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VIA ECF

The Honorable Katherine B. Forrest
United States District Judge
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl St.
New York, NY 10007-1312

Re: *Regeneron Pharmaceuticals, Inc. v. Ablexis, LLC*, Case. No. 14-CV-1651 (KBF)
[rel. 14-CV-1650 (KBF)]

Dear Judge Forrest:

Defendant Ablexis, LLC ("Ablexis") respectfully requests this Court to **compel Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") to produce documents related to the prosecution of non-U.S. patent applications related to the '018 patent-in-suit.** Regeneron has refused to produce these documents, despite their plain relevance to this case.

Ablexis served Regeneron with Rule 34 document requests on April 14, 2014. (Ex. 1). Regeneron responded with written objections on May 14, 2014. (Ex. 2). On June 27, 2014, Ablexis detailed the deficiencies in Regeneron's production. (Ex. 3). In particular, Ablexis requested clarification why Regeneron had refused to produce documents in response to Request for Production No. 6, which concerns non-U.S. patent applications related to the patent-in-suit. The parties met and conferred on July 7, 2014. At the meet and confer, Regeneron again refused to produce documents in response to Request No. 6, but asked Ablexis if it would consider narrowing the request. In the interest of cooperation, Ablexis took Regeneron's request under advisement, but reiterated that documents relating to the requested non-U.S. patent applications were relevant. After giving careful consideration to Regeneron's request, Ablexis determined that Request No. 6 sought relevant documents and, given the scope of the patent family of which the '018 patent is a member, was reasonable and not overly broad. Ablexis subsequently notified Regeneron that it would not narrow Request No. 6. Regeneron again refused to produce documents in response to Request No. 6. (Ex. 4).

Request No. 6 asks for:

All documents and things concerning any foreign proceeding, whether judicial or administrative, whether pending or concluded, whether *inter partes* or *ex parte,* involving the '018 patent, or any Related Application or Related Patent, and all searches, studies, investigations, reports, analyses, or other documents and things concerning the above.

"Related Application" and "Related Patent" are defined to mean:

(1) any patent or patent application, whether pending, abandoned, published or granted that claims priority or benefit to or ultimately to U.S. Patent No. 6,586,251, Application No. 09/732,234, or Provisional Application No. 60/244,665, and (2) any continuation, continuation-in-part, divisional, reissue, substitution, term adjustment, extension, reexamination, patent of addition, supplementary protection certificate, or foreign counterpart of any patent or patent application identified in part (1).[1]

On information and belief, Regeneron has patent applications pending around the world that are related to the '018 patent-in-suit. Regeneron's statements and actions (both internal and external) in these non-U.S. proceedings are relevant to assess noninfringement, invalidity, and unenforceability of the '018 patent. Non-U.S. prosecution documents are relevant for a number of reasons and should be produced. As Regeneron previously told the Court, "relevance, for purposes of discovery, is an extremely broad concept." (14-CV-1650 D.I. 60 at 2, *citing Chen-Oster v. Goldman, Sachs & Co.*, 293 F.R.D. 557, 561 (S.D.N.Y. 2013)). Regeneron cannot claim that documents, in a clearly relevant area, are not subject to production. This District has previously ordered parties to produce the files of non-U.S. patent agents. *Golden Trade, S.R.L. v. Lee Apparel Co.*, 143 F.R.D. 514, 524-526 (S.D.N.Y. 1992).

Non-U.S. prosecution documents are also relevant to claim construction. A limiting statement by Regeneron about a term in a non-U.S. proceeding that is also at issue in this case is relevant and discoverable and could help construe the claims at issue in this case. The Federal Circuit recently reiterated its reliance on non-U.S. prosecution documents to construe claims. *See, e.g., Starhome GmbH v. AT&T Mobility LLC,* 743 F.3d 849, 858 (Fed. Cir. 2014); *Apple Inc. v. Motorola, Inc.*, 2014 U.S.App.LEXIS 7757, at *49-53 (Fed. Cir. Apr. 25, 2014). Had Regeneron not delayed its production, additional evidence might already be available for the preliminary phases of claim construction.

Non-U.S. prosecution documents are also relevant for estoppel and noninfringment purposes. *Caterpillar Tractor Co. v. Berco.*, 714 F.2d 1110, 1116 (Fed. Cir. 1983)

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[1] The '665 U.S. application, filed October 31, 2000, is the earliest application to which the '018 patent claims benefit. The '234 U.S. application, filed December 7, 2000, issued as the '251 patent, the first U.S. patent in the priority chain of the '018 patent.

("representation[s] to foreign patent offices should be considered ... when [they] comprise relevant evidence."); *Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n.*, 109 F.3d 726, 732 (Fed. Cir. 1997). In *Tanabe*, the Federal Circuit considered representations made to non-U.S. patent offices and found them relevant in finding noninfringement under the doctrine of equivalents. 109 F.3d at 733-34. To the extent Regeneron plans to rely on the doctrine of equivalents, representations made to non-U.S. patent offices are, therefore, relevant and should be produced.

Non-U.S. prosecution documents are also relevant for enforceability purposes.[2] For example, in the *Therasense* litigations, one question at issue was whether a patent was unenforceable for inequitable conduct because of the prosecutor's failure to disclose arguments made to the European Patent Office that contradicted statements made to the USPTO. *Therasense v. Becton, Dickenson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011). Such conduct is a concern in this litigation. In 2013, Merus, and Kymab Ltd. (and later joined by several other companies), filed Oppositions against European Patent No. 1 360 287 B1, a European patent in the same family as the '018 patent-in-suit. This Opposition referenced prior art that was not disclosed during prosecution of the application that issued as the '018 patent. (14-cv-1650 D.I. 75 at 1). The circumstances surrounding the lack of disclosure are highly relevant to a finding of inequitable conduct. *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 1179-82 (Fed. Cir. 1995) (inequitable conduct found because of failure to disclose material reference to the PTO that was disclosed to foreign patent offices).

To the extent Regeneron argues that Ablexis Request No. 6 is overbroad, it is not. Ablexis is only asking for documents concerning the non-U.S. prosecution of patent applications related to the '018 patent. Regeneron's '018 patent cannot be analyzed in a bubble. The '018 patent, though filed in 2011, claims priority through at least six patent applications all the way back to 2000 (the '665 provisional application). The patents and applications in the '018 family have counterparts throughout the world. It is Regeneron that chose to claim priority to these other patents and applications. Accordingly, Regeneron has made all of the patents and applications related to the '018 family relevant to this action.

Regeneron may argue that Ablexis should be forced to obtain the non-U.S. patent documents itself, if they are available publicly. This is not reasonable. Ablexis does not only seek public documents. Ablexis also seeks internal documents which can only be obtained from Regeneron's files. In addition, it would be extremely burdensome for Ablexis to seek public documents related

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[2] In its July 21, 2014 response letter concerning Merus's Interrogatory No. 3, Regeneron argues that inequitable conduct allegations need to be pleaded to be relevant. (14-CV-1650 D.I. 77). This is a circular argument. Ablexis has not yet pleaded inequitable conduct because such allegations must be pleaded with particularity. Ablexis currently needs facts from discovery that Regeneron is withholding to make any such pleadings. The subject matter of inequitable conduct is relevant to the present action and Ablexis reserves all rights to amend the pleadings to add counterclaims or defenses of inequitable conduct.

to the non-U.S. members of the '018 family. First, Ablexis does not know the countries in which Regeneron filed applications related to the '018 patent. Indeed, Ablexis asked for that information in its Interrogatory No. 4, but Regeneron refused to provide an answer. (Ex. 5). Second, even if Ablexis did know the countries where Regeneron filed applications related to the '018 patent, it would be extremely burdensome to obtain to those documents. Other countries do not have the same online system for obtaining publicly-filed documents that exists in the United States. In many cases, a non-U.S. patent agent needs to be hired to make specific requests in the local patent offices at considerable expense. On the other hand, it should be easy for Regeneron to produce those documents to Ablexis. Regeneron simply needs to turn over its files, or otherwise obtain them from its patent agents.

Ablexis respectfully requests an order compelling production of documents responsive to Ablexis Request for Production No. 6 by August 8, 2014, so that they may be considered in connection with claim construction and other issues in this case.

Respectfully submitted,

/s/ James F. Haley, Jr.

James F. Haley, Jr.
Attorney for Defendant Ablexis, LLC

Ordered

This letter motion is too "net" on relevance of the requested documents -- the assertions on page 2 are simply broad statements re "noninfringement, invalidity, and unenforceability." Of course, you need to give some indication of "how" or "why." Please submit no more than 2 pages on relevance by Noon 7/23/14. Plaintiff shall take such relevance statements into account in any opposition.

7/22/14

K. B. Forrest
USDJ