IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENETICS INSTITUTE, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 08-290-SLR
	)	
NOVARTIS VACCINES AND DIAGNOSTICS, INC.,	)	
	)	
	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 24th day of February, 2010, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent No. 4,868,112 ("the '112 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:[1]

1. "**[T]runcated Factor VIII protein which is an active procoagulant**:"[2] A Factor VIII protein that promotes blood coagulation and lacks a portion of the amino acid sequence of the human Factor VIII protein.

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[1]Because the court has found no interference-in-fact, the court has not construed the disputed limitations of defendant's patents, U.S. Patent Nos. 6,060,447 ("the '447 patent") and 6,228,620 ("the '620 patent").

[2]'112 patent, claims 1, 5, 9 and 10.

The only dispute presented by this limitation involves plaintiff's assertion that Factor VIII's role in coagulation be explained, that is, "a Factor VIII protein that promotes the activation of Factor X, which promotes blood coagulation." Plaintiff has argued that this explanation finds support in the specification ('112 patent, col. 19:24-25; col. 24:28-31 and Table 3) by the disclosure of an assay (the "Kabi COATEST") which, as specifically explained in defendant's later-filed '447 patent, "measures the generation of activated Factor X(Xa) as a linear function of the concentration of exogenously supplied Factor VIIIC." ('447 patent, col. 11:4-8) There is no such specific explanation of Factor VIII's role in blood coagulation in the '112 patent or in the prosecution history. (*See, e.g.*, D.I. 84 at JA000214-220, where the applicant's focus was on the activation of Factor VIII, not on the role Factor VIII played in the "blood coagulation cascade") Indeed, given that the applicant recognized that "the role, if any, of the B domain in the biological functioning of FVIII was not known and is still not known" at the time of the application, and that "the reason for the increased expression level [of the "Factor VIII deletion variants, likewise,] was unknown" at the time of the application (*see id.* at JA000218), the intrinsic record is not consistent with plaintiff's assertion that, in 1986 (when the '112 patent was filed), "activation of Factor X" was "the well recognized role Factor VIII play[ed] in the blood coagulation cascade."

2. "**[H]aving a peptide sequence of human factor VIII:C but lacking a peptide region selected from the group consisting of**:"[3] Having the amino acid sequence of the human Factor VIII protein lacking only the particular segment of the

[3]'112 patent, claim 10.

human Factor VIII protein in one of the specified alternatives (a), (b) or (c).

Plaintiff makes three arguments in support of its broad interpretation of the above (that is, "lacking a peptide region **of at least** the regions identified in (a), (b) or (c)"). First, in an interference, the PTO gives the claims their "broadest reasonable interpretation." When reviewing the case law cited by plaintiff, however, the above principle characterizes a proceeding under § 135(a) (an interference may be declared whenever an application is made for a patent which, **in the opinion of the Director**, would interfere with any pending application), not in a § 291 proceeding. Aside from the different fora, the two proceedings "raise different issues," to wit, "[p]atent application claims are given their broadest reasonable interpretation during examination proceedings, for the simple reason that before a patent is granted the claims are readily amended as part of the examination process." *Stampa v. Jackson*, 65 U.S.P.Q.2d 1942, 1945-46 (B.P.A.I. 2002). Therefore, the ordinary rules governing claim construction should apply in this § 291 proceeding.

Second, plaintiff argues that the PTO necessarily followed plaintiff's proposed construction in granting a patent term extension for the '112 patent and, consistent with the above, the PTO's "determination [i.e., granting the extension], based on its construction of claim 10 of the '112 patent, is given great deference that can only be overcome by clear and convincing evidence that the term extension was invalid." Again, the case law cited by plaintiff does not support their argument. In *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290-91 (Fed. Cir. 2006), Ranbaxy argued that, when correctly construed, the patent did not cover Pfizer's commercial product. The

Federal Circuit noted that Ranbaxy's argument depended on its proffered claim construction, which the Court had already rejected (in favor of and having accepted the district court's proffered claim construction). In *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 299 (Fed. Cir. 1990), the Court acknowledged that the Commissioner should be accorded significant deference, but only to the limited extent of his agency's technical expertise, to wit, "whether any patented chemical compound named in a patent term extension application fell within the statutory definition of 'product,' but not what 'product' was to mean." Claim construction is a matter of law and, therefore, does not fall within the PTO's technical expertise (assuming that the PTO went through the claim construction exercise in the first instance).

Finally, according to plaintiff, the use of the Markush claim language in claim 10 does not prevent the claim from reading on larger deletions, so long as one of the specifically stated regions is missing. Aside from broad language in the specification,[4] plaintiff relies on the prosecution history to support its construction. More specifically, new claim 29 was added disclosing "[a] procoagulant protein having a peptide sequence substantially the same as that of human Factor VIII:C but lacking a peptide region **within the region** selected from the group consisting of: . . ." (D.I. 84 at JA000212) In distinguishing his invention from the prior art, the applicant argued that the "FVIII deletion variants" identified in the specification not only were active but were

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[4]"X represents a polypeptide sequence **of up to 949 amino acids** substantially duplicative of sequences of amino acids within the sequence Ser-760 through Arg-1708 . . . Protein domain X may comprise a continuous but shorter sequence selected from the region Ser-760 through Arg-1708." ('112 patent, col. 2:12-35)

expressed at surprisingly substantial levels (albeit for unknown reasons). (*Id.* at JA000218) The claims were again rejected, the examiner explaining that, "[w]ith respect to applicant's arguments concerning the 'unexpected' level of expression . . ., it is reiterated that the claims are not limited to the DNA constructs which are expressed at the argued unexpected levels. Accordingly, the unexpected results are not relevant as the claims are not limited to the factors which result in the enhanced levels of expression." (*Id.* at JA000226) In response, the applicant further amended claim 29 by deleting the phrases "within a region" and "substantially the same as that" and adding the phrase "truncated human Factor VIII:C protein which is an" active procoagulant protein.[5] (*Id.* at JA000227 and JA000231) In his accompanying remarks, the applicant noted that "[t]he Examiner agreed in the interview that applicant was first in the art to make such deletions, and that the invention encompasses patentable subject matter, although the precise scope of the patentable subject matter was not agreed upon. The Examiner did agree that the claims would be allowable if **limited to deletions of at least** the size shown to yield the reported results. In order to expedite prosecution, applicant's attorney agreed to so limit the claims with the understanding that applicant may pursue claims of broader scope in a continuing application." (D.I. 84 at

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[5]"10 (29) (amended). A truncated human Factor VIII:C protein which is an active procoagulant protein having a peptide sequence [substantially the same as that] of human Factor VIII:C but lacking a peptide region [within a region] selected from the group consisting of:

(a) the region between Pro-1000 and Asp-1582;
(b) the region between Thr-778 and Pro-1659; and
(c) the region between Thr 778 and Glu-1694."

(D.I. 84 at JA000231)

JA000232)(emphasis added) Given the well known purpose of Markush groups, I interpret this analysis as one limiting, not expanding, the scope of the claim to more specifically define the operative regions of the Factor VIII protein known to the applicant at the time.

In sum, I decline to accept plaintiff's claim construction in this regard, as it is supported by neither the case law nor the intrinsic record.

United States District Judge