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In *Bayer Healthcare v. Baxalta* (March 1), the Federal Circuit illustrates the fundamental algorithm for claim construction and exemplifies the operation of specification disclaimer and prosecution history disclaimer.

Background: Facts & The Issue

Bayer's patent was directed to human Factor VIII that is PEGylated at the B-domain.[1] Factor VIII is a polypeptide involved in blood coagulation, and its recombinant form is FDA-approved for treatment of hemophilia.

The patent teaches that PEGylation was known to lengthen the half-life of Factor VIII in the bloodstream and thereby reduce the frequency of administration and the cost of treatment. But, according to the patent, the prior art methods of Factor VIII PEGylation, which randomly PEGylated at hundreds of potential sites spanning Factor VIII's several structural domains, suffered from significant disadvantages, including PEGylation at sites that decreased biological activity, reduced yields of the desired mono-PEGylated product, and challenges for good manufacturing processes. Bayer's patent claims Factor VIII selectively PEGylated at one of its structural domains, the B-domain, which the patent asserts avoids or reduces the disadvantages of the prior art.

One issue was whether the claim phrase "at the B-domain" should be construed broadly as "attachment at the B-domain such that the resulting conjugate retains functional factor VIII activity" or more narrowly as "at a site that is not any amine . . . site in factor VIII and is in the B-domain." The correct answer depended on whether Bayer had disclaimed, in the specification or in the prosecution history, PEGylation at amine sites – locations that were used in the prior art random PEGylation methods.

The district court construed the claim language broadly, finding no disclaimer. Baxalta appealed.

Background: Relevant Black Letter Law

1. Claim Construction: Specification Disclaimer/Disavowal
   a. In general, the "specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor," and where "the inventor has dictated the correct claim scope . . . the inventor's intention, as expressed in the specification, is dispositive."[2]
   b. Two basic forms:
      i. Specification makes clear that the invention "does not include a particular feature."[3]
      ii. The invention is clearly limited to a particular form of the invention.[4]
   c. Legal standard: "To disavow claim scope, the specification must contain 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.'"[5]

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[1] The claim recites "An isolated polypeptide conjugate comprising a functional factor VIII polypeptide and one or more biocompatible polymers . . . wherein the biocompatible polymer comprises polyalkylene oxide and is covalently attached to the functional factor VIII polypeptide at the B-domain." Polyethylene glycol (PEG) is a frequently-utilized biocompatible polyalkylene oxide. Factor VIII has six structural domains: A1-A2-B-A3-C1-C2.

[2] *Phillips v. AWH* Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005)(en banc).

[3] *Hill-Rom Services v. Stryker,* 755 F.3d 1367, 1372 (Fed. Cir. 2014)(citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.,* 242 F.3d 1337, 1341 (Fed. Cir. 2001)).

[4] *Id.*

[5] *Continental Circuits v. Intel*, 915 F.3d 788, 796-97 (Fed. Cir. 2019)(quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.,* 653 F.3d 1296, 1306 (Fed. Cir. 2011). The standard has also been characterized by the Federal Circuit as "exacting." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012); *see also Poly-America v. API Industries*, 839 F.3d 1131, 1136 (Fed. Cir. 2016)("the standard for disavowal is exacting, requiring clear and unequivocal evidence that the claimed invention includes or does not include a particular feature.").

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i. "In general, statements about the difficulties and failures in the prior art, without more, do not act to disclaim claim scope."[6]

ii. "While disavowal must be clear and unequivocal, it need not be explicit."[7]

d. Disclaimer/disavowal by disparagement:

i. "To find disavowal of claim scope through disparagement of a particular feature, we ask whether 'the specification goes well beyond expressing the patentee's preference . . . [such that] its repeated derogatory statements about [a particular embodiment] reasonably may be viewed as a disavowal.'"[8]

ii. A particular feature can be disclaimed "when the specification distinguishes or disparages prior art based on the absence of that feature."[9]

2. Claim Construction: Prosecution History Disclaimer/Disavowal

a. A "fundamental precept in our claim construction jurisprudence," which "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution."[10]

i. "The doctrine is rooted in the understanding that "[c]ompetitors 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."[11]

b. Legal standard: "Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution."[12]

c. Disclaimer/disavowal by applicant's statements during prosecution:

i. "This may occur, for example, when the patentee explicitly characterizes an aspect of his invention in a specific manner to overcome prior art."[13]

ii. Statements and arguments that are merely vague, ambiguous, or subject to other reasonable interpretation are not sufficient to surrender claim scope.[14]

What *Bayer Healthcare* Adds or Changes:

Bayer Healthcare does not change or notably refine the law of claim construction, but it does nicely illustrate the fundamental algorithm for construing claims and provides examples of the analyses for specification- and prosecution history-disclaimer/disavowal.

Fundamental Algorithm for Claim Construction

> The organization of the claim construction section of this decision embodies the fundamental algorithm for claim construction: Start with the plain language of the claims ("plain meaning"), then analyze the specification for all that it teaches that might alter the plain meaning ("specification-modified plain meaning"), and then move to the prosecution history to determine how it informs or necessarily limits the specification-modified

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[6] *Retractable Techs., Inc. v. Becton, Dickinson & Co.,* 653 F.3d 1296, 1306 (Fed. Cir. 2011).

[7] *Poly-America v. API Industries*, 839 F.3d 1131, 1136 (Fed. Cir. 2016).

[8] *OpenWave Systems v. Apple*, 808 F. 3d 509, 513 (Fed. Cir. 2015)(quoting *Chicago Bd. Options Exch., Inc., v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012)). Although "repeated" statements were at issue in OpenWave, repeated statements are not necessarily required.

[9] *Poly-America,* 839 F.3d at 1136.

[10] *Aylus Networks v. Apple,* 856 F.3d 1352, 1359 (Fed. Cir. 2017)(quoting *Omega Eng'g, Inc. v. Raytek Corp.,* 334 F.3d 1314, 1323-24 (Fed. Cir. 2003).

[11] *Id.* (quoting *Biogen Idec, Inc. v. GlaxoSmithKline LLC,* 713 F.3d 1090, 1095 (Fed. Cir. 2013)).

[12] *Purdue Pharma v. Endo Pharmaceuticals*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see also Omega Eng'g.,* 334 F.3d at 1326 ("our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.").

[13] *Purdue Pharma*, 438 F.3d at 1136; *see also Regents Univ. Minn. v. AGA Medical*, 717 F.3d 929, 942 (Fed. Cir. 2013)("When an applicant tells the PTO that a prior art reference lies outside the scope of his claim, he is bound by that argument.").

[14] *Omega Eng'g, Inc. v. Raytek Corp.,* 334 F.3d 1314, 1325 (Fed. Cir. 2003)("To balance the importance of public notice and the right of patentees to seek broad patent coverage, we have thus consistently rejected prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope" and "[r]ather, we have required the alleged disavowing statements to be both so clear as to show reasonable clarity and deliberateness . . . and so unmistakable as to be unambiguous evidence of disclaimer.").

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plain meaning ("final interpretation").[15] This may seem embarrassingly simple, but I have encountered surprisingly senior in-house patent lawyers who neither understand this simple algorithm nor employ it in their patent analyses.[16]

In *Bayer Healthcare*, the Federal Circuit determined first that the plain language of the claims "requires PEGylation at the B-domain as a region" but "does not require PEGylation at any particular amino acid sites in the B-domain, let alone exclude from its scope any specific amino acids as attachment sites in the B-domain."

Specification Disclaimer/Disavowal

Baxalta argued that Bayer had disclaimed conjugation of PEG at primary amine sites (*e.g.,* lysine residues)[17] by disparaging in the specification prior art PEGylation methods that used primary amine sites:

> Random modification of FVIII by targeting primary amines (N-terminus and lysines) with large polymers such as PEG and dextran has been attempted with varying degrees of success.[18]
>
> This random approach, however, is much more problematic for the heterodimeric FVIII. FVIII has hundreds of potential PEGylation sites including the 158 lysines, the two N-termini, and multiple histidines, serines, threonines, and tyrosines, all of which could potentially be PEGylated with reagents primarily targeting primary amines.[19]

The Federal Circuit determined that these statements were insufficient to disclaim/disavow conjugation at primary amines in the B-domain, explaining that the specification "disparages random PEGylation of FVIII, including random PEGylation targeting amines like lysines, but nowhere disparages non-random, site-directed amine/lysine PEGylation at the B-domain."

This emphasizes the importance of the scope of potential disparaging statements – here, prior art *random* PEGylation was disparaged but not necessarily the *underlying structural linkages* by which PEG was conjugated.

Prosecution History Disclaimer/Disavowal

Baxalta also argued that the manner by which Bayer distinguished random PEGylation prior art during prosecution disclaimed/disavowed conjugation at amine sites. In particular, Bayer argued in a reply brief on appeal:

> Much of the Patent Office's prior arguments relied upon possible conjugation at *amines* or carboxy sites, which are present not only in the B-domain but in other domains. *Any conjugation with these reactive groups is random and does not ensure that attachment occurs at the B-domain*.

This was a closer case, as the italicized language appears to assert that any conjugation at lysine residues or other amine sites is part and parcel of the disparaged prior art. The Federal Circuit acknowledged merit in Baxalta's argument, but explained that "when the entire passage from Bayer's reply brief is read together, it is clear that '[a]ny conjugation' refers to the conjugations allegedly disclosed by [the prior art Bayer was distinguishing]" and "it does not follow that Bayer defined all conjugations with amines . . . as random." As such, "Bayer distinguished the prior art on the ground that it did not teach non-random PEGylation at the B-domain, and . . . did not clearly and unmistakably disclaim all PEGylation at amines."

This emphasizes the importance of the full context of potential disparaging statements – here, the context created ambiguity (at least) that precluded a clear and unmistakable disclaimer/disavowal of claim scope.

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[15] I've left out extrinsic evidence because this case involved only the intrinsic evidence.

[16] Truly I do not get it. They somehow never read *Phillips* or any of the myriad other Federal Circuit decisions that lay out the law of claim construction. But claim construction determines the scope of a patent claim, and therefore essentially determines whether a claim is valid or infringed. Digging into the law of claim construction can only yield better advice, improved strategy, more wins, and fewer expensive losses.

[17] Not surprisingly, Baxalta's accused product is PEGylated at lysine residues in the B-domain (taking advantage of the higher concentration of lysine residues in that domain to target PEGylation there).

[18] US Pat. No. 9,364,520 at col. 3, lines 50-53.

[19] *Id.* at col. 3, line 63 to col. 4, line 1.

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