IP News Alert

# FAILURE TO CHALLENGE EXAMINER'S CHARACTERIZATION CAN BIND YOU TO A LIMITED CLAIM SCOPE

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- A patent claim's scope can be limited where the patent applicant does not explicitly challenge a Patent and Trademark Office characterization.
- Incorporation by reference of a claim term definition can be insufficient where the incorporated text states that the definition is "as used herein."

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Recently, in *Biogen Idec, Inc. v GlaxoSmithKline LLC (Biogen)*, a panel of the Federal Circuit limited the scope of a patentee's claims through a generous application of the doctrine of prosecution history estoppel. Estoppel occurs where a clear and unmistakable disavowal of claim scope during examination of a patent overcomes the heavy presumption that claim terms carry their full ordinary and customary meaning. In *Biogen*, the Court implicitly ignored precedent and found that estoppel was found where an applicant failed to challenge an examiner's characterization of its claims explicitly during the examination of the patent application. Previously, the Court had stated that estoppel should not be based on the examiner's remarks, but on the conduct (statements) of the applicant. The Court also appeared to take a more relaxed view of the standard that estoppel must be clear, unmistakable and based on the unambiguous remarks of the applicant. Applicants need to be especially vigilant regarding an examiner's characterization of their claims and, if that characterization is too narrow, must challenge the examiner's characterization to avoid any potential perception of a disclaimer.

In *Biogen*, the Federal Circuit considered the meaning of the claim term "anti-CD20 antibody" in Biogen's patent, U.S. Patent No. 7,682,612. The patent claimed a method of treating Chronic Lymphocytic Leukemia ("CLL") in a patient by administering a substance known as an anti-CD20 antibody in an amount effective to treat the CLL. The anti-CD20 antibody binds to a protein, the CD20 antigen, on the surface of a patient's B cells. Biogen had developed a specific anti-CD20 antibody known as Rituxan® (rituximab) and discovered that anti-CD20 antibodies like rituximab are useful to treat CLL.

Biogen sued Glaxo, claiming that Biogen's patent covered Glaxo's product, a different anti-CD20 antibody known as Arzerra® (ofatumumab). Unlike rituximab, which is chimeric (it is partially human, partially non-human), Glaxo's antibody is human. It is also believed to bind to a different part (epitope) of CD20. Biogen urged that the term "anti-CD20 antibody" be construed according to its plain and ordinary meaning, which Biogen stated was "an antibody that binds to a cell surface CD20 antigen." However, the district court construed the term "anti-CD20 antibody" more narrowly, in a manner that excluded Glaxo's anti-CD20 antibody.

The Federal Circuit affirmed the district court's construction, holding that "anti-CD20 antibody" meant "rituximab and

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antibodies that bind to the same epitope of the CD20 antigen with similar affinity and specificity as rituximab." The Court stated that the applicants had unequivocally and unambiguously disavowed the broader meaning of the term to obtain the patent, surrendering that claim scope.

In reaching its finding, the Court considered and discounted the fact that the Patent:

1. provided a description for "anti-CD20 antibody" that includes a range of affinity (i.e., ranging from $10^{-5}$ to $10^{-9}$ M);
2. states that the anti-CD20 antibody preferably comprises a number of types, including chimeric and human antibodies, and includes claims directed to chimeric and human antibodies;
3. identifies rituximab as but "a particularly preferred" chimeric anti-CD20 antibody; and
4. incorporates by reference an earlier patent, which defines an anti-CD20 antibody as used therein as "an antibody which specifically recognizes ... CD20."

**A failure to challenge the examiner's characterization directly can be a disclaimer of broader claim scope.**

During prosecution of the patent, the examiner rejected the claims, stating that the specification did not provide enablement commensurate with the claim scope. She indicated that the claim scope could include "any and all anti-CD20 antibodies, no matter the specificity or affinity for the specific epitope on the circulating tumor cells," but stated that the specification was only enabling for rituximab and another chimeric anti-CD20 antibody. The applicants responded that one of skill in the art could readily identify an antibody that binds to CD20 with similar affinity and specificity as does rituximab, and could produce other anti-CD20 antibodies "and screen such antibodies for those having an affinity and functional activity similar to rituximab." The examiner then withdrew the rejection.

Although the applicants did not refer to the epitope explicitly in their response, the Court found that they had adopted the examiner's characterization of the claimed antibodies when they "limited their claims to antibodies similar to [rituximab]" and "did not directly challenge the examiner's characterization." Thus, the Court found that it was "clear" that they were limiting their invention to antibodies that have a similar specificity and affinity for the specific epitope to which rituximab binds.

Biogen contended that because its patent incorporated an earlier patent by reference, the earlier patent's broader definition of "anti-CD20 antibody" should control. The Court disagreed, stating that, because the earlier patent's definition of the term began: "[a]s used herein, the term 'anti-CD20 antibody' is . . . .," it expressly and uniquely defined "anti-CD20 antibody" for use within that earlier patent. The Court found that the definition "does not necessarily reflect how a person of ordinary skill in the art would understand the disputed term in the context of [Biogen's] patent." Rather, according to the Court, the definition may be a "special definition" given to a claim term by the earlier patentee. Further, the Court stated that, regardless, this is a case where prosecution history disclaimer overcomes the presumption of plain and ordinary meaning.

**Business Implications**

A patent owner's success in a patent infringement suit depends on a finding that the accused infringer's acts fall within the



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scope of the claims. Therefore, a sufficiently broad construction of claims is essential for a patent owner. Be vigilant in studying an examiner's characterization of your claims regardless of the type of rejection and, if you think it is too narrow, directly challenge the characterization in order to avoid the possibility of a disclaimer. If a particular definition or description is key to your claim's meaning, include it directly into your specification rather than incorporating it by reference from another source, particularly where the source's definition includes the phrase "as used herein."

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