# United States Court of Appeals for the Federal Circuit

---

**BIOGEN IDEC, INC. AND GENENTECH, INC.,**
*Plaintiffs-Appellants,*

**v.**

**GLAXOSMITHKLINE LLC AND GLAXO GROUP LIMITED,**
*Defendants-Appellees.*

---

2012-1120

---

Appeal from the United States District Court for the Southern District of California in No. 10-CV-0608, Judge Roger T. Benitez.

---

Decided: April 16, 2013

---

JOHN ALLCOCK, DLA Piper LLP, of San Diego, California, argued for plaintiffs-appellants. With him on the brief were KATHRYN RILEY GRASSO, STANLEY J. PANIKOWSKI and AARON FOUNTAIN. Of counsel on the brief were MEREDITH MARTIN ADDY, Steptoe & Johnson, LLP, of Chicago, Illinois. Of counsel was RAMA C. ELLURU, of Washington, DC.

LISA M. FERRI, Mayer Brown LLP, of New York, New York, argued for defendants-appellees. With her on the brief were BRIAN W. NOLAN; VERA A. NACKOVIC and ANDREA C. HUTCHINSON, of Chicago, Illinois.

---

Before DYK, PLAGER, and REYNA, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* REYNA.
Dissenting opinion filed by *Circuit Judge* PLAGER.

REYNA, *Circuit Judge*.

Biogen Idec Inc. and Genentech, Inc. (collectively, "Biogen") seek review of the district court's construction of the disputed claim term "anti-CD20 antibody" that narrowed the term based on prosecution history disclaimer. Under that construction, Biogen stipulated that it could not prove infringement by GlaxoSmithKline LLC and Glaxo Group Ltd. (collectively, "GSK"). Biogen took that approach in order to appeal the district court's claim construction. We conclude that the district court did not err in finding a clear and unmistakable disclaimer and, therefore, we *affirm*.

## I. BACKGROUND

In the mid-1990's, scientists from Biogen discovered that patients with Chronic Lymphocytic Leukemia (CLL) could be treated using anti-CD20 antibodies like Biogen's Rituxan® (rituximab). CLL is a cancer in which a type of white blood cell called a B lymphocyte ("B cell") becomes cancerous. Normal B cells of CLL patients undergo a malignant transformation, which causes the cells to replicate and accumulate in the bloodstream, bone marrow, and certain tissues at much higher levels than in a healthy person. Symptoms of CLL include fatigue, fevers, bleeding, and infections caused by a decrease in the number of red blood cells and platelets due to the overabundance of B cells in the blood stream. *Biogen Idec, Inc.*

*v. GlaxoSmithKline LLC*, No. 10-CV-00608, 2011 U.S. Dist. LEXIS 120043, at *2 (S.D. Cal. Oct. 17, 2011). Patients also exhibit signs of the condition including enlarged lymph nodes and spleen from an excess of B cells in the tissue of those organs. *Id.* As a result, researchers sought a treatment regime that mitigated both the symptoms and signs of CLL by reducing the number cancerous B cells without the deleterious side effects stemming from other treatments such as radiation or chemotherapy.

Fortunately, both normal and cancerous B cells have a portion of the CD20 antigen protein exposed beyond the cell surface. Anti-CD20 antibodies are capable of targeting and binding to these CD20 antigens on the B cell's surface. Once the anti-CD20 antibody successfully attaches to the CD20 antigen, it destroys the B cell regardless of whether it is normal or cancerous. For patients with CLL, administering the anti-CD20 antibodies thus mitigates the symptoms and signs caused by the condition while still allowing their bodies to replenish normal B cells.

Biogen sought a patent covering, *inter alia*, a method for treating patients with CLL involving administering a therapeutically effective amount of the anti-CD20 antibody. It was eventually awarded U.S. Patent No. 7,682,612 ("the '612 patent"), entitled "Treatment of Hematologic Malignancies Associated with Circulating Tumor Cells Using Chimeric Anti-CD20 Antibody." The patent was not limited to any particular type of anti-CD20 antibody and, in fact, has dependent claims claiming specific types of antibodies: chimeric,[1] rituximab,

---

[1] Chimeric antibodies are antibodies with human and nonhuman (typically rodent) regions.

humanized,[2] and human. In describing its preferred embodiment, the patent explains that

> the anti-CD20 antibody will bind CD20 with high affinity, i.e., ranging from $10^{-5}$ to $10^{-9}$ M. Preferably, the anti-CD20 antibody will comprise a chimeric, primate, PRIMATIZED®, human, or humanized antibody. Also, the invention embraces the use of antibody fragments . . . and aggregates thereof.

'612 patent col. 2 ll. 45–51. But in this regard, the specification acknowledges that "a particularly preferred chimeric anti-CD20 antibody is RITUXAN® (rituximab), which is a chimeric gamma 1 anti-human CD20 antibody." *Id.* col. 3 ll.18–20. Additionally, the '612 patent incorporates by reference U.S. Patent No. 5,736,137 ("the '137 patent"), which teaches the isolation, screening, and characterization of Rituxan®. The '137 patent also defines an "anti-CD20 antibody" as used *therein* as "an antibody which specifically recognizes a cell surface . . . typically designated as the human B lymphocyte restricted differentiation antigen Bp35, commonly referred to as CD20." '137 patent col. 6 l. 65 to col. 7 l. 2.

At the time of Biogen's discovery, scientists already knew that available anti-CD20 antibodies could treat certain cancers of the lymph nodes, called B-cell lymphomas, such as non-Hodgkins lymphoma. Unlike CLL, however, lymphomas are characterized by B cells with a greater density of CD20 antigen targets on the surface and fewer cancerous B cells in the bloodstream. Thus, lymphomas were readily treated with anti-CD20 antibodies, but it remained doubtful whether they would be effective against CLL.

---

[2] Humanized antibodies are antibodies with substantially human regions.

Initially, it was believed that only one large loop, or epitope, of the CD20 antigen's protein chain was exposed on the cancerous B cell's surface, which made that loop the only suitable target for an anti-CD20 antibody. After Biogen filed its application for the '612 patent, other researchers discovered that the CD20 antigen had a second small loop, to which other anti-CD20 antibodies could attach.

During prosecution of the '612 patent, the examiner rejected all the claims because the specification did not provide enablement commensurate with the scope of the claimed invention, which, under the "broadest reasonable interpretation" standard applied by the U.S. Patent and Trademark Office (PTO), included "any and all anti-CD20 antibodies, no matter the specificity or affinity for the specific epitope on the circulating tumor cells." Joint App'x 307. "[S]election of an antibody as an immunotherapeutic agent," continued the examiner, "is an unpredictable task as the antibody must possess sufficient specificity and a high degree of affinity for its target for use as an immunotherapeutic agent and because these qualities are dependent on the physiology of the particular pathology and the accessibility of the target antigen." *Id.* The examiner acknowledged that the specification was enabling for Rituxan®, but that it was "silent concerning what sort of specificity and affinity would be necessary" for other anti-CD20 antibodies. *Id.* In response, Biogen pointed to its disclosure of Rituxan® and maintained that

> even though antibodies directed to the same antigen might have different affinities and functional characteristics, one of skill in the art could readily identify an antibody that binds to CD20 with similar affinity and specificity as does RITUXAN® using techniques that are well known in the art. . . . With that knowledge in hand, the skilled artisan could readily produce anti-CD20 antibodies using

> similar techniques, and screen such antibodies for those having an affinity and functional activity similar to RITUXAN®.

Joint App'x 324–25. After considering Biogen's arguments, the examiner withdrew her enablement rejection, and the claims eventually issued.

In 2002, GSK, in collaboration with Genmab A/S, developed a breakthrough anti-CD20 antibody, Arzerra® (ofatumumab), which is distinctly different from Rituxan® in several respects. Whereas Rituxan® attaches to the large loop, it is believed that Arzerra® attaches to the second small loop previously thought to be hidden inside the cell. This means that the Arzerra® anti-CD20 antibody differs from the Rituxan® anti-CD20 antibody with regard to specificity, or ability of the antibody to bind to a particular epitope of an antigen, and affinity, or tightness of the bond between the antibody and the antigen. Likewise, unlike Rituxan®, which is a chimeric antibody, Arzerra® is a fully human antibody, so there is less of a risk that the body will reject it and develop antibodies against it. Researchers believe that its fully human characteristic permits the antibody to bind to the small loop. Additionally, because Arzerra® binds to the small loop, it has a much greater affinity for the CD20 antigen, which means that it can bind longer, giving the antibody more time to kill the target B cell.

In March 2010, Biogen sued GSK for infringement of the '612 patent, asserting claims 1-4, 6, 8-10, 14-17, 20-22, and 58-60. GSK counterclaimed, alleging noninfringement, invalidity, and unenforceability of those claims. The district court held a *Markman* hearing, and on October 18, 2011, construed the following terms: "effective to treat the chronic lymphocytic leukemia," "anti-CD20

antibody"/"CD-20 binding fragment,"[3] and "does not include treatment with a radiolabeled anti-CD20 antibody"/"radiation is not used." For the term, "anti-CD20 antibody," Biogen proposed the broad construction "an antibody that binds to a cell surface CD20 antigen." The district court, however, adopted GSK's construction of "rituximab and antibodies that bind to the same epitope of the CD20 antigen with similar affinity and specificity as rituximab." *Biogen*, 2011 U.S. Dist. LEXIS 120043, at *31. It based this conclusion on prosecution history disclaimer wherein Biogen limited that term to overcome the examiner's enablement rejection. Following this construction, which excluded GSK's accused Arzerra® product, Biogen stipulated to noninfringement, and on November 15, 2011, the court entered judgment against Biogen under Federal Rule of Civil Procedure 54(b). Biogen subsequently appealed to this court. We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1).

## II. STANDARD OF REVIEW

Claim construction is an issue of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Accordingly, this court reviews district court claim constructions *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

## III. DISCUSSION

Claims terms "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Vitronics*

---

[3] The claim construction issues concerning "anti-CD20 antibody" and "CD-20 binding fragment" are indistinct; thus, they will be addressed collectively under the term "anti-CD20 antibody."

*Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). But a term's ordinary meaning must be considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history. *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003); *see also Phillips*, 415 F.3d at 1314. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317. In the latter circumstance, we have recognized that a "clear and unmistakable" disavowal during prosecution overcomes the "'heavy presumption' that claim terms carry their full ordinary and customary meaning." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323, 1326 (Fed. Cir. 2003); *see also Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) ("A heavy presumption exists that claim terms carry their full ordinary and customary meaning, *unless it can be shown the patentee expressly relinquished claim scope*." (emphasis added)). Thus, when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered. *Id.* at 1324.

Prosecution history disclaimer plays an important role in the patent system. It "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Id.* Such statements can take the form of either amendment or argument. *See Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999); *see also Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008) ("Statements made during prosecution may also affect the scope of the claims."). For this reason,

the entirety of a patent's file history captures the public record of the patentee's representations concerning the scope and meaning of the claims. *Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1372 (Fed. Cir. 2005) (quoting *Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000)); *see also Elkay*, 192 F.3d at 979 ("[I]t is the totality of the prosecution history that must be assessed, not the individual segments of the presentation made to the [PTO] by the applicant . . . ."). Competitors are entitled to rely on those representations when determining a course of lawful conduct, such as launching a new product or designing-around a patented invention. *Id.* Beyond the notice function and reliance-based aspects of a patent's prosecution history, it "provides evidence of how the [PTO] and the inventor understood the patent." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1327 (Fed. Cir. 2009) (quoting *Phillips*, 415 F.3d at 1317) (alteration in original).

This case requires us to analyze how the PTO and the inventors understood the disputed term, "anti-CD20 antibody," in the '612 patent to determine if the inventors disclaimed claim scope during prosecution of that patent. Biogen maintains that all the evidence—including the claims, the specification, and statements made by all parties recorded in the prosecution history—indicates that the term was used according to its plain and ordinary meaning, "an antibody that binds to a cell surface CD20 antigen." For purposes of our analysis, we initially assume without deciding that neither the claims nor the specification compel a construction contrary to the one offered by Biogen. The question becomes whether statements in the prosecution history are sufficient to overcome the "heavy presumption" that the term carries its full ordinary and customary meaning advanced by Biogen. We conclude that they are.

During prosecution of the '612 patent, the examiner rejected all pending claims because the specification did

not enable a person skilled in the art to practice the full scope of the claims, which could have encompassed "any and all anti-CD20 antibodies, no matter the specificity or affinity for the specific epitope on the circulating tumor cells." Joint App'x 307. Instead, according to the examiner, the specification only enabled Rituxan®, rituximab, and 2B8-MX-DTPA.[4] It was not enabling for other anti-CD20 antibodies, which had different structural and functional properties.

In response, rather than challenging the examiner's understanding of the crucial terms, the applicants argued that the specification was enabling for anti-CD20 antibodies with similar affinity and specificity as Rituxan®. Indeed, the applicants conceded that other "antibodies directed to the same antigen [i.e., CD20] might have different affinities and functional characteristics," and limited their claims to antibodies similar to Rituxan® nonetheless. Joint App'x 324. While the applicants may not have repeated the examiner's language *verbatim et literatim*, it is clear that they were limiting their invention to what the examiner believed they enabled: antibodies that have a similar specificity and affinity for the specific epitope to which Rituxan® binds.[5]

---

[4] 2B8-MX-DTPA, like Rituxan®, is a chimeric anti-CD20 antibody. *See generally* '137 patent.

[5] Pointing to another portion of the prosecution history, Biogen maintains that the novel aspect of the '612 patent is its recognition that *any* anti-CD20 antibody could treat CLL. Joint App'x 325. This argument, however, does not alter our analysis where the applicants overcame the examiner's enablement rejection by explicitly relinquishing claim scope. *See Computer Docking Station*, 519 F.3d at 1377 ("[A] disavowal, if clear and unambiguous, can lie in a single distinction among many.").

Biogen now argues that because it never explicitly referred to any particular "epitope"—and because CD20 was only thought to have one epitope at the time the patent application was filed—the applicants were merely referring to specificity and affinity in their general sense; that is, anti-CD20's general preference for B cells regardless of the particular CD20 epitope to which it binds. Read in context, however, the full prosecution history does not support Biogen's position. The examiner began by characterizing antibodies by their specificity and affinity for a specific epitope, and the applicants adopted that characterization when they limited their claims to antibodies similar to Rituxan®. While disavowing statements must be "so clear as to show reasonable clarity and deliberateness," *Omega*, 334 F.3d at 1325, this requirement does not require the applicant to parrot back language used by the examiner when clearly and deliberately responding to a particular grounds for rejection. If an applicant chooses, she can challenge an examiner's characterization in order to avoid any chance for disclaimer, but the applicants in this case did not directly challenge the examiner's characterization. *See TorPharm Inc. v. Ranbaxy Pharm., Inc.*, 336 F.3d 1322, 1330 (Fed. Cir. 2003) ("Whether the patentee chooses to dispute the examiner's view of matters is relevant to claim interpretation, for there a court may need to ascertain exactly what subject matter was actually examined and allowed by the PTO."). Rather, they simply discussed specificity and affinity with regard to the disclosure of the '612 patent, which was narrowly limited to Rituxan®, rituximab, and 2B8-MX-DTPA. The disclaimer of antibodies that do not have a similar affinity and specificity for the specific epitope to which Rituxan® binds was clear and unmistakable. Accordingly, the district court properly limited the scope of the claim term, "anti-CD20 antibody," based on prosecution history disclaimer.[6]

---

[6] We are mindful that "it is the applicant, not the

Biogen makes two arguments regarding why the claim term's full plain and ordinary meaning should control, both of which are unpersuasive. First, Biogen argues that the claims envisage a difference between claim one's broad coverage of any and all anti-CD20 antibodies, and the specific types of antibodies listed in the dependent claims—chimeric, rituximab, humanized, and human. *See* '612 patent col. 8 ll. 31–38. Biogen also asserts the general caution against importing a preferred embodiment into the claims. Biogen's Br. 32. Our cases make clear, however, that where found, prosecution history disclaimer can overcome the presumption of claim differentiation. *Regents of Univ. of Cal. v. DakoCytoma-*

---

examiner, who must give up or disclaim subject matter that would otherwise fall within the scope of the claims." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1124 (Fed. Cir. 2004). This case, however, differs markedly from those frequently raising this admonition. Those cases typically involve an applicant standing silent when confronted by statements made by the examiner during prosecution, most often in the examiner's Statement of Reasons for Allowance. *See, e.g.*, *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1345–47 (Fed. Cir. 2005); *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1079 (Fed. Cir. 2003). This case deals not only with applicants letting stand an examiner's narrow characterization of a claim term, but also their adoption of that characterization to overcome the examiner's enablement rejection. Thus, the acquiescence cases are inapposite. *See TorPharm*, 336 F.3d at 1330 ("[T]he public is entitled to equate an inventor's acquiescence to the examiner's narrow view of patentable subject matter with abandonment of the rest.").

*tion Cal., Inc.*, 517 F.3d 1364, 1375–76 (Fed. Cir. 2008). Furthermore, the applicants' disclaimer in this case is not necessarily inconsistent with other possible embodiments or even the dependent claims, so long as they involve chimeric, humanized, or human antibodies that are similar to Rituxan®. *Cf. Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1308 (Fed. Cir. 2000) (adopting a claim construction that excluded the preferred and sole embodiment in light of, *inter alia*, prosecution history disclaimer).

Second, Biogen contends that because the '612 patent incorporated the '137 patent by reference, the latter patent's definition of "anti-CD20 antibody" should control. The problem with this argument is that the '137 patent expressly and uniquely defines "anti-CD20 antibody" for use therein, that is, within the '137 patent. '137 patent col. 6 l. 65 ("As used *herein*, the term 'anti-CD20 antibody' is . . . ." (emphasis added)). The definition, therefore, does not necessarily reflect how a person of ordinary skill in the art would understand the disputed term in the context of the '612 patent. *See Phillips*, 415 F.3d at 1313. Rather, it may very well be that this is a "special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." *Id.* at 1316. Even assuming the '137 patent conveyed "anti-C20 antibody's" plain and ordinary meaning, this is a case where prosecution history disclaimer overcomes the presumption of plain and ordinary meaning as we concluded above.

We have considered Biogen's other arguments, but find no basis for reversing the district court's claim construction.

## IV. CONCLUSION

For the foregoing reasons, we affirm the district court's conclusion that "anti-CD20 antibody" as used in

the '612 patent is limited by prosecution history disclaimer.

**AFFIRMED**

COSTS

No costs.

# United States Court of Appeals for the Federal Circuit

---

**BIOGEN IDEC, INC. AND GENENTECH, INC.,**
*Plaintiffs-Appellants,*

**v.**

**GLAXOSMITHKLINE LLC AND GLAXO GROUP LIMITED,**
*Defendants-Appellees.*

---

2012-1120

---

Appeal from the United States District Court for the Southern District of California in No. 10-CV-0608, Judge Roger T. Benitez.

---

PLAGER, *Circuit Judge*, Dissenting.

Because I do not find anywhere in the majority opinion or in the prosecution history that clear and unmistakable evidence of a disclaimer as required by our precedents, I cannot agree with the majority that such a disclaimer was made by Biogen during the prosecution of its application for the '612 patent; I respectfully dissent.

The parties do not dispute that the plain meaning of the claim term "anti-CD20 antibody" is "an antibody that binds to a cell surface CD-20 antigen." Nor do the parties dispute that the written description of the '612 patent supports that plain meaning. Indeed, the majority con-

cedes that "neither the claims nor the specification [sic] compel a construction contrary to the one offered by Biogen." Maj. Op. at 9. The only dispute is whether the applicants disclaimed the plain meaning of "anti-CD20 antibody" during prosecution.

The majority purports to tease out of the prosecution history such a disclaimer. The doctrine of prosecution disclaimer promotes the public notice function of a patent's intrinsic evidence and protects the public's reliance on definitive statements made during prosecution. *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). However, the give-and-take that is often part of the process of negotiation between an examiner and an applicant may result in less-than-clear understandings, as happened here. Making too much of such ambiguous statements "does not advance the patent's notice function or justify public reliance." *SanDisk Corp. v. Memorex Products, Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005). Accordingly, we have consistently declined to invoke the doctrine of prosecution disclaimer in the absence of "an unambiguous disavowal that *clearly and unmistakably* disclaims" the plain meaning of a disputed claim term. *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1342 (Fed. Cir. 2012) (emphasis added).

The prosecution history of the '612 patent makes clear that one may practice the claimed invention by administering RITUXAN® and RITUXAN®-like antibodies to a CLL patient. *See* J.A. 325 (stating that "[t]he antibodies to be used for the claimed immunotherapy were described in detail in U.S. Patent 5,736,137," which "describes the isolation, screening and characterization of RITUXAN®"). The question we must answer, however, is whether the prosecution history makes it clear that using RITUXAN®-like antibodies is the *only* way to practice the claimed invention, and that no other antibodies can be used.

The specific prosecution history on which the majority seems to rely is the following:

> Examiner:
>
> Claims 1 and 12 are broadly drawn to '. . . an anti-CD20 antibody or fragment thereof'. This is broadly interpreted for examination purposes to be any and all anti-CD20 antibodies, no matter the specificity or affinity for the specific epitope on the circulating tumor cells. While the specification is enabling for the application of RITUXAN®, RITUXIMAB® and 2B8-MX-DTPA in the treatment of hematologic malignancies, the specification is not enabling in the application of all other anti-CD20 antibodies, which may have different structural and functional properties.

J.A. 307.

> Applicants:
>
> Applicants respectfully submit that even though antibodies directed to the same antigen might have different affinities and functional characteristics, one of skill in the art could readily identify an antibody that binds to CD20 with similar affinity and specificity as does RITUXAN® using techniques that are well known in the art. . . . With that knowledge in hand, the skilled artisan could readily produce anti-CD20 antibodies using similar techniques, and screen such antibodies for those having an affinity and functional activity similar to Rituxan®.

J.A. 324–25.

Does this constitute a clear and unmistakable disclaimer of all antibodies *except* RITUXAN® and RITUXAN®-like antibodies? I do not think so. The examiner was addressing an enablement issue; the applicants'

response was at worst a non-response to the examiner's concern, and at best a statement that antibodies other than RITUXUN® and RITUXUN®-like antibodies that had similar affinity and specificity are included in the claims. "Similar" does not mean "same." Applicants' usage of "similar" is inconsistent with an acceptance by the applicants of the narrow confines proposed by the examiner's reference to the "specificity or affinity for the specific epitope."

Regarding the introduction of the "epitope" issue, much of the dispute before us centers on whether the applicants disclaimed antibodies that bind to a different binding site (or epitope) than does RITUXAN®. Biogen argues that the disputed claim term covers antibodies that bind to CD20 generally. The majority, however, affirms the district court's decision to the contrary, importing a specific "epitope" into its claim construction.[1] The majority does so because applicants purportedly adopted the examiner's limitation on this point. *See* Maj. Op. at 11. Yet applicants in their response omitted the very term "epitope" that the majority claims they adopted as a limitation. And while the applicants' decision to omit "epitope" from their response could mean that the applicants silently accepted this limitation suggested by the examiner, it also could mean that the applicants silently rejected it. Even more to the point, when applicants spoke in their disputed statement of binding, they did not

---

[1] The district court construed "anti-CD20 antibody," as "rituximab and antibodies that bind to the same epitope of the CD20 antigen with similar affinity and specificity as rituximab." *Biogen Idec, Inc. v. GlaxoSmithKline LLC,* No. 10-CV-00608, 2011 U.S. Dist. LEXIS 120043, at *31 (S.D. Cal. Oct. 17, 2011).

say as construed by the district court "bind[s] to the same epitope"; applicants said "binds to CD20."[2]

Applicants' statements—when considered in light of either the range of antibodies included in the claim, or the specific epitope to which the antibodies might attach—fail to meet the "clear and unmistakable" standard set forth in our case law. This is especially true given our case law that it is the applicant, not the examiner, who disclaims claim scope. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1124 (Fed. Cir. 2004); *see also Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1379 (Fed. Cir. 2005). It was the examiner, not the applicants, who invoked the concept of epitopes. *Compare* J.A. 307-09 *with* J.A. 324-28. But it is the applicant, not the examiner, who must give up or disclaim subject matter that would otherwise fall within the scope of the claims, and an applicant's silence regarding statements made by the examiner during prosecution cannot amount to a clear and unmistakable disavowal of claim scope. *See Sorensen*, 427 F.3d at 1379; *see also Salazar v. Procter & Gamble Col.*, 414 F.3d 1342, 1345 (Fed. Cir. 2005).

Nothing in the intrinsic record made by the applicants links the efficacy of the recited antibodies to a particular epitope of CD20. To the contrary, the intrinsic evidence repeatedly links the efficacy of the antibodies to their ability to selectively target the CD20 antigen, as opposed to other antigens. *See*, *e.g.*, J.A. 44-45 ('612 patent, discussing the inventive concept of targeting the CD20 antigen, and incorporating the '137 patent by reference);

---

[2] Applicants' comment and the district court's construction both state "with similar affinity and specificity as [RITUXAN®]" after discussing where the binding occurs. Therefore, the fundamental difference between the applicants' comment and the construction is the district court's limitation of binding to a specific epitope.

J.A. 325-26 (prosecution history, linking the efficacy of the antibodies to their ability to bind CD20); J.A. 376 ('137 patent, discussing the inventive concept of targeting the CD20 antigen).

Nowhere in the prosecution history did the applicants state that antibodies that bind to the same epitope on CD20 with similar affinity and specificity as RITUXAN® must be used, or that antibodies lacking those characteristics must not be used. To the contrary, the applicants repeatedly made clear—including in the same discussion as the allegedly disclaiming statement—that because the invention was based on the discovery that anti-CD20 antibodies could treat CLL, the claimed methods were not limited to the use of any particular type anti-CD20 antibody. *See*, *e.g.*, J.A. 325-26 (arguing that "the novelty of the presently claimed invention does not lie in an anti-CD20 antibody per se" and that anti-CD20 "antibodies to be designed in the future for use in the claimed methods would certainly be encompassed").

By ignoring most of the prosecution history and reading something into the above dialogue between the examiner and the applicants that is not there, it is possible to argue, as GSK has done, that the "anti-CD20 antibodies" that may be used in the claimed methods are limited to only RITUXAN®-like antibodies. But it is at least equally possible, and more correct, to read the applicants' prosecution arguments as contemplating the use of antibodies other than RITUXAN®-like antibodies. And when a prosecution argument is subject to more than one reasonable interpretation, it cannot rise to the level of a clear and unmistakable disclaimer. *01 Communique Lab. Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012). We have long followed the rule that even a poorly-phrased prosecution argument does not a disclaimer make.

Finally, the '612 patent incorporates by reference the '137 patent, which has a broader definition than the

majority's claim construction for "anti-CD20 antibody." The majority opinion tries to distinguish the '137 patent's definition as only applying "herein"—or, in other words, in the '137 patent. *See* Maj. Op. at 13. This distinction misses the mark.

First, what the majority opinion dismisses as the "special definition" of "anti-CD20 antibody" found in the '137 patent is contained in the *incorporated* patent, not in the *incorporating* one. Thus, even assuming that the applicants of the '137 patent were acting as their own lexicographer when broadly defining the term "anti-CD20 antibody," the '612 patent then incorporated this "special definition" into its own disclosure. Indeed, that is the whole point of incorporation by reference—to incorporate disclosure from another application. If there was ever any doubt on this point, the prosecution history explicitly affirms the reliance on the '137 patent with respect to the antibodies at issue. And this affirmation occurs right in the middle of the allegedly disclaiming discussion of the CD20 antibody relied upon by the majority. *See* J.A. at 324-25.

As I read the record, it was error for the district court to construe the claims as requiring the use of "[RITUXAN®] and antibodies that bind to the same epitope of the CD20 antigen with similar affinity and specificity as [RITUXAN®]." *Biogen Idec, Inc.*, 2011 U.S. Dist. LEXIS 120043 at *31. Because the district court's construction eviscerates the "clear and unmistakable" requirement for prosecution disclaimer, I cannot join the majority in affirming that erroneous construction. I would reverse the district court's claim construction in favor of the plain meaning of "anti-CD20 antibody" as set

out at the beginning of this opinion, and remand for further proceedings under the proper claim construction.[3]

[3] Given the breadth of the plain meaning construction, nothing in this analysis precludes GSK on remand from the opportunity to raise the issue of validity on the grounds that were troubling the examiner, and which the alleged disclaimer is purported to address.