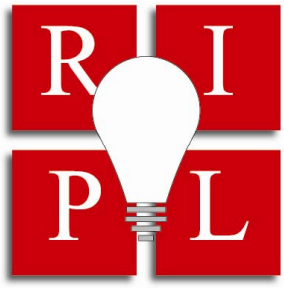
THE JOHN MARSHALL
REVIEW OF INTELLECTUAL PROPERTY LAW



WHEN ENOUGH IS NOT ENOUGH: CAN POST FILING EXPERIMENTAL DATA BRIDGE THE GAP IN PATENT DISCLOSURE OF NON-ENABLING SPECIFICATIONS IN THE UNPREDICTABLE ARTS?

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ABSTRACT

On issues of 35 U.S.C. §112, the Federal Circuit has been inconsistent in determining the extent to which patent applicants need to disclose examples of their claimed inventions in patent specifications to fully enable their patent claims. Confusion as to how many or what types of examples amount to sufficient disclosure is augmented for inventions in the unpredictable arts, such as chemistry, biotechnology, and pharmaceuticals. Current practice skewing towards disclosure of examples in greater numbers is a misguided effort to satisfy enablement, as shown by patents at issue in two recent Federal Circuit cases. A qualitative approach to disclosure is recommended, and post filing experimental data is proposed as a limited remedy to retroactively fill gaps in disclosure during patent prosecution.

Cite as Fei Sha, *When Enough Is Not Enough: Can Post Filing Experimental Data Bridge the Gap in Patent Disclosure of Non-Enabling Specifications in The Unpredictable Arts?*, 18 J. MARSHALL REV. INTELL. PROP. L. 496 (2019).

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I. INTRODUCTION

What do you do when enough is not enough? For instance, inventors are informed by the United States Patent and Trademark Office ("USPTO") or a federal court that not enough examples of their invention are disclosed in their patent application to support the patent claims.[1] What can they do to remedy the insufficiency?[2] What if numerous examples are already disclosed in the patent specification?[3] When forty-one examples of a therapeutic antibody may still be deemed insufficient, what more can be done?[4] What is needed to overcome such a ruling or objection from the USPTO and federal courts? One must turn to 35 U.S.C. §112(a) in order to begin to answer this question.[5]

Defining patent enablement, 35 U.S.C. §112(a) ambiguously provides that disclosure of an invention in the specification of a patent or patent application is adequate when it enables a person having ordinary skill in the art ("PHOSITA") to practice the claimed invention.[6] Moreover, the specification must disclose an optimal way of practicing the claimed invention, as contemplated by the inventor.[7] At the same time, U.S. patent law does not require the specification to describe how to make and use every possible variant of a claimed invention.[8] Rather, people with ordinary

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[1] *In re* Vaeck, 947 F.2d 488, 490, 492–93, 495 (Fed. Cir. 1991) (A claimed invention encompassing a chimeric hybrid DNA derived from bacteria and capable of being expressed in one hundred fifty different genera of cyanobacteria was found not enabled in view of a specification disclosing expression of the hybrid DNA in only one particular species of cyanobacteria illustrated in nine examples.); *see also* U.S. Patent No. 5,516,693 cols. 5–14.

[2] *See id.* (Given that heterologous gene expression in cyanobacteria was unpredictable at the time of filing of the subject patent, additional working examples beyond the nine examples disclosed that illustrate the heterologous gene expression in additional species of cyanobacteria could have sufficiently enabled the patent specification.).

[3] U.S. Patent No. 8,829,165 (Filed as a continuation of parent U.S. Patent No. 8,030,457, it disclosed forty-one examples of the subject invention in the patent specification.).

[4] *See* Amgen v. Sanofi, 872 F.3d 1367, 1372–76, 1378–79 (Fed. Cir. 2017).

[5] 35 U.S.C. §112(a). The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

[6] *See id.*

[7] *See id.*

[8] AK Steel v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed

skill in the art that seek to practice the invention should be able to fill any gaps in the disclosure of the invention with their own knowledge, with proof of existing background art and routine experimentation.[9] PHOSITAs are expected to be able to extrapolate beyond the disclosed examples, or embodiments, in their practice of the invention.[10] So, how can patent applicants draft the specification so as to meet the PHOSITA halfway, so to speak, without giving away the tricks used to develop the invention?

The standard of enablement has evolved over the past few decades.[11] Most notably, following the boom in the chemical, biotechnological, and pharmaceutical industries, the enablement requirement was heightened such that disclosure of a single embodiment was no longer sufficient to demonstrate the full scope of a patent.[12] For example, certain types of inventions in biotechnology have an even stricter standard for enablement.[13]

Post filing data is a possible remedy that patent applicants can rely on to fill in any identifiable gaps in the initial disclosure.[14] Although limited, post filing experimental data can be filed to supplement the specification by demonstrating an enabling disclosure of the invention.[15] Therefore, certain post filing data can be used to enable claims in the unpredictable arts, including biotechnology.[16] However, this must be done with caution and used in appropriate circumstances, which will be discussed below.

First, the evolution of the standard governing enablement will be examined. Once that is clearly established, two recent notable examples of patents disclosing large numbers of embodiments of the claimed inventions will be analyzed in detail with respect to enablement of the patent specification. Finally, a recommended course of action will be proposed for patent practitioners to follow to ensure that patent applications that they work on satisfy the enablement requirement under U.S. Patent Law.

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embodiments.").

[9] *Id.*

[10] *Id.*

[11] *Compare* Genentech v. Novo Nordisk 108 F.3d 1361, 1365–68 (Fed. Cir. 1997) (holding patent not enabling when subject invention shown by embodiments to be reduced to practice only in *E. coli* bacteria), *with* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding that a patent need only disclose a single embodiment to satisfy enablement).

[12] *See* Chiron v. Genentech, 363 F.3d 1247, 1254-1256 (Fed. Cir. 2004) (holding claims invalid when they included two different antibodies and disclosure fell short of providing a specific and useful teaching through embodiments of all antibodies within the scope of the claims).

[13] Ariad Pharms. v. Eli Lilly, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (When a genus of a biomolecule is claimed in a patent, adequate written description of representative species of the biomolecules themselves is required in the specification.); *see also* Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004) (Antibodies can be claimed in terms of their binding affinity to an antigen only if that antigen is fully characterized by its structure, formula, chemical name, and physical properties.).

[14] *See* Amgen v. Hoechst Marion Roussel, 314 F.3d 1313, 1336 (Fed. Cir. 2003) (Enablement was satisfied when the specification was "buttressed by numerous post filing publications that demonstrated the extent of the enabling disclosure.").

[15] *See id.*

[16] *See id.*

II. BACKGROUND

35 U.S.C. §112(a) requires that a disclosure of "the manner and process of making and using [an invention]" in a written description, namely a patent specification, must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to practice the full scope of the invention.[17] A specification is not enabling if a PHOSITA would not be able to practice the subject invention without "undue experimentation."[18] Since 1988, the Federal Circuit uses eight probative *Wands* factors to determine whether a specification requires undue experimentation.[19] Although the factors are "illustrative, not mandatory,"[20] the Federal Circuit follows the spirit of the factors in its opinions.[21]

Satisfying enablement becomes complicated in view of two co-existing lines of cases that set seemingly opposite standards. Historically, the Federal Circuit has ruled that disclosure of a single embodiment is sufficient to enable a broad claim in the applied sciences.[22] More recently, the Federal Circuit held that multiple examples, or illustrative embodiments, are necessary to enable the full scope of a claimed invention.[23] The latter group of cases often involves inventions in the unpredictable arts, like chemistry, biotechnology, and pharmaceuticals, wherein a slight variation in method can yield unpredictable results or may not work at all.[24] In *Sitrick v. Dreamworks, LLC*, the Federal Circuit began reconciling the previous

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[17] 35 U.S.C. §112(a); *see also* The Manual of Patent Examining Procedure ("MPEP") §§ 2164, 2164.01(a–b) (Enablement requires the specification to describe how to make and use the full scope of the claimed invention without undue experimentation.).

[18] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[19] *Id.* The *Wands* factors are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims.

[20] Amgen v. Chugai Pharm., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

[21] *See* Streck v. Research & Diagnostic Sys., 665 F.3d 1269, 1288 (Fed. Cir. 2012); Enzo Biochem, Inc. v. Calgene, 188 F.3d 1362, 1371 (Fed. Cir. 1999); *Genentech*, 108 F.3d at 1365.

[22] *See* Invitrogen v. ClonTech Labs., 429 F.3d 1052, 1071 (Fed. Cir. 2005) (holding that the operable method of achieving the claimed invention was fully described in the patent specification, distinguishing the case from precedent finding a lack of enablement in view of a failure to disclose *any* way of practicing a claimed invention); CFMT v. Yieldup, 349 F.3d 1333, 1338 (Fed. Cir. 2003); Johns Hopkins Univ. v. CellPro, 152 F.3d 1342, 1355, 1359, 1361 (Fed. Cir. 1998); *Spectra-Physics*, 827 F.2d at 1533; *In re* Rasmussen, 650 F.2d 1212, 1215 (C.C.P.A. 1981); *In re* Marzocchi, 439 F.2d 220, 223 (C.C.P.A. 1971).

[23] Auto. Techs. v. BMW et al., 501 F.3d 1274, 1281–83 (Fed. Cir. 2007) (Claims to a side-impact crash sensor for automobile airbags were improperly construed broadly in view of the single example provided in the specification, which disclosed only a mechanical sensor when the claims also covered an electrical sensor.); Liebel-Flarsheim v. Medrad, 481 F.3d 1371, 1378–79 (Fed. Cir. 2007) (Claims to a high-pressure medical injection system held invalid and could not cover a similar invention sold by the alleged infringer with a jacketless injector, because the specification recited specifically an injector with a pressure jacket.); *AK Steel*, 344 F.3d at 1243–44 (Claims covering a Type 1 or Type 2 aluminum coating were deemed as non-enabling because the specification only described a Type 2 coating, thus causing undue experimentation to fill in the gaps.); *In re* Cavallito, 282 F.2d 363, 367 (C.C.P.A. 1960).

[24] *See, e.g.*, *Enzo Biochem*, 188 F.3d at 1374–77 (Although specifications may outline the theoretical application of a technique in a wide variety of organisms, the practical application of the claimed technique may involve many variables that scientists do not yet understand, thereby making the actual practice of the technique unpredictable.).

distinct sets of rulings, holding that the patent disclosure must enable the full scope of the claimed invention, regardless of how many embodiments it takes.[25] Thus, broadly construed claims are subject to invalidation if the claims are supported by a narrow disclosure.[26]

Enabling broadly construed claims is easier said than done. The complexities inherent in biotechnology patents make such an endeavor difficult because a patent applicant cannot broadly claim an invention if in reality, only part of that invention is enabled.[27] Broad claims to a method for producing any mammalian peptide of interest in a plant cell need support from embodiments that show how to practice that method in both monocots and dicots.[28] The same idea applies to antisense technology claimed to apply in a wide range of organisms,[29] recombinant DNA plasmids encoding for non-nascent human insulin claimed to be expressed in microorganisms,[30] live vaccines claimed to target any pathogenic RNA virus,[31] and gene expression vectors claimed to be transformable in hundreds of species of cyanobacteria.[32]

Inclusion of too many or all possible embodiments of a claimed invention in order to demonstrate support for every species covered by the claims, however, is not a feasible course of action either.[33] Complete disclosure would require a patent

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[25] *See* Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1000 (Fed. Cir. 2008) (Claims to a method of integrating a user's audio signal or video image were broad enough to cover both movies and video games, so the patent specification must enable both embodiments.).

[26] *Id.*; *see also In re* '318 Patent Litigation, 583 F.3d 1317, 1324–25, 1327 (Fed. Cir. 2009).

[27] *See, e.g.*, *In re* Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993) (holding that a patent specification containing a single example of producing gamma-interferon protein in only one dicot plant species, tobacco, does not enable a biotechnician of ordinary skill in the art to produce *any* type of mammalian protein in *any* type of plant cell).

[28] *See id.*; *see also* Plant Genetics Sys. V. Dekalb Genetics, 175 F.Supp 2d 246, 256–59, 264–65 (D. Conn. 2001) (Like *In re Goodman*, a patent specification disclosing an Agrobacterium-mediated transformation method that works only in dicot plant cells does not enable a broad claim of transformation purported to cover all plant cells, including monocots and dicots, because a significant amount of experimentation is needed beyond what is taught in the specification to secure stable insertion of a heterologous gene into monocot plant cells.).

[29] *See Enzo Biochem*, 188 F.3d at 1372–74 (Where claims are broadly drafted to encompass application of a highly unpredictable antisense RNA technology in a wide range of cells, both eukaryotic and prokaryotic, but the patent specification only taught the practice of antisense technology to control expression of three specific genes in *E. coli* bacteria, the patent does not broadly enable the use of antisense technology in all cells.).

[30] *See* Regents of the Univ. of California v. Eli Lilly, 119 F.3d 1559, 1566–68 (Fed. Cir. 1997) (A description of rat insulin cDNA is not a description of the cDNA of all the broad classes of vertebrate and mammalian insulin; to enable such an invention, an adequate description of the claimed DNA molecule is required, such as cDNA of the recombinant plasmids, written as a precise definition, such as by structure, formula, chemical name, or physical properties, and not as a mere wish or plan for practicing the claimed invention.).

[31] *See In re* Wright, 999 F.2d 1557, 1562, 1564 (Fed. Cir. 1993) (Claims to methods of producing non-pathogenic live vaccines against any pathogenic RNA virus that can be used to protect all living organisms against that virus, need support in the disclosure of examples of an entire range of vaccines shown to be *in vivo* immune-protective to a variety of RNA viruses in humans.).

[32] *See Vaeck*, 947 F.2d at 490, 492–93, 495 (Claims to bacteria-derived chimeric genes for transformation and expression in one hundred and fifty different genera of cyanobacteria hosts were found to be not enabled when the specification disclosed, through nine examples, successful transformation of the chimeric genes in only one particular species of cyanobacteria.).

[33] *In re* Angstadt, 537 F.2d 498, 502–03 (C.C.P.A. 1976).

application to have thousands of examples, forcing an inventor to carry out an unreasonably large number of experiments.[34] In an unpredictable technology, inclusion of a large number of very similar embodiments would also not enable a broadly claimed invention.[35]

Recently, in *Amgen v. Sanofi*, U.S. Patent No. 8,829,165 ("'165 patent") was nearly invalidated for lack of enablement despite disclosing a large number of embodiments in support of its claims.[36] The '165 patent relates to an antigen binding protein, namely a monoclonal antibody, that specifically binds to Proprotein Convertase Subtilisin Kexin Type 9 ("PCSK9").[37] Forty-one examples were disclosed in the specification in support of the patent claims.[38] The application for the '165 patent was filed on April 10, 2013 as a continuation of U.S. Patent No. 8,030,457, from which the forty-one embodiments originated.[39] The examples disclosed all possible aspects of the invention, known at the time of filing, for antigen binding proteins that bind to PCSK9.[40]

Amgen v. Sanofi was remanded for a new trial on several issues, including sufficiency of disclosure for enabling the '165 patent.[41] With respect to patent prosecution, the patent-in-suit raises an important question: what kinds of examples should be disclosed when forty-one of them may not be enough to meet the enablement requirement?

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[34] *Id.*

[35] *See* Glaxo Wellcome v. Eon Labs Mfg., No. 00 Civ. 9080 (LMM), 2002 U.S. Dist. LEXIS 14950, at *1, *3–5 (S.D.N.Y. Aug. 13, 2002).

[36] *See Sanofi*, 872 F.3d at 1371–72.

[37] U.S. Patent No. 8,829,165.

[38] *Id.* at cols. 73–124.

[39] *Id.*; *see also* U.S. Patent No. 8,030,457, claiming:

> 1. An isolated neutralizing antigen binding protein that binds to a PCSK9 protein comprising the amino acid sequence of SEQ ID NO:1, wherein the neutralizing antigen binding protein comprises:
>
> A heavy chain polypeptide comprising the following complementarity determining regions (CDRs): a heavy chain CDR1 that is a CDR1 in SEQ ID NO:49; a heavy chain CDR2 that is a CDR2 in SEQ ID NO:49; a heavy chain CDR3 that is a CDR3 in SEQ ID NO:49 and a light chain polypeptide comprising the following CDRs: a light chain CDR1 that is a CDR1 in SEQ ID NO:23, a light chain CDR2 that is a CDR2 in SEQ ID NO:23; and a light chain CDR3 that is a CDR3 in SEQ ID NO:23.

Parent patent claims an isolated monoclonal antibody that binds to PCSK9 via at least one or two of its amino acid residues, thereby blocking the binding of PCSK9 to low density lipoprotein receptor ("LDLR") by 80% efficacy, the result of which is reduced levels of low-density lipoprotein cholesterol ("LDL-C") in patients.

[40] U.S. Patent No. 8,829,165, claiming:

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

(subject patent directed to a genus of antibodies that bind to specific amino acid residues on PCSK9 that block it from binding to LDLRs, thereby resulting in reduced LDL-C levels in patients with high cholesterol).

[41] *See Sanofi*, 872 F.3d at 1371, 1375, 1381.

Arising from a patent dispute in another recent case, this one before the Supreme Court,[42] U.S. Patent No. 8,598,219 ("'219 patent") relates to a shelf-life stable intravenous formulation of palonosetron hydrochloride for the treatment of nausea and vomiting symptoms after emetogenic chemotherapy.[43] Application for the '219 patent was filed on May 23, 2013 as a continuation-in-part of U.S. Patent No. 7,947,724 ("'724 patent").[44] The '724 patent initially described seven embodiments of the drug and an eighth embodiment describing a different formulation was submitted as part of the specification filed for the '219 patent.[45]

Although the '219 and '724 patents were considered on issues other than enablement,[46] it would nevertheless be interesting and informative to examine the enablement issue because it is not so clear which embodiments of the formulations, as claimed, can have a shelf life of either twenty-four or eighteen months.[47] If it were disclosed which embodiments spoke to the stability aspect of the claimed invention,

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[42] *See* Helsinn Healthcare v. Teva Pharm. USA, No. 17-1229, slip op. at 1, 1–2 (U.S. January 22, 2019), *aff'g* 855 F.3d 1356, 1360–61, 1363, 1367 (Fed. Cir. 2017) (involving U.S. Patent No. 8,598,219 and other related patents, this case dealt with issues relating to the on-sale bar under the America Invents Act ("AIA"), but the subject patent was previously subject to an enablement challenge in a post-grant review case, Accord Healthcare v. Helsinn Healthcare (P.T.A.B. 2013) (settled without decision Sept. 2, 2014), before the Patent Trial and Appeal Board ("PTAB")).

[43] U.S. Patent No. 8,598,219 (filed as a continuation-in-part of U.S. Patent No. 7,947,724, adding an eighth example of the subject invention, a palonosetron hydrochloride pharmaceutical injection, to the patent specification in support of the elements relating to the drug's stability claimed in independent claims 1 and 8).

[44] *Id.*; *see also* U.S. Patent No. 7,947,724, claiming:

> 1.A pharmaceutically stable intravenous solution for reducing emesis or reducing the likelihood of emesis comprising:
>
> from 0.03 mg/ml to 0.2 mg/ml palonosetron or a pharmaceutically acceptable salt thereof, buffered at a pH of from 4.0 to 6.0; and a pharmaceutically acceptable sterile aqueous carrier including a tonicifying effective amount of mannitol and from 0.005 mg/ml to 1.0 mg/ml EDTA.
>
> (Whereas the subject patent claimed a pharmaceutical single-use dose of the same formulation at a certain range of concentrations, and being stable for twenty-four months, or alternatively eighteen months, when stored at room temperature.).

[45] *Compare* U.S. Patent No. 7,947,724 *with* U.S. Patent No. 8,598,219, which claims:

> 1.A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:
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> palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base; from 0.005 mg/mL to 1.0 mg/mL EDTA; and from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is *stable at 24 months when stored at room temperature.*
>
> (emphasis added) (Compared to the parent patent, the subject patent describes a third formulation of the drug, as an additional eighth embodiment, comprising slightly different reagents and a plastic container plus rubber stopper closure system presumably for increased shelf life.).

[46] *Helsinn*, No. 17-1229 at 1–2, *aff'g* 855 F.3d at 1363, 1367 (The issue decided on certiorari is "whether . . . an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.").

[47] See U.S. Patent No. 8,598,219.

and the addition of the eighth embodiment as post filing data did in fact help close the gap in disclosure, how exactly would that be achieved?[48]

Clarifying this dilemma inevitably leads to answering the big question: exactly what kind of disclosure is sufficient to satisfy the enablement requirement under 35 U.S.C. §112(a)?[49] Admittedly, this is too enormous of a question to tackle in a comment. Hence, elucidation and resolution of this standing conflict in patent enablement will be attempted from the perspective of post filing data.[50]

Post filing data is evidence generated after the filing date of the patent application that is used to demonstrate an enabling disclosure.[51] Post filing evidence may incorporate advances that would make the disclosure presently enabling, even though it was not clearly enabled as of the filing date.[52] Post filing technical evidence demonstrating enablement can come in various forms.[53] It can be sorted into three basic categories: (1) affidavits reflecting what occurred prior to filing of the application; (2) post filing generated technical evidence demonstrating that the claimed invention is not enabled; and (3) post filing generated technical evidence that the invention does have utility or that the disclosure is enabling.[54] In a prosecution context, the inventor may still be working on developing the invention, so there may be additional post filing evidence generated that could be used to support the enabling disclosure.[55]

However, use of post filing data can go awry. *Enzo Biochem v. Calgene* sees the patent holder present post filing data to demonstrate enablement in the wrong way.[56] The post filing data, in the form of a declaration, made conclusory statements and included only routine experimentation.[57] It provided nothing in the form of new information to support the disclosure of the claimed invention.[58]

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[48] *See id.*

[49] *See* 35 U.S.C. §112(a).

[50] *See In re* Brana, 51 F.3d 1560, 1566–67 (Fed. Cir. 1995) (allowing post filing data to substantiate any doubts as to the asserted [claims] since [it] pertains to the accuracy of a statement already in the specification).

[51] *See id.* at 1565, 1567 (specification disclosing an anti-tumor drug described the claimed compounds as having "a better action and a better action spectrum as antitumor substances" than known compounds tested *in vivo* for anti-tumor activities in two lymphocytic leukemia tumor models, but it was deemed non-enabling so the patent applicant submitted a declaration that listed anti-tumor activity test results of the claimed compounds in the same leukemia tumor models, showing that the claimed invention would likely be useful as anti-cancer agents as disclosed in the specification).

[52] *Id.* at 1567 (The declaration can be used to support the accuracy of statements already made in the patent specification about the claimed invention.).

[53] *Id.* (The declaration was filed after the filing date of the patent application to prove that the disclosure found therein was enabling at the time of filing, but not to render an insufficient disclosure enabling after filing.).

[54] *See In re* Hogan, 559 F.2d 595, 602, 604–06, 608–09 (C.C.P.A. 1977).

[55] *See Brana*, 51 F.3d at 1567 (The "declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since it pertains to the accuracy of a statement already in the specification.").

[56] Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1375–76 (Fed. Cir. 1999) (A declaration was submitted to the USPTO after the subject patent applications were rejected ten times on the ground of non-enablement due to a concern that antisense technology was too unpredictable to be practiced in cells other than *E. coli* without some enabling disclosure in those other types of cells.).

[57] *Id.* (The declaration made largely conclusory assertions of enablement about the claimed invention and provided mere routine experimentation based on the written descriptions in the

Post filing data is a limited solution that can only be invoked carefully during patent prosecution to convince a USPTO patent examiner that the broad claims are fully supported by the existing disclosure of the patent specification.[59] Because it is limited, post filing data can only fill in the gaps between the claimed invention and the specification to a certain degree, the extent of which will help define what a patent applicant must disclose in a specification to satisfy the enablement requirement.

One must keep in mind the big picture, which is the scope of enablement must correlate with the scope of the claims.[60] Thus, proper inquiry when using post filing data to fill in gaps in disclosure is whether the post filing data can do so such that there will be reasonable correlation between the scope of enablement in the disclosure and the scope of the claims.[61]

III. ANALYSIS

The number of embodiments disclosed in a patent application deemed by the Federal Circuit to be sufficient to enable the invention claimed therein has fluctuated to both extremes.[62] When examples of an invention are completely absent from a specification, such disclosure only proposes an unproven hypothesis, and is clearly not enabling.[63] However, when patent claims are construed more broadly than the examples disclosed in the specification, the Federal Circuit has vacillated over the years about the number and types of disclosures that satisfy the enablement requirement.[64]

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patent specifications.).

[58] *See id.*

[59] Gould v. Quigg, 822 F.2d 1074, 1077–79 (Fed. Cir. 1987).

[60] Leonard v. Maxwell Motor Sales, 252 F. 584, 589-90 (2d Cir. 1918) (Judge Learned Hand addressed the ability to draw generalizations not expressly supported by a disclosure.).

[61] *See Vaeck*, 947 F.2d at 495 ("There is no reasonable correlation between the narrow disclosure in [the applicants'] specification and the broad scope of protection sought in the claims encompassing gene expression in any or all cyanobacteria."); *see also Wands*, 858 F.2d at 736-37; *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (noting the first paragraph of §112 requires that the scope of protection sought bears a reasonable correlation to the scope of enablement provided in the specification).

[62] *Compare Invitrogen*, 429 F.3d at 1071 (holding that "the enablement requirement is met if the description enables any mode of making and using the claimed invention"), *Johns Hopkins*, 152 F.3d at 1360–61 (The disclosure of a single embodiment of producing an anti-My-10 antibody is deemed sufficient to enable the broader genus of claimed antibodies.), *with Auto. Techs.*, 501 F.3d at 1283 (holding that knowledge of a PHOSITA cannot fill in deficiencies in disclosure of a single embodiment of a mechanical crash sensor invention, when the subject patent also claimed an electrical crash sensor), *Sitrick*, 516 F.3d at 1000 (holding that PHOSITA could not take the single-example disclosure of the subject patent and practice the claimed invention without undue experimentation), and *Chiron*, 363 F.3d at 1254 (holding that disclosure of embodiments to a monoclonal antibody that binds human c-erbB-2 antigen, a nascent technology at the time, fell short of providing a "specific and useful teaching" of the two different antibodies claimed in the patent).

[63] *'318 Patent Litigation*, 583 F.3d at 1327 ('318 patent did not have any examples of what constituted the subject invention, rather it merely "state[d] a hypothesis and propose[d] testing to determine the accuracy of that hypothesis."); *see also* U.S. Patent No. 4,663,318.

[64] *Compare Hoechst*, 314 F.3d at 1335–36 (Patent claims found to be enabling although construed more broadly than the single example disclosed in the patent specification, because the

As recently as 2012, specifications disclosing a single embodiment were found to sufficiently enable a claimed invention because the knowledge of a PHOSITA can fill in any remaining gaps in disclosure.[65] The Federal Circuit decided that any complications that a PHOSITA may encounter while practicing the full scope of a claimed invention can be dispelled by simply following the teachings within the patent.[66] By doing so, the PHOSITA can avoid undue experimentation.[67]

At the same time, "a patentee who chooses broad claim language must make sure the broad claims are fully enabled."[68] When there are distinct aspects or variations of a claimed invention of equal or mutual significance, disclosure of multiple embodiments describing each of those aspects or variations is necessary to enable the full scope of the patent.[69] In *Sitrick*, claims relating to the integration of audio signals or video images were construed to include both movies and video games.[70] However, the court found the claims to be non-enabling because the specification failed to disclose embodiments describing integration of user images in movies, teaching the invention only in relation to video games.[71] Likewise, in *Chiron*, the scope of the claims in the patent-in-suit included two different antibodies.[72] The court also found these claims to be non-enabling because the specification did not teach all of the antibodies within the scope of the claims, and the antibody technology was too nascent for a PHOSITA to have knowledge to fill in the gaps in disclosure.[73] Thus, rather than trying to draft a specific number of embodiments to achieve the goal of sufficient disclosure in a patent specification, it is more important to describe embodiments for each key aspect or variation of an invention, as set out in the patent claims, in order to satisfy 35 U.S.C. §112(a).[74]

This qualitative, rather than quantitative, approach to disclosure in patent specifications makes sense in view of the apparent dilemma relating to the lack of

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court looked to not only the disclosure providing a method of making and using the invention, but also what was known in the art to fill in any gaps in the disclosure.), and *Streck*, 665 F.3d at 1291 (finding that "no undue experimentation would be necessary once the teachings of the subject patent were known," the court held the patent claims to be enabling despite being construed more broadly than the single embodiment disclosed in the specification), *with Auto. Techs.*, 501 F.3d at 1283 (Patent claims held to be not enabling when construed more broadly than the example disclosed, because the court found that practicing the full scope of the claimed subject invention would require undue experimentation, since knowledge of a PHOSITA cannot supply the missing information where the specification should supply novel aspects of the invention.), and *Liebel-Flarsheim*, 481 F.3d at 1380 (Claims held to be not enabling when construed to include a single embodiment disclosed in the specification as well as a second alternative embodiment, especially when the specification provided no guidance as to how to make or use the alternative embodiment and even taught away from the alternative embodiment.).

[65] *Streck*, 665 F.3d at 1289.

[66] *Id.* at 1291.

[67] *Id.*

[68] *Sitrick*, 516 F.3d at 999.

[69] *See Chiron*, 363 F.3d at 1256 (Although an aspect of the claimed invention included binding of an antibody to a breast cancer antigen, the patent disclosure only enabled murine antibodies and fell short of providing a specific and useful teaching of all antibodies, particularly chimeric antibodies, within the scope of the claimed invention.).

[70] 516 F.3d at 999.

[71] *See id.* at 999–1000.

[72] *See* 363 F.3d at 1250-51.

[73] *Id.* at 1254-56.

[74] *See* 35 U.S.C. §112(a).

enablement of the '165 patent at issue in *Amgen v. Sanofi*.[75] Briefly, the '165 patent invention comprises: 1) an antigen binding protein in the form of an isolated monoclonal antibody that competitively or selectively binds to PCSK9 at the location of at least four of PCSK9's amino acid residues such that the antibody reduces binding of LDLR to PCKS9 by at least eighty percent; and 2) a pharmaceutical composition of the antigen binding protein that may be coupled with an active agent for administration in patients seeking treatment for high cholesterol or LDL levels in their blood serum.[76] A method of making the recombinant antigen binding protein, by injection of vector molecules that transfer coding information of the protein into host cells for inducing production of the protein, was disclosed in the specification but not claimed in the '165 patent.[77]

The '165 patent lists the full range of various possible amino acid sequences of the antigen binding protein.[78] In addition, figures show the structure of PCSK9, the structures of the various possible heavy chain and light chain portions of the antigen binding protein, the binding efficiency of the antigen binding protein to PCSK9, and its effect on PCSK9 and LDL.[79] Numerous embodiments of the invention describe the possible amino acid sequences and combinations of heavy chain and light chain segments of the antibody,[80] the possible types of antibodies that the antigen binding protein can be,[81] the range of pharmaceutical formulations using the antigen binding protein,[82] the function of the antigen binding protein,[83] and the effect of the pharmaceutical formulations.[84] The forty-one specific examples detail the

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[75] *See Amgen v. Sanofi*, 872 F.3d at 1372–73, 1375; U.S. Patent No. 8,829,165.

[76] *See* U.S. Patent No. 8,829,165 cols. 3–124.

[77] *Compare id.* at cols. 7, 45–49, 73–77, and 81–84, *with id.* at cols. 427–430.

[78] *Id.* at cols. 123–428 (SEQ ID NOS: 1-575); *see also id.* at cols. 3–17, 40–42, 47, 50, 60–63, 85, 104–05, 110–11, and 122.

[79] *Id.* at figs. 4A–12F, 14A–14B, 16A–21D, 23A–25F, and 27A–28D.

[80] *Id.* at cols. 3–6, and 12–17. For example:

In some aspects, the invention comprises an isolated antigen binding protein that binds PCSK9 comprising: A) one or more heavy chain complementary determining regions (CDRHs) selected from the group consisting of: (i) a CDRH1 from a CDRH1 in a sequence selected from the group consisting of SEQ ID NO: 74, 85, 71 . . . In some embodiments, the isolated antigen binding protein comprises at least one CDRH of A) and at least one CDRL of B). In some embodiments, the isolated antigen binding protein comprises at least two CDRH of A) and at least two CDRL of B).

[81] *Id.* at cols. 6–7. For example:

In some embodiments, the isolated antigen binding protein is a monoclonal antibody, a polyclonal antibody, a recombinant antibody, a human antibody, a humanized antibody, a chimeric antibody, a multi-specific antibody, or an antibody fragment thereof. . . . In some embodiments, the isolated antigen binding protein is a human antibody. In some embodiments, the isolated antigen binding protein is a monoclonal antibody. In some embodiments, the isolated antigen binding protein is of the IgG1-, IgG2-IgG3- or IgG4-type. In some embodiments, the isolated antigen binding protein is of the IgG4- or IgG2-type.

[82] *Id.* at cols. 7–9. For example:

In some aspect, the invention comprises a pharmaceutical composition comprising at least one antigen binding protein as described herein and a pharmaceutically acceptable excipient. In some embodiments, the pharmaceutical composition further comprises an additional active agent. In some embodiments, said additional active agent is selected from the group consisting of a radioisotope, radionuclide, a toxin, or a therapeutic and a chemotherapeutic group.

[83] *Id.* For example:

In some aspects, the invention comprises an isolated antigen binding protein that competes for binding to PCSK9 with an antigen binding protein disclosed herein.

[84] *Id.* For example:

generation, optimization, and functional characterization of the antigen binding protein.[85]

It is undeniable that the '165 patent discloses a lot of information about the claimed invention.[86] However, nowhere in the abundance of information does the specification describe how the antigen binding protein definitively binds to PCSK9.[87] The best it does is estimate all of the possible locations on PCSK9 at which the antigen binding protein can bind in relation, measured by Angstrom, to any one of the four hundred and seventeen amino acid residues 31–447 on PCSK9.[88] Yet, the '165 patent claims many times over that "the isolated monoclonal antibody binds to at least" one of numerous amino acid residues on PCSK9.[89]

In view of hundreds of possibilities of where the antigen binding protein can bind to PCSK9, a PHOSITA would not be able to practice this invention without undue experimentation. Moreover, the specification provides no guidance regarding exactly how the antigen binding protein is supposed to bind to PCSK9,[90] so a PHOSITA would likely not be successful in achieving the outcome intended by the inventor when practicing this invention. The fact that forty-one examples are disclosed in the specification is immaterial if they all teach around the key aspect of the invention recited in the claims. Thus, silence on the mechanism of binding between the antigen binding protein and PCSK9 critically renders the '165 patent non-enabling.

The inventors of the '219 patent, on the other hand, sought to add an eighth embodiment to their continuation-in-part patent application derived from their parent patent in which only seven embodiments were disclosed.[91] The eighth example in the '219 patent is an additional formulation of the liquid injectable palonosetron invention that is different from the other two formulations in that it does not comprise of the tonicifying agent, mannitol.[92] Instead, the eighth

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In some aspects, the invention comprises a neutralizing antibody that binds to PCSK9 and reduces a low density lipoprotein receptor (LDLR) lowering effect of PCSK9 on LDLR.

[85] *Id.* at cols. 73–124 (The forty-one examples include immunization and titering of the hybrid mice producing the antibodies, generation of hybridomas, selection of antibodies to PCSK9, production of recombinant human antibodies and hybridomas, sequence analysis of the heavy and light chains of the produced antibodies, characterization of the antibodies' ability to bind PCSK9, efficacy assay to see how well the antibodies block LDLR from binding PCSK9, detection of levels of serum cholesterol in mice before and after treatment with the antibody, tracking the effect of the antibody on serum cholesterol over time, and testing treatment using the antibody in human patients.).

[86] *See id.* at 1–124.

[87] *See id.*

[88] *Id.* at cols. 9–12. For example:

In some aspects, the invention comprises a neutralizing antigen binding protein that binds to PCSK9, wherein the antigen binding protein binds to PCSK9 at a location within residues 31-447 of SEQ ID NO: 3. In some embodiments, when the antigen binding protein is bound to PCSK9, the antibody is positioned 8 angstroms or less from at least one of the following residues of PCSK9: S153, I154, P155, R194 . . . In some embodiments, the antibody is positioned 5 angstroms or less from at least one of the following residues of PCSK9: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381.

[89] *Id.* at cols. 427–430 (Almost all of the patent claims recite a binding connection between the isolated monoclonal antibody and at least one amino acid residue on PCSK9.).

[90] *See id.* at 1–124.

[91] *Compare* U.S. Patent No. 8,598,219 cols. 7–9, *with* U.S. Patent No. 7,947,724 cols. 7–9.

[92] *Id.*

embodiment's formulation relies on sodium chloride as the tonicifying agent.[93] This seems contrary to the third example, originating from the parent patent, which teaches away from using sodium chloride by disclosing adding mannitol as providing "superior stability" for the palonosetron solution.[94]

Regardless, having a palonosetron formulation without mannitol in the specification does not make the '219 patent immune to enablement challenges. The purpose of disclosing embodiments with different formulations was to show that various palonosetron solutions can maintain their stability under varying conditions of temperature and light when stored on the shelf for eighteen to twenty-four months.[95] However, the specification seems to provide no example or support for the claims reciting that the palonosetron solutions are stable at room temperature for such periods of time.[96]

Following the reasoning above as applied to the '165 patent, a PHOSITA may be able to practice the invention here. But there is no guarantee that the outcome will be as intended by the inventors, because no proof was given in the specification that any of the palonosetron formulations were shelf-stable at room temperature for over

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[93] U.S. Patent No. 8,598,219 col. 9.

Example 8

Formulation III

The following is a representative pharmaceutical formulation and container closure for palonosetron that is useful for intravenous infusion formulations.

Ingredient	Amount (mg)
Palonosetron Hydrochloride	0.75
Sodium Chloride	450.0
EDTA	2.5
Sodium citrate	18.5
Citric acid monohydrate	7.8
WFJ	q.s. to 50 mL
Sodium hydroxide solution and/or hydrochloric acid solution	pH 4.8 ± 0.5
Container closure system	plastic container plus rubber stopper (isoprene)

[94] U.S. Patent No. 7,947,724 col. 7.

Example 3

Tonicifying Agent

Formulations of palonosetron hydrochloride in citrate buffer were prepared including either a) sodium chloride or b) mannitol. The palonosetron hydrochloride formulation including mannitol showed superior stability. The optimum level of mannitol required for an isotonic solution was found to be 4.15%. (emphasis added)

[95] *See* U.S. Patent No. 8,598,219 cols. 7–9.

[96] *See id.* at cols. 1–9.

eighteen or twenty-four months.[97] In the end, the PHOSITA would still need to carry out undue experimentation when practicing the invention in order to achieve the intended outcome. Thus, if the issue of enablement were presented on writ of certiorari for the '219 patent in the case between *Helsinn* and *Teva*,[98] patent owner Helsinn would likely not have been able to overcome an argument of the '219 patent being non-enabling, unless a further continuation-in-part application were filed with post filing experimental data.

Although it may be clearer what should *not* be done when enablement is at issue, the question of what can be done is more difficult to figure out. Post filing data is a helpful but limited solution to fill in any unexpected gaps in disclosure after a patent application has already been filed. Post filing data should not be used incorrectly to introduce any new matter into the existing patent application.[99]

In fact, patent applicants should be aware that the determination of what kind of post filing data may be used to prove that a specification is enabling rests on facts surrounding a patent at issue and its existing disclosure, in view of 35 U.S.C. § 112(a). They should bear in mind that § 112(a) provides two interrelated requirements: that the written description describes what the subject invention is and how it works; and that the description enables a PHOSITA to practice the invention purely based on reading the specification.[100] *Brana* allows post filing data only to "substantiate any doubts" as to what is asserted in the patent because it relates to the accuracy of a statement already existing in the specification.[101] Consequently, if disclosures about an aspect of a claimed invention are missing from the specification, there would be no way to add in new matter after filing of the patent application to fill that void.[102] In *Brana*, test data was submitted and accepted during patent prosecution to support a statement *already made* in the

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[97] *See id.*

[98] *See Helsinn*, No. 17-1229 at 1–2, *aff'g* 855 F.3d at 1363, 1367 (The issue on certiorari related to the on-sale bar under the AIA.).

[99] *See Rasmussen,* 650 F.2d at 1214 (broadening a claim under 35 U.S.C. § 112 does not add new matter to the disclosure in the specification, which is prohibited under 35 U.S.C. § 132, because disclosure is that which is taught, not that which is claimed); *see also* MPEP § 2163(I)(B) (holding that proscription against the introduction of new matter into a patent application serves to prevent a patent applicant from adding new information that goes beyond the subject matter originally filed).

[100] *See* 35 U.S.C. § 112(a); MPEP § 2164 (showing that enablement requires the specification to describe how to make and use the invention), whereas MPEP § 2161 is a separate and distinct requirement from enablement (Written description requires that the specification describe the claimed invention in sufficient detail that a PHOSITA can understand the invention and can reasonably conclude that the inventor had possession of and actually invented the claimed invention at the time of filing.).

[101] *See Brana*, 51 F.3d at 1567 (A declaration submitted after the filing date of a patent application showed the effect of a claimed anti-tumor drug in two different types of cancer, as established in the patent specification.).

[102] *See '318 Patent Litigation*, 583 F.3d at 1325 ('318 patent claiming a method of treating Alzheimer's disease with galanthamine did not contain anything of substance to describe what constituted the invention, so there are no statements in the specification for post filing test data to even support.); see also *Brana*, 51 F.3d at 1567.

patent specification at the time of filing.[103] Post filing data is also allowed for purposes of confirming what is speculated in the specification.[104]

Post filing data can be considered for enablement challenges not when it is offered for the purpose of adding knowledge of the art after a patent application is filed, but when it is offered as evidence to show a level of ordinary skill in the art at the time of filing.[105] Given this, post filing data can be used to confirm and substantiate results that were predicted in the specification at the time of filing.[106] Its main purpose is to support the accuracy of or to help elucidate statements made in the specification.[107]

So, post filing data may be generally admissible to prove the "state of the art" at the time of filing, depending on the particular technology of the claimed invention. Some experimental data missing from the specification at the time of filing may be permissibly added using post filing data, because a PHOSITA would have been able to extrapolate beyond the embodiments in the specification and interpolate between them in order to fill in any gaps left by the once missing experimental data. Proof of the "state of the art" at the time of filing in the mind of a PHOSITA would indicate that the PHOSITA is able to understand or foresee the full scope of the claimed invention from its initial or existing disclosure.[108]

Post filing data should not be seen as a catch-all for fixing insufficient enablement, far from it in fact.[109] It is essential to focus on disclosing all aspects of an invention in the specification when drafting a patent application. If a claim covers a range of embodiments, the disclosure must contain sufficient written description to adequately enable the full scope of the range of embodiments.[110] In other words, if a claim reads on distinctly different embodiments of an invention, the specification must sufficiently enable each of those embodiments.[111]

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[103] *Brana*, 51 F.3d at 1562.

[104] *Id.* at 1567.

[105] *See Hogan*, 559 F.2d at 605 (holding that the use of later submissions as evidence to show the state of the art existing at the time of filing of the patent application is allowed).

[106] *See Brana*, 51 F.3d at 1567.

[107] *Id.*

[108] *See Marzocchi*, 439 F.2d at 223–24 (holding that the breadth of the scope of a disputed term "polyethyleneamine" in the claims of the patent-in-suit was sufficiently supported by disclosure of a single example compound in the patent specification, because a PHOSITA would be able to understand which chemical compounds the term encompasses, and thus what compounds the patent covers, based on the PHOSITA's own knowledge in the art).

[109] *See Cavallito*, 282 F.2d at 367 (holding that a specification with nineteen examples adequately enabled a broad claim covering hundreds of thousands of compounds because the sufficiency of a disclosure depends not on the number, but rather on the nature of the claimed compounds and the nature of the supporting disclosures).

[110] *See Liebel-Flarsheim*, 481 F.3d at 1378 (establishing that the disclosure must teach the full range of embodiments in order for the claims to be enabled).

[111] *See Auto. Techs.*, 501 F.3d at 1285 (An inference of "distinctly different" embodiments might arise when the applicant provides substantial written description for one embodiment and relatively little written description for another.).

IV. PROPOSAL

It is important to remember that post filing data cannot be implemented to supply what is missing from the description of an invention disclosed in a patent specification.[112] Rather, post filing data can only be used to support or further explain the description of the invention that is *already* disclosed in the patent specification.[113] A patent applicant must possess all parts of the invention claimed at the time of filing of the patent application.[114]

With this in mind, a patent specification should disclose at the outset all aspects of the invention as claimed in at least the independent claims. By doing so, the boundaries of disclosure contained within the four corners of the patent application will cover all claimed aspects of the invention. In other words, when drafting, a patent applicant should be certain that all necessary information supporting the claims is disclosed or described in the patent specification with sufficient particularity to ensure that a PHOSITA will be able to practice the invention and understand or recognize that the patent applicant possessed the invention being claimed at the time of filing.[115] Otherwise, the specification may be deemed as non-enabling. Disclosure of all necessary information means that all essential or critical features of the invention, as defined in the claims, are adequately described in the specification, with the exception of certain features that are either conventionally or feasibly known in the art.[116]

In the unpredictable arts,[117] it is especially important for the patent specification to sufficiently describe "distinguishing identifying characteristics" of the invention in order to support the claims.[118] To do so, a specification can show reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit.[119]

In the '165 patent at issue in *Amgen v. Sanofi*, among forty-one examples testing the binding of the antigen binding protein to PCSK9 described in the specification, there is not one disclosure describing the mechanism of binding and the location on PCSK9 to which the antigen binding protein actually binds.[120] A patent

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[112] *See* MPEP § 2163(I)(B) (providing that "proscription against the introduction of new matter into a patent application serves to prevent a patent applicant from adding new information that goes beyond the subject matter that was originally filed").

[113] *See Brana*, 51 F.3d at 1563.

[114] MPEP § 2163(I) ("[A]pplicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." (quoting *Lockwood v. Amer. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997))).

[115] MPEP § 2163(I)(A).

[116] *Id.*

[117] *Enzo Biochem*, 188 F.3d at 1372.

[118] MPEP § 2163(I) (One must define a compound by "whatever characteristics sufficiently distinguish it" from others.); *see also Eli Lilly*, 119 F.3d at 1568–69, and *Chugai*, 927 F.2d 1200 at 1206.

[119] MPEP § 2163(I) ("[R]eference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material" and "description of the deposited material needs to be as complete as possible" such that "the more information provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

[120] *See* U.S. Patent No. 8,829,165 cols. 73–124.

that claims as its invention a novel antibody that functions by competitively binding to another protein should, at minimum, disclose how the antibody actually binds to that target protein, unless such functions may be predictable in view of the teachings of the specification.[121] A patent applicant drafting an application for a novel protein should aim to elucidate, through disclosure in the specification, the functional mechanism of the novel protein if the function of that protein is a key aspect of the claimed invention (it is, most of the time).

Similarly, nowhere in the specification of the '219 patent is proof of stability of the palonosetron formulation at eighteen or twenty-four months disclosed, even though stability for those lengths of time are claimed as elements of the invention.[122] The examples of different formulations of the drug do not describe testing of stability of those different formulations under varying conditions of temperature, light, and time spent on the shelf *beyond* fourteen days of storage.[123] If the length of time that a compound, pharmaceutical or otherwise, can remain stable on the shelf is claimed as an element of the invention, then a patent application should disclose with specificity the testing parameters under which the compound remains stable and for how long remains stable.[124] Other characterizations of compounds, such as molecular weight, composition, solubility, crystal structure, chirality, and binding specificity and affinity, claimed as an element of an invention should also be supported by disclosures in the specification showing testing done to define such characteristics.[125]

While drafting a patent application, an applicant should focus on the scope of the disclosures regarding each aspect of the claimed invention, rather than the number of examples used to support the disclosures.[126] After all, the scope of the claims should be less than or equal to the scope of the enablement.[127] If broad claims are made, then the scope of the disclosures in the patent specification should provide teachings of comparable breadth.[128] At the same time, it is advisable to not disclose too many details that would allow competitors to exploit the claimed invention without putting in extra effort of their own. Thus, the scope of an enabling disclosure should be just broad enough to sufficiently teach a PHOSITA how the claimed invention should be carried out.

Although it is tempting to draft the disclosures as broadly as possible, by using more general terms or statements to predict certain effects that may extend beyond the disclosed invention, doing so without the proper support from test data would only invite a patent examiner's rejection of the patent application during

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[121] *See id.* at cols. 3–124, 427–30.

[122] *See* U.S. Patent No. 8,598,219.

[123] *See id.*

[124] *See id.*

[125] *See Fisher*, 427 F.2d at 839 (The patent at issue did not set forth with particularity the chemical structure or adequate physical characteristics of an injectable adrenocorticotrophic hormone concentrate to sufficiently identify its composition.).

[126] *See Chiron Corp.*, 363 F.3d at 1253 (An enabling disclosure of a specification must be commensurate in scope with the claims under consideration.); *Chugai*, 927 F.2d at 1213 (The patent disclosure must be sufficient enough to enable a PHOSITA to carry out the claimed invention "commensurate in scope" with what is covered by the claims.).

[127] *Sitrick*, 516 F.3d at 999.

[128] *Id.* ("[A] patentee who chooses broad claim language must make sure the broad claims are fully enabled.").

prosecution.[129] Accordingly, an applicant should take care not to make such unsupported general statements that go beyond the scope of the disclosed embodiments, especially for an invention in the unpredictable arts.[130]

If a claimed feature or aspect of an invention is not described in sufficient detail in the application upon filing, then post filing data may be used to supplement or clarify what is already disclosed in the specification.[131] Of course, the extent to which post filing data can fill gaps in disclosure is limited, so it would not be wise to look to post filing data as a total saving grace when a patent examiner rejects an application due to non-enablement.[132] Supplemental experimental data submitted after filing should only serve a purpose of bridging the gap between a PHOSITA's understanding of the teachings already found in the specification and the PHOSITA's own knowledge in the art.[133] As long as the patent specification is drafted properly and addresses each aspect claimed of a subject invention, the post filing experimental data may be used to elaborate on the subject matter already disclosed in the specification.[134]

V. CONCLUSION

35 U.S.C. § 112(a) sets the standard for enablement of patent applications.[135] Yet, putting this requirement into practice has not become straightforward over

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[129] *See* MPEP § 2163.03(V) (A "claim may lack written description support when (1) the claim defines the invention in functional language specifying a desired result but the disclosure fails to sufficiently identify how the function is performed or the result is achieved, or (2) a broad genus claim is presented but the disclosure only describes a narrow species with no evidence that the genus is contemplated" (quoting *Ariad Pharms.*, 598 F.3d at 1349–50); and "the appearance of mere indistinct words in a specification or a claim . . . does not necessarily satisfy that requirement." (quoting *Enzo Biochem v. Gen-Probe*, 323 F.3d 956, 968 (Fed. Cir. 2002))).

[130] *See Spectra-Physics*, 827 F.2d at 1533 (Courts, until recently, were likely to uphold a broad claim directed to inventions in the predictable arts, even if it encompassed other embodiments that were inadequately disclosed.).

[131] MPEP § 716.09 (Once an "examiner has established **. . .** lack of enablement, the burden falls on the applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would have been able to make and use the claimed invention using the disclosure as a guide" (quoting *In re Brandstadter*, 484 F.2d 1395 (C.C.P.A. 1973)); and "[e]vidence to supplement a specification which on its face appears deficient . . . must establish that the information which must be read into the specification to make it complete would have been known to those of ordinary skill in the art." (quoting *In re Howarth*, 654 F.2d 103, 106 (C.C.P.A. 1981))).

[132] *See id.*

[133] *See* MPEP § 716.09 (Affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite, nor are affidavits or declarations purporting to explain the disclosure or to interpret the disclosure of pending applications.).

[134] *Id.*

[135] 35 U.S.C. § 112(a) ("[T]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."); *see also* MPEP § 2163, and *Ariad Pharms.*, 598 F.3d at 1336 (Federal Circuit has held, since 2010, that 35 U.S.C. § 112 contains both a written description requirement and an enablement requirement, so that a patent specification must describe the invention sufficiently for a PHOSITA to understand that the inventor possessed the

time.[136] Here, a further attempt is made to figure out how much disclosure is enough, by elucidating the requirements for drafting a patent specification with sufficient disclosure of the invention that supports its corresponding patent claims.[137] Moreover, submission of post filing data is proposed as a limited solution in response to a patent application being deemed as non-enabling.[138]

Two recent examples of non-enabling patents represent the ongoing confusion as to what information should actually be disclosed in a patent specification in order to enable the claimed invention.[139] The way the patents are drafted emphasizes a misguided effort to bulk up the specification with numerous embodiments describing only some aspects of the respective claimed inventions.[140] Instead, the drafters of these patents should have made disclosures in the specifications covering each and all of the claimed aspects of the inventions.[141] This is the proper way to ensure that the claimed inventions are supported by their respective patent specifications.[142]

Only after all aspects of a claimed invention are adequately disclosed in a patent specification can post filing data apply to supplement any deficiencies or confusion about how the invention is described during patent prosecution.[143] Post filing data does not apply when there are holes in the description of the claimed invention such that not all aspects of the invention are addressed in the specification.[144] Drafters of patent applications should be cautious to not rely on post filing data after the fact to fill in missing aspects of a claimed invention that the applicant is responsible for disclosing initially at the time of filing. Nevertheless, post filing data generated from additional experimentation after the filing of a patent application that was done pursuant to reducing the claimed invention to practice is acceptable to supplement the disclosure in the patent specification.[145]

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subject matter claimed and, separately, must teach a PHOSITA how to make and use the invention.) (A holding that has been contested up until and including *Sanofi*, 872 F.3d 1367.).

[136] *See Streck*, 665 F.3d at 1269; *Sitrick*, 516 F.3d at 993; *Liebel-Flarsheim*, 481 F.3d at 1371; *Auto. Techs.*, 501 F.3d at 1274; *AK Steel*, 344 F.3d at 1234; *Hoechst*, 314 F.3d at 1313; *Johns Hopkins*, 152 F.3d at 1342; *Chugai*, 927 F.2d 1200 at 1200; and *Spectra-Physics*, 827 F.2d at 1524.

[137] *See id.*

[138] *See* MPEP § 2163(I)(B).

[139] *See* U.S. Patent Nos. 8,829,165 and 8,598,219.

[140] *See* U.S. Patent No. 8,829,165 cols. 73–124 (Forty-one embodiments characterize the binding possibilities between an antigen binding protein and PCSK9, but none described the actual binding mechanism between the antibody and antigen.), and U.S. Patent No. 8,598,219 cols. 7–9 (Eight embodiments describe different formulations of an injectable pharmaceutical drug, but none of the examples disclosed the actual measured shelf-life of the formulations even though stability at room temperature is claimed as an element of the invention.).

[141] *See* MPEP § 2163(I)(A) (A claimed invention is not sufficiently disclosed in the specification if an essential or critical aspect of the invention, claimed as an element in the patent claims, is not adequately described and is also not conventional or known in the art by a PHOSITA.).

[142] *See id.*

[143] *See* MPEP § 716.09.

[144] *Gould*, 822 F.2d at 1077–79 (Later dated submissions cannot supplement an insufficient disclosure in a prior dated patent application to render it enabling, but they can instead be offered to show the level of ordinary skill in the art at the time of filing of the patent application.).

[145] *See Brana*, 51 F.3d at 1562 (Post filing data can demonstrate enablement; an inventor may experiment after the filing date of the patent to show that the disclosure is enabling; for example, inventors were not certain at the time of filing of their patent that their drug would be successful in treating a specific disease, so they obtained data from clinical tests run to assess the drug's efficacy for treating the disease, and the post filing clinical study results were permitted to be used.).