

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG; ABBOTT BIORESEARCH CENTER, INC.; and ABBOTT BIOTECHNOLOGY LTD.,)	
)	
Plaintiffs,)	Civil Action No.
)	09-11340-FDS
v.)	
)	
CENTOCOR ORTHO BIOTECH, INC., and CENTOCOR BIOLOGICS, INC.)	
)	
Defendants.)	
)	

**MEMORANDUM AND ORDER ON DEFENDANT’S MOTION TO AMEND
PRELIMINARY INVALIDITY AND NON-INFRINGEMENT CONTENTIONS**

SAYLOR, J.

This is a patent dispute involving a pharmaceutical product. Plaintiffs Abbott GmbH & Co., KG; Abbott Bioresearch Center, Inc.; and Abbott Biotechnology Ltd. (collectively “Abbott”) seek a judgment that the drug Stelara, manufactured by defendants Centocor Ortho Biotech, Inc., and Centocor Biologics, Inc. (collectively “Centocor”), infringes upon its patents. Centocor seeks declarations of non-infringement and invalidity of Abbott’s patents and seeks review of a decision of the Patent and Trademark Office’s (“PTO”) Board of Patent Appeals and Interferences.

The Court issued its original claim construction order on March 15, 2011; it was amended to correct an error on March 17. The Court issued a second amended claim construction order on May 6 after it granted Centocor’s request to add “human antibody” to the list of disputed terms.

Centocor has moved to amend its preliminary invalidity and non-infringement contentions

in four ways. First, it requests, with Abbott's assent, to add an additional prior-art reference (Tomlinson et al., J. Mol. Biol. 256:813 (1996)) that was identified during discovery. Second, it seeks to add contentions that Stelara is not a "human antibody" as defined by Abbott's patents. Third, it seeks to include additional examples of how the term "IC₅₀" is indefinite. Finally, it seeks to add a number of additional prior-art references in light of the Court's March 17 claim construction order.¹

I. Analysis

In its Initial Scheduling Order, the Court stated that the preliminary and non-infringement contentions may be amended after October 8, 2010 "only by leave of court, for good cause shown." The present motion, which was filed on April 14, 2011, states without further elaboration that "there is good cause for amending [Centocor's] validity contentions to account for the Court's March 17, 2011 claim construction order in this case." (Def. 2d Mot. to Amend Validity Contentions).

This statement is insufficient to justify some of Centocor's proposed additions. Although the Court's "good cause" requirement was not intended to set an impossibly high bar, Centocor must do more than make conclusory statements where it is not obvious to the Court why amendments should be made.

Nevertheless, the Court has enough information to consider and rule on at least some of the proposed additions. First, it sees no reason to deny Centocor's request where Abbott does not contest the addition. Accordingly, the motion will be granted with regard to the assented-to

¹ The majority of these changes are embedded, without notation or reference, in the text of Centocor's proposed amended validity contentions. The Court's description of these changes is based on a version of the amended validity contentions, filed by Abbott, that tracks all changes to the document.

reference. Second, the Court's recently-issued amended claim construction interprets "human antibody" in a way that makes Centocor's proposed related amendment obsolete. Accordingly, the motion will be denied as to the contention that Stelara is not a "human antibody."

The reasons for Centocor's remaining changes are not immediately apparent. Based on the record before it, the Court can discern no relationship between the IC₅₀ examples and the Court's March 17 claim construction order. And without looking up each of the prior art references, there is no way for the Court to determine their nature and effect. In the absence of more specific justifications, the Court concludes that good cause has not been shown as to these additions, and the motion will be denied to that extent.

II. Conclusion

For the foregoing reasons, the motion to amend preliminary invalidity and non-infringement contentions is GRANTED as to the assented-to prior art reference and otherwise DENIED.

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: May 6, 2011