IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Plaintiff,

v.

GENENTECH, INC. and BIOGEN IDEC INC.,

Defendants.
_____/

No. C 08-4909 SI; C 09-4919 SI

ORDER GRANTING IN PART PLAINTIFF'S MOTION FOR LEAVE TO AMEND ITS PLEADINGS AND INFRINGEMENT CONTENTIONS

On March 5, 2010, the Court held a hearing on plaintiff's motion to amend its pleadings and infringement contentions. For the reasons stated below, the Court GRANTS the motion in part and will allow plaintiff to amend its pleadings and infringement contentions with respect to Avastin®.

BACKGROUND

On October 27, 2008, Sanofi-Aventis filed a complaint for patent infringement against Genentech and Biogen Idec. Sanofi's complaint alleges that Genentech and Biogen have and are infringing two patents "by making, using, selling and/or offering for sale in the United States . . . certain biotherapeutics made in the United States in mammalian cell suspension cultures . . . including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzamuab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase)." Compl. ¶¶ 17, 24. The patents-in-suit relate to the use of DNA derived from human cytomegalovirus (HCMV). Genentech and Biogen filed a complaint for declaratory relief seeking a declaration that these products did not infringe Sanofi's patents.

On September 3, 2009, Sanofi filed its infringement contentions. Those contentions relate solely to Rituxan®. In its infringement contentions, Sanofi stated, *inter alia*, that its contentions were based on information known to Sanofi at the time, and that Sanofi relied upon Biogen and Genentech's representations that the other eight products included in the complaint were not manufactured with CMV enhancer. Sanofi now moves to amend its (1) Disclosure of Asserted Claims and Preliminary Infringement Contentions pursuant to Patent Local Rule 3-6 to add Avastin® and Xolair® to its infringement contentions and (2) the pleadings to clarify its assertions of infringement against these products. Sanofi's motion to amend is based upon independent testing that Sanofi claims shows that Avastin® and Xolair® are in fact made using a CMV enhancer. Genentech and Biogen oppose amendment on numerous grounds.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 15, a plaintiff may amend its complaint "once as a matter of course before being served with a responsive pleading," and "only with the opposing party's written consent or the court's leave" thereafter. Fed. R. Civ. P. 15(a). "The court should freely give leave when justice so requires." *Id.*; *see also Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 712 (9th Cir. 2001) ("We have stated that this policy is to be applied with extreme liberality.") (internal citation omitted). Rule 15 embodies a strong federal policy in favor of deciding cases on their merits. Thus, leave to amend is freely given unless the opposing party can establish a factor such as "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, [or] futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Owens*, 244 F.3d at 712 ("In determining whether leave to amend is appropriate, the district court considers 'the presence of any of four factors: bad faith, undue delay, prejudice to the opposing party, and/or futility.' ") (quoting *Griggs v. Pace Am. Group, Inc.*, 170 F.3d 877, 880 (9th Cir. 1999)).

"[T]he nonmovant bears the burden of showing why amendment should not be granted." *Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 666 (Fed. Cir. 1986). "The single most important factor is whether prejudice would result to the nonmovant." *Id.* (citing cases). "Where there is lack of prejudice

to the opposing party and the amended complaint is obviously not frivolous, or made as a dilatory maneuver in bad faith, it is an abuse of discretion to deny such a motion." *Id*. (quoting *Hurn v. Ret. Fund Trust of Plumbing, Heating & Piping Indus*., 648 F.2d 1252, 1254 (9th Cir. 1981)).

DISCUSSION

Sanofi seeks to amend its infringement contentions and clarify its pleadings based on testing performed by Eurofins Megadagenomix GmbH ("Eurofins"). Eurofins performed DNA extractions on Rituxan®, Avastin®, Xolair®, and Herceptin®, followed by polymerase chain reactions ("PCR") with primers specific to CMV enhancer DNA, to amplify any CMV enhancer DNA present in the drug products. According to Sanofi, the Rituxan®, Avastin®, and Xolair® samples all showed the same signs of residual DNA from the CMV enhancer, and the Herceptin® sample did not. Sanofi asserts that the detected DNA sequences were the same sequence as set forth in the patents-in-suit except for a single substituted base pair, and thus that the Eurofins testing is evidence that Avastin® and Xolair® infringe the patents-in-suit.

Genentech and Biogen oppose the motion to amend on numerous grounds. They argue that the Eurofins testing is suspect, and they have submitted an expert declaration from Dr. Carl Batt in which he provides a detailed critique of the Eurofins testing. Based upon Dr. Batt's declaration, as well as other evidence such as Genentech's submissions to the Food and Drug Administration regarding the production of Avastin® and Xolair®, Genentech and Biogen argue that any patent infringement claims could not survive summary judgment, and thus that amendment would be futile. Defendant Genentech also argued at the hearing that the laboratory tests performed by Eurofins were "junk science," and did not provide any compelling evidence that plaintiff's patented sequence was present in either Avastin® or Xolair®. Sanofi has provided its own expert report from Dr. Randolph Wall in which he opines that the Eurofins data is reliable and "compelling" evidence of the use of the CMV enhancer in the production of the drugs. Sanofi argues that it has made out a *prima facie* case of infringement, and that defendants' assertion that the infringement claims would not survive summary judgment is an admission that Sanofi can at least state a claim of infringement with regard to Avastin® and Xolair®.

The Court finds that Sanofi has made a sufficient factual showing in support of the amended

infringement claim for Avastin®, but not for Xolair®. The PCR tests performed by Eurofins demonstrate that portions of an HCMV enhancer are present in at least some samples of Avastin®. *See, e.g.,* Kokojohn Decl., Exhibit 8 at 8. When the amplified DNA was sequenced and compared to plaintiff's patent, Eurofins found that portions of the two DNA sequences matched up exactly. Kokojohn Decl., Exhibit 8 at Enclosure 5-6. The matching sequences lend credence to plaintiff's contention that the HCMV DNA found in Avastin® is that of the patented enhancer, rather than contamination from HCMV that occurs ubiquitously in nature. Although the results from the Eurofins testing do not conclusively indicate the presence of the patented sequence in Avastin®, plaintiff has provided the Court with enough evidence to warrant further investigation. While Dr. Batt's critiques have some force, the dueling expert declarations raise issues of fact inappropriate for resolution at this stage of the litigation.

Conversely, the PCR tests performed on Xolair® do not show any convincing evidence of the presence of the patented sequence. The purported positive results are inconclusive at best, as most of the Xolair® samples tested do not show any evidence of HCMV DNA, and even those that do are inconsistent in size. *Id*. at 13-15. In addition, the tests for Xolair® do not contain positive or negative controls, which makes judging the validity of those particular tests difficult. *Id*. Without strong results indicating that the patented sequence is present in Xolair®, the Court finds that adding Xolair® to the infringement contentions is unwarranted.

Genentech and Biogen also contend that Sanofi has unduly delayed in seeking to amend, and they argue that Sanofi could and should have had the Eurofins testing performed earlier. Sanofi asserts that it did not conduct the testing earlier based on Genentech's representations that Avastin® and Xolair® were not produced with the CMV enhancer. Sanofi also states that once Genentech refused to provide further discovery on the processes used for making products other than Rituxan®, Sanofi obtained samples for testing and retained Eurofins. Sanofi argues that once it had the testing performed it moved expeditiously to amend the infringement contentions.

The Court agrees with defendants that Sanofi has not provided a satisfactory explanation of why it did not have this testing performed earlier. However, even if Sanofi could have had the testing performed at an earlier date, the Court finds that amendment will not delay this case. Discovery is

ongoing, and the pretrial schedule and hearing on the claim construction will likely be modified due to defendant's successful motion to disqualify Sanofi's counsel.

Defendants also argue that they will be prejudiced by the amendment because "expanding" the case will increase discovery. However, while the parties' focus thus far may have been whether Rituxan® infringes the patents-in-suit, Avastin® is included in Sanofi's complaint for infringement and defendants' complaint for declaratory relief. Moreover, the prospect of additional discovery, on its own, does not constitute undue prejudice. *See Genentech Inc. v. Abbott Labs.*, 127 F.R.D. 529, 531 (N.D. Cal. 1989).

CONCLUSION[1]

For the foregoing reasons, the Court GRANTS IN PART plaintiff's motion to amend the pleadings and the preliminary infringement contentions. (Docket No. 233). Plaintiff shall file an amended complaint and amended preliminary infringement contentions no later than **April 1, 2010**.

IT IS SO ORDERED.

Dated: March 20, 2010

SUSAN ILLSTON
United States District Judge

[1] Biogen argues that it will suffer particular prejudice because it has never manufactured, sold, or promoted Avastin® and that it is an "innocent bystander" in any dispute between Sanofi and Genentech over these products. Biogen asserts that if amendment is allowed, the burden imposed on Biogen should be avoided by adjudicating issues related to Biogen first. When these issues are raised appropriately, the Court will consider such scheduling provisions as may be appropriate to minimize the impact of this amendment on Biogen.