IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD	:	
v.	:	CIVIL NO. 17-cv-01065-MSG-RL
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC.	:	

MEMORANDUM AND ORDER CONCERNING DOC. NO. 70

Defendants (collectively, "Boehringer"), filed a motion to compel production of supply, distribution, and manufacturing agreements (BI Mot.) Doc. No. 70. Plaintiffs (collectively, "AbbVie") filed a response (AV Res.; Doc. No. 78) and Boehringer filed a reply (BI Rep.; Doc. No. 85). Boehringer requested "[d]ocuments and things from February 9, 1996, to December 18, 2014, concerning any supply, distribution, or manufacturing agreements concerning adalimumab or a formulation containing adalimumab, including, but not limited to, proposed and executed agreements." Request for Production of Documents and Things (Second Set) No. 30 (RPD No. 30). BI Mot. Exh. 1 at 7. AbbVie objects to the production of responsive documents from the period after January 2003, the date it concedes Humira was on sale or offered for sale. AV Res. at 4. AbbVie also objects because production of these documents for a 20 year period would require it to search in multiple locations around the country and world. *Id*. It would also be necessary to address confidentiality obligations with numerous third parties. *Id*. AbbVie does not supply any detail on the number of documents involved or the number of locations that will have to be searched. *Id*.

Boehringer contends the documents are relevant to its "on sale" defense. BI Mot. at 1. Under 35 U.S.C. § 102(b), if a patented product was "on sale" more than one year before the filing date of the patent, the patent is invalid. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 424 F.3d 1276, 1283 (Fed. Cir. 2005); *Apotex Inc. v. Cephalon, Inc.*, No. 06-2768, 2011 WL 6090696, at 13 (E.D. Pa. Nov. 7, 2011) (citing to *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68, (1998) and *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1327 (Fed. Cir. 2001)). Boehringer points out that AbbVie asserts patents filed as recently as October 18, 2013, "more than a decade after adalimumab was approved by the FDA (on December 31, 2002) and first sold in the United States by AbbVie (in January 2003)." BI Mot. at 3.

AbbVie is willing to produce "executed distribution agreements dated before January 2003, to the extent of such agreements." [sic] AV Res. at 4. Boehringer has agreed to limit its request for documents after January 2003 "to those concerning manufacture, distribution, or sale in the United States (not worldwide) up through 2011." BI Rep. at 3.

Both executed and proposed agreements may be relevant to the "on sale" defense. *See Merck & Cie v. Watson Laboratories, Inc.*, 822 F.3d 1347, 1351 (Feb. Cir. 2016) (a commercial offer to sell may invalidate a patent).

I find that AbbVie's limitation of the time period to 2003 does not suffice. Patents affecting Humira were filed as recently as 2013. Roughly speaking, that which was "on sale" must match the contours of the patent it seeks to invalidate. If the patent changes, it is likely that the contours of the "on sale" defense may change as well.

As modified in my order, below, the document request is reasonably relevant to the claims and defenses in the case, and proportional to the needs of the case. The

financial stakes are large; the parties' resources abundant; AbbVie has the documents, and Boehringer does not have access to them; the information may be important to an "on sale" defense, which is not an inconsiderable possibility in this case, given the spread of patents over a number of years; and the burden of discovery does not outweigh its likely benefit. Fed. R. Civ. Pro. 26(b)(1).

Accordingly, on this ___ day of May, 2018, it is **ORDERED**, that AbbVie shall produce all documents and things requested in RPD No. 30 from February 9, 1996 to January 31, 2003 (worldwide and United States) and from January 31, 2003 to December 31, 2011 (United States). AbbVie must produce not only executed distribution agreements, but also (1) supply and manufacturing agreements and (2) proposed distribution, supply and manufacturing agreements.

BY THE COURT:

s/ Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE