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# *IMMUNEX CORPORATION v. SANOFI-AVENTIS U.S. LLC, GENZYME CORPORATION, REGENERON PHARMACEUTICALS, INC.*

*We hope that you continue to stay safe and healthy.*

**By:** Daniel A. Geselowitz, Ph.D.

## Introduction

This is a consolidated appeal to the U.S. Court of Appeals for the Federal Circuit (CAFC) from two U.S. PTO Patent Trial and Appeal Board decisions in the *inter partes* reviews of U.S. Patent 8,679,487 ("the '487 patent"), owned by Immunex. Sanofi-Aventis, *et al*. challenged the '487 patent, the patent being directed to certain human antibodies. The '487 patent was challenged in the following two *inter partes* reviews: the first *inter partes* review challenge contested the interpretation or construction of the claim term "**human antibodies**," while the second *inter partes* review challenge concerned issues of inventorship. This paper is directed to the first *inter partes* review challenging the interpretation or construction of the claim term "human antibodies."

## Background

The '487 patent is directed to antibodies that bind to the human interleukin-4 (IL-4) receptor, which might be useful in the treatment of inflammatory disorders. Claim 1 reads as follows:

> An isolated **human antibody** that competes with a reference antibody for binding to human IL-4 interleukin-4 (IL-4) receptor, wherein the light chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:10 and the heavy chain of said reference antibody comprises the amino acid sequence of SEQ ID NO:12." [Emphasis added.]

A key issue from a scientific standpoint is that antibodies produced from animals (such as, a mouse) are different from antibodies produced by a human. In practice, it is possible to have antibodies that are "chimeric," with some regions of the antibody being human and others (in particular, "complementarity-determining regions" (CDRs)) being non-human. On appeal, the text recited in the CAFC's decision summarizing this distinction is set forth as follows:

> In "humanized" antibodies, only the CDRs are nonhuman—the antibodies' amino acid sequences, including the portions responsible for immune reaction, are almost entirely human in origin. Further, fully human antibodies can be made in which even the CDRs are human in origin.

Amid infringement litigation, Sanofi-Aventis, *et al*. filed the *inter partes* review challenge, which argued that the claims were unpatentable over two references, "Hart" and "Schering-Plough." The Hart reference describes a commercially available murine antibody that meets all the limitations of claim 1-except that it is fully murine, not human. But Schering-Plough reference teaches humanizing such murine antibodies by "grafting" their CDRs onto an otherwise fully human antibody. The U.S. PTO Board concluded that the claims of the '487 patent were obvious over these references.

## CAFC Decision

In Immunex's appeal, Immunex asked the CAFC to change the applicable standard in interpreting patent claims. The CAFC decided to use the **"Broadest Reasonable Interpretation" standard (or generally referred to as the "BRI standard") in interpreting patent claim language**.

The key issue in the appeal is the recitation of "human antibody" in claim 1 of the '487 patent. The U.S. PTO Board had determined that the BRI standard interpretation of "human antibody * * * includes both fully human and partially human antibodies" [emphasis added]. This interpretation is to include "humanized" antibodies and is the basis of the obviousness rejection. Immunex, however, argued that "humanized" is not the same as "human."

In reviewing the key issue on the interpretation of "human antibody," the CAFC used the BRI standard in view of the U.S. Supreme Court decision in *Teva Pharms. USA, Inc. v. Sandoz, Inc*. based on the review of **intrinsic evidence** (namely, the patent specification, claims, and prosecution history).

*First*, in the CAFC's review of the claim language itself, the CAFC concluded that: "[b]ut nothing in the claim's language restricts 'human antibodies' to those that are fully human." *Second*, in the CAFC's further review of the specification of the '487 patent, the CAFC noted that: "[h]ere, however, **we are without an express definition [of 'human antibody']**" [emphasis added]. The CAFC also noted that: "[t]he specification also repeatedly clarifies that some "human" antibodies are "fully human." The court then concluded as follows:

> Accordingly, the language of the specification confirms a broadest reasonable interpretation of "human antibodies" that includes those that are partially human—including "humanized" antibodies.

*Lastly*, the CAFC found that the patent's prosecution history was consistent with this interpretation. The court noted that in an Office Action, the Examiner expressly wrote that the amended "human" antibodies encompassed "humanized" antibodies, but Immunex made no effort to contradict the Examiner from this interpretation. Accordingly, the U.S. PTO Board's claim interpretation is correct and the Board's judgment is affirmed holding that the '487 patent is invalid as obvious based on the Hart and Schering-Plough references.

**Summary and Key Points** It is essential that all terms in a claim are well defined in the specification and claims, and that arguments made during prosecution regarding the meaning of claim terms are consistent. Intrinsic evidence (the specification, claims, and prosecution history) takes precedence over extrinsic evidence.

**Washington D.C. Office:**
**4th Floor**
**1420 K Street, N.W.**
**Washington, DC 20005**
**U.S.A.**
**Tel: 202.659.2930**
**Fax: 202.962.0011**
**correspondence@kqhpatentlaw.com**
**www.kqhpatentlaw.com**

**Tokyo Liaison Office:**
**21st Floor**
**Shin-Marunouchi Center Building**
**1-6-2 Marunouchi, Chiyoda-ku**
**Tokyo, JAPAN 100-0005**
**Tel: 03.3216.7188**
**Fax: 03.3216.7210**