Bayer has not indicated that Onyx objects to the production of these materials. Ex. A. Defendants request the Court to order Bayer to either produce the documents or proffer a written objection from Onyx to the production of these materials and the reasons therefore, taking into consideration Defendants' willingness to maintain them on an outside-counsel-only basis.

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[3] Commercial success does not rebut obviousness if that success is attributable to features of the invention that are found in the prior art. *E.g.*, *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006).

[4] Earlier today Bayer informed Defendants that Amgen, which has acquired Onyx, has objected to the production of confidential Onyx exhibits addressed by experts and fact witnesses, as well as the testimony of the damages experts in that matter. Defendants have followed up with Amgen to determine whether it will agree to production of these materials on an outside-counsel-only basis, and are hopeful that Amgen will consent to production under these terms since it would afford even greater protection of those documents than they presumably received in the Bayer/Onyx litigation.

Respectfully submitted,

*/s/ Nathan R. Hoeschen*

Nathan R. Hoeschen (No. 6232)

cc: Clerk of Court (via hand delivery)
Counsel of Record (via electronic mail)