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Enablement For Life Sciences Patents Requires Sweat Equity

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Don't call it a comeback; it's been here for years. Remember the so-called super-enablement standard? That misnomer was once used to characterize the written description requirement under Title 35 U.S. Code Section 112, primarily in the chemical and biological arts.

Meanwhile, the legal construct that serves as the plainspoken, reasonable person standard in patent law — the actual enablement requirement — lingered awkwardly and inconsistently in dicta. Small wonder that disclosure requirements for biotechnology genus claims with functional language have been a source of confusion for life science patentees.

Confusion begets confusion. The multiple challenges over the years to whether Section 112 contains a written description requirement separate from an enablement requirement have been misguided. Written descriptions and enablement are statutorily distinct and police claim scope by very different means: The epistemological, highfalutin "possession" test for written description is the near antithesis of the folksy, "sweat of the brow" test for enablement.

Enablement in particular is noteworthy in this day and age. The time and effort required to get the job done should not be discounted. Success requires showing up and putting real time in. In that sense, enablement is the sweat equity of invention.

While written description compliance has historically been the most frequent challenge to the validity of patent claims, recent case law reveals a shift in focus. In both pretrial and post-trial district court orders and in U.S. Court of Appeals for the Federal Circuit opinions, courts have been invalidating claims to functionally defined genera involving both small and large molecules based on a lack of enablement.[1]

These decisions have been met with both cheer and jeer from life sciences practitioners around the globe. Supporters are heralding the proper realignment of Section 112 law, while critics deem it improper for courts to take such everymen analyses away from jurors.

A Section 112 Retrospective: How Did We Get Here?

Patentees have long battled with the question of what is sufficient disclosure to both describe and

enable a broad claim scope. There is an inherent tension with broad claims described by function, particularly in fields where it can be difficult to predict what would be covered by a functionally claimed genus.

Focus on the Written Description Requirement in the Life Sciences

Written description has been the longtime darling of Section 112. A demise in the validity of functional genus claims for insufficient written description traces its roots to the 1990s, when U.S. Circuit Judge Alan Lourie of the Federal Circuit scrutinized the disclosure for biological inventions based on existing law that had developed for chemical inventions.

Analogizing that "[a] gene is a chemical compound, albeit a complex one," Judge Lourie found a lack of written description due to insufficient detail on how to prepare or isolate analog genes encompassed in a DNA claim.[2] The former chemist Judge Lourie then authored a series of decisions relating to nucleic acids and chemical compounds, holding that a description of their function or a method of obtaining them was inadequate and a recitation of structural features was needed.[3]

Judge Lourie's articulation of the written description requirement for biological inventions carried the day in Section 112 law for the next two decades. Under this standard, a claimed genus of genes, small molecules or antibodies can be satisfied by reciting actual nucleotide sequences, compounds or antibody sequences, respectively, of either a representative number of species or that provides the structural features common to the members of the genus so that a skilled artisan can visualize or recognize members of the genus.[4] An epistemological standard if there ever was one.

Shifting Focus to the Enablement Requirement

Enablement aficionados will wince at the recollection of how this requirement was often downplayed as either being superfluous (such that "written description and enablement rise and fall together") or less stringent than this two-prong written description standard ("requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.").[5]

Perhaps as a ricochet to these presumptions, enablement began to have a heyday. The enablement inquiry has evolved into a doctrinal tool for limiting patent scope based on the so-called Wands factors to assess whether undue experimentation was required to make and use the full scope of the claims.[6] With the last key factor being "the breadth of the claims", enablement law is well-positioned to suss out the validity of functional genus claims. And indeed it has risen to the challenge.

Enablement With Teeth

In 2013, the Federal Circuit held that the experimentation needed to synthesize and screen a huge number of chemical compounds, even if routine, can trigger a finding of nonenablement.[7] In 2017, Chief Judge Sharon Prost held that post-priority date evidence showing potentially undue experimentation could evidence nonenablement and that the characterization of an antigen was insufficient to support functional claims to a genus of antibodies.[8]

Following a remand trial on written description and enablement, the district court overturned the jury's finding of validity and held that undue experimentation was required to make and use the full scope of the genus of claimed antibodies that bind to residues on PCSK9 and blocked binding to low density

lipoprotein receptors.[9]

For those who have not been following enablement law closely over the past few years, there is a new sheriff in town. Just as Judge Lourie made his mark on written description law, enablement rulings have largely been authored by two sheriffs or, rather, chiefs: Chief Judge Prost of the Federal Circuit and Chief Judge Leonard Stark of the U.S. District Court for the District of Delaware.

They have each penned decisions holding that functional genus claims are not enabled unless every species within the genus could be obtained without undue experimentation.[10] Notably, not one of these cases involved a jury verdict of invalidity due to a lack of enablement, and Idenix Pharmaceuticals LLC cancelled a $2.54 billion jury verdict. Enablement may still have a way to go before its reasonable man standard is embodied in a reasonable jury.

Where Are We Now?

The current requirement that every species of a broad genus must be enabled is a far cry from the earlier cases that found enablement satisfied with disclosure of at least one embodiment within the scope of the claim.[11] Now, excessive experimentation, even if routine and systematic, can trigger a finding of nonenablement if there is a single category or type of embodiment (one of many) that would be unable to be practiced without undue experimentation.[12]

Many of the decisions have hinged on the sheer workmanlike number of possible candidates to be made and tested to see if they satisfy the claimed function (potentially “millions” in Wyeth and Cordis Corp. v. Abbott Laboratories, “tens of thousands” in Enzo Life Sciences Inc. v. Roche Molecular Systems, “billions” in Idenix Pharmaceuticals LLC v. Gilead Sciences Inc., , a “countless number” in MorphoSys AG v. Janssen Biotech Inc. and an undetermined quantity in Amgen Inc. v. Sanofi SA) that would need to be made and tested to understand if they had the claimed functionality. When “systematic” and “routine” experimentation can be held undue, this is enablement on steroids.[13]

The lesson learned hearkens back to the caution that “a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.”[14] In other words, greed is not always good. The enablement requirement forces patentees to be honest about the quid pro quo that grants patent rights in exchange for a patentee's disclosing the fruits of its hard-earned labor to the public.

Whereas the written description requirement is intended to prevent patentees from claiming an inventive contribution too broadly and potentially risk sweeping after-arising technology into the claim scope, enablement is a little more basic. Enablement cautions one not to be too greedy. Many of the enablement decisions arose as a result of the patentee's needing a broad claim construction to capture the accused infringer. The chief judges’ warning is clear: Do not discount the sweat equity required to support such broad claims.

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[1] See, e.g., Idenix Pharm. LLC v. Gilead Sci. Inc., No. 18-1691 (Fed. Cir. Oct. 30, 2019); Amgen Inc. v. Sanofi, No. 14-1317 (D. Del. Aug. 28, 2019); Enzo Life Sciences, Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019); MorphoSys AG v. Janssen Biotech, Inc., 358 F. Supp. 3d 354 (D. Del. 2019).

[2] See Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (holding that conception of the human erythropoietin gene was not achieved until after the gene had been isolated and identified).

[3] See Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993) (an adequate written description of the DNA coding for beta interferon required its nucleotide sequence); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997) (rat insulin cDNA and a general method of producing human insulin cDNA was inadequate written description for genus claims directed to human insulin cDNA).

[4] E.g., Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956 (Fed. Cir. 2002) (a public deposit of nucleic acid probes representative of the claimed genera that selectively bound to N. gonorrhoeae constituted adequate written description); University of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004) (method claims covering a genus of non-steroidal compounds that selectively inhibit activity of the PGHS-2 gene were enabled but lacked written description when no compounds had been disclosed); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc) (functional genus claims directed to reducing Nuclear Factor Kappa B activity in eukaryotic cells lacked written description when the specification failed to recite synthesis of the prophesized molecules and satisfy either the representative number of species or structure/function correlation test); AbbVie Deutschland GmbH v. Janssen Biotech., Inc., 759 F.3d 1285 (Fed. Cir. 2014) (structurally similar IL-12 antibodies disclosed in the specification were not representative of the structurally diverse yet functionally similar genus of claimed antibodies).

[5] Ariad, 598 F.3d at 1352 (emphasis added); see also Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("[t]he purpose of the 'written description' requirement is broader than to merely explain how to 'make and use.'").

[6] In re Wands, 858 F.2d 731 (Fed. Cir. 1988).

[7] See Wyeth and Cordis Corp. v. Abbott Labs, 720 F.3d 1380 (Fed. Cir. 2013) (holding that claims to a new use for an existing class of compounds containing a macrocyclic triene ring were invalid due to the need for undue experimentation to determine which compounds performed the function).

[8] See Amgen Inc. v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017); cert. denied, 139 S. Ct. 787 (2019) (overturning the "newly characterized antigen" test from Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004)).

[9] See Amgen Inc. v. Sanofi, No. 14-1317 (D. Del. Aug. 28, 2019).

[10] See MorphoSys AG v. Janssen Biotech, Inc., 358 F. Supp. 3d 354 (D. Del. 2019) (screening of conservative variants of anti-CD38 antibodies would require considerable time and effort, and not every member of the class could be obtained without undue experimentation); Trustees of Boston Univ. v. Everlight Elecs. Co., 896 F.3d 1357 (Fed. Cir. 2018) (claims directed to LED semiconductors with gallium nitride layers invalid due to non-enablement and physical impossibility of preparing one of six embodiments); Enzo Life Sciences, Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019) (broad claims to labeled polynucleotide probes were nonenabled, due to the amount of work needed to

determine whether each and every oligonucleotide was hybridizable and detectable upon hybridization); Idenix Pharm. LLC v. Gilead Sci. Inc., No. 18-1691 (Fed. Cir. Oct. 30, 2019) (claims to methods of treating HPV with "2'-methyl-up" nucleoside compounds invalid for lack of enablement due to the high quantity of "experimentation not prediction" needed to synthesize and screen compounds meet the functional limitations).

[11] See, e.g., Spectra-Physics Inc. v. Coherent Inc., 827 F.2d 1524 (Fed. Cir. 1987).

[12] See Everlight, Idenix.

[13] Contra Cephalon, Inc. v. Watson Pharma., Inc., 707 F.3d 1330 (Fed. Cir. 2013) ("difficult" and "complicated" experimentation not undue).

[14] MagSil Corp. v. Hitachi Global Storage Techs., Inc., 687 F.3d 1377, 1381 (Fed. Cir. 2012).