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The authors provide a strategic framework for building a defense of a patent before an AIA-enabled proceeding challenge, with a focus on written description weaknesses.

Strengthening Pending and Future Application Portfolios in Advance of Potential Attack in AIA Proceedings

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In 2011, enactment of the America Invents Act significantly changed the way that U.S. patents may be challenged, establishing three new proceedings for the Patent and Trademark Office to reconsider the patentability of issued patents: inter partes review, covered business method and post-grant review. The first two proceedings, inter partes review and covered business method, have already been put to heavy use, with over 2,600 IPR petitions and over 300 CBM petitions having been filed with the new Patent Trial and Appeal Board.

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These proceedings have changed the way parties litigate validity disputes,[1] including validity disputes over drug and biotech patents. The PTAB, however, has yet to institute a PGR proceeding. The reason for this disparity is straight forward: Post-grant review may only be instituted on patents with priority dates that post-date March 15, 2013.[2] We anticipate a significant uptick in PGR filings as more eligible patents issue.[3]

Written description weaknesses can serve as the basis for attacking priority benefit in all three types of proceeding (thus opening up the patent to intervening art and different types of art under the AIA if the effective date is found to be after March 15, 2013)[4] or as a basis for unpatentability in PGRs and CBMs.[5] Patent applicants and owners should consider defending against ei-

[1] Patentability rather than validity is determined in these AIA proceedings (in which there is no presumption of validity). *See, e.g.*, 35 U.S.C. § 311(b).

[2] A patent is eligible for post-grant review if it, or any application in its priority chain, ever had a claim with an effective priority date after March 15, 2013. Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11083 (Feb. 14, 2013) (85 PTCJ 543, 2/22/13). This is true even if no claim in the patent itself has a pre-March 16, 2013, effective priority date.

[3] Some of these patents may be filed under the Prioritized Examination (Track One) Program, which expedites issuance. As of Oct. 9, 2014, over 2,600 Track One applications have been filed in Art Unit 1600 (which examines biotechnology and drug-related applications).

[4] See Millonig, Longsworth, and Smith Law360 article on IPRs, An Alternative Attack In Inter Partes Review, New York, Oct. 29, 2014.

[5] For a general description of the applicable statutes for each type of proceeding, see Longsworth and Hammond, Post-Grant Reviews at the Patent Office: How They Could Be Used to Challenge Biotech and Pharma Patents, Bloomberg BNA's

ther type of written description attack in front of the PTO. This article will address how to avoid (or correct) such written description weaknesses in patent applications and patents.[6]

Written Description: Lessons From Recent Federal Circuit Case Law

Recent court opinions highlight potential written description issues that may be used to attack patents in these new PTO proceedings. Details of these opinions are discussed below. By keeping these opinions in mind when drafting patent applications or amending claims in existing applications, applicants and owners may avoid or minimize similar written description issues.[7] This article provides several strategies and suggestions for doing so in the discussion below.

Be careful drafting claims encompassing a broad or large genus:

The following two cases involve patents in which claims were added during prosecution to dominate a competitor's product years after the patent's effective filing date.

AbbVie v. Janssen.[8] In the unpredictable arts, a genus claim that includes a functional limitation must be supported by a specification disclosing a structure-function relationship (unless known in the art) or describing representative species. In *AbbVie v. Janssen*, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's judgment that claims reciting a functional limitation were invalid as lacking adequate written description support.[9] The claims at issue are directed to a genus of antibodies with a specified minimum binding affinity for IL-12.

The court stated that the antibodies were defined not structurally, but with ''functional language to define a desired result.'' The court discussed two factors for determining whether a claimed genus is adequately described: if a specification describes structural features common to the genus or describes a representative number of species. The court agreed with the jury that in the unpredictable art of making antibodies with improved binding affinity, in which predicting a correlation between structure and function is difficult and not described in the art, the specification must provide such a correlation. Alternatively, the specification must describe species with enough variability within the claim scope to be representative of the scope of the genus.

Concerning a structure-function correlation, the court agreed that the specification did not describe any. And the evidence showed that a trial and error approach was more successful than attempting to predict changes to produce antibodies with improved binding.

Concerning the disclosed species, the evidence sufficiently showed that, although numerous species were disclosed (more than 200), they were structurally highly similar. For example, the disclosed species shared 90 percent sequence similarity and included only one type of constant light and constant heavy chain.[10] In contrast, the claims encompass highly variable antibodies, including an antibody (the accused product) that shared only 50 percent sequence identity with the disclosed antibodies. The claims also encompass antibodies that had types of constant light and heavy chains (including the accused antibody) that differed from the disclosed species. In an analogy to real estate, the court stated that ''the disclosed species only abide in a corner of the genus'' and thus were not representative of the genus.

Synthes v. Spinal Kinetics.[11] In a complex or unpredictable art, one species does not provide sufficient written description support for a genus encompassing other, different species where replacement of one species for another is not a matter of simple substitution. In *Synthes v. Spinal Kinetics*, the claims at issue were directed to artificial spine discs for an intervertebral implant comprising a plurality of ''openings.'' The patentee argued that ''openings'' encompassed any kind of opening in any position, including peripheral grooves and internal slots. Under this construction, the claims encompassed the accused device, which had internal slots. The accused infringer successfully asserted that the specification did not adequately describe such a broad construction where all of the examples had peripheral grooves.

The court considered evidence showing several facts, including: significant differences in biomechanical properties existed between those grooves and slots, changing from peripheral grooves to internal slots was not simple and had required months of effort, and the field of intervertebral implants was unpredictable. These factors would lead a skilled artisan to conclude that internal slots would not serve the same function as the disclosed grooves. Because substantial evidence supported these facts, the majority affirmed the jury's verdict of invalidity.[12]

Patent, Copyright and Trademark Journal, Nov. 14, 2014 (89 PTCJ 112, 11/14/14) (BNA Article).

[6] Applicants should also consider submitting an expert declaration in response to a written description rejection during prosecution (e.g., testifying on what the specification reasonably conveys about a disputed claim term to a person of ordinary skill in the art). After issuance, if the patent is challenged in a petition for IPR, CBM or PGR, the patent owner generally may submit this declaration, but not new declaration testimony, in its preliminary response to support its argument that the petition should be denied, *See, e.g.*, 37 C.F.R. § 42.107(c); IPR2014-00572, Paper 10 at 10, n. 2 (P.T.A.B. Sept. 29, 2014).

[7] For issued patents, see the Law360 article by Longsworth, Covert and Smith that describes reissue strategy that patent owners may use. Patent Armoring Via Reissue Proceedings, New York, Sept. 16, 2014.

[8] *AbbVie Deutchland GmBH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 111 U.S.P.Q.2d 1780 (Fed. Cir. 2014) (88 PTCJ 651, 7/11/14).

[9] Judge O'Malley's concurring opinion characterized the majority's holding and opinion on invalidity based on lack of written description support to be dicta because, in her opinion, it was unnecessary for affirming the district court judgment. She would instead have addressed only the prejudicial effect of the jury instruction about the burdens of proof, which the patentee had challenged on appeal, and would have either affirmed the district court's invalidity holding (if they were not prejudicial) or ordered a new trial (if they were prejudicial).

[10] The most abundant antibody, IgG, is made of two light chains and two heavy chains. Each chain contains a variable and a constant region. The variable region binds antigen and the constant region performs certain immunological functions. Several types of constant region exist for each chain.

[11] *Synthes USA, LLC v. Spinal Kinetics, Inc.*, 734 F.3d 1332, 108 U.S.P.Q.2d 1661 (Fed. Cir. 2013) (87 PTCJ 11, 11/1/13).

[12] Judge Taranto dissented. In his opinion, the patent challenger had failed to show that the differences between the broad claim terms and the disclosed specific embodiments for

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To avoid or minimize problems such as those in *AbbVie* or *Synthes*, draft applications to include structure-function relationships or to disclose more varied species that are representative of the genus. For example, in *AbbVie*, the applicant could have included prophetic examples of antibodies with other types of constant regions. Preferably, these would share less than 90 percent homology with the 200+ species that were disclosed. In applications that have already been filed, claim narrowly at the outset (e.g., when filing a continuing application) such that the disclosed species are representative of the narrow genus. If no amendments are made during prosecution, it may be possible to rely on the doctrine of equivalents to encompass competitors during district court litigation (assuming the patent survives PTO litigation).

Include adequate support for negative claim limitations:

In re Bimeda.[13] Negative claims limitations are supported if they are expressly disclosed. *In re Bimeda* involved claims directed to a ''prophylactic method of controlling infection'' in a cow teat by sealing it using a seal formulation. The limitation that the seal formulation be ''acriflavine-free'' was added during ex parte reexamination. There, the applied art disclosed seal formulations containing antibiotics and other anti-infectives such as acriflavine.

The examiner rejected the amended claims as lacking written description support because the term ''acriflavine'' did not appear in the specification and the specification generally disclosed formulations excluding all antibiotics. In the examiner's view, the amended claims encompassed formulations that excluded acriflavine but could include antibiotics or other anti-infectives.[14] The PTAB affirmed the rejection.

On appeal to the Federal Circuit, the court found that substantial evidence supported the board's conclusion. The court agreed that the specification, in which the formulations excluded all anti-infectives, was inconsistent with allowing the claimed formulation to contain antibiotics or other non-acriflavine anti-infectives.[15]

To avoid the *In re Bimeda* situation when drafting an application, an applicant should search the prior art and include as many examples of prior art terms as possible. In new and existing applications, the applicant should try to use positive claim limitations (i.e., Markush groups) that necessarily narrow a claim where the specification lacks explicit support for a term she'd like to exclude. In *Bimeda*, if the patentee had included a list of anti-infectives that were not in the prior art (and a statement indicating that the claimed formulation could include these anti-infectives), then the claims could have been drafted to comprise them as a Markush group. Such a group would necessarily have excluded those in the prior art (notwithstanding that the patentee had not identified and included support in the specification for disclaiming all prior art anti-infectives).

Include support for subgenuses that include different combinations of characteristics:

Novozymes v.DuPont.[16] A specification that discloses each limitation of a claim to a subgenus that recites the combination doesn't necessarily show that the inventors possessed the claimed subject matter if the inventors did not make and show functioning species within the claim scope.[17] *Novozymes*, like *AbbVie* and *Synthes*, involved a patentee who drafted claims to capture a competitor's product years after the patent's earliest filing date.

The claims at issue recite a variant of a bacterial (*Bacillus stearothermophilus*) alpha-amylase enzyme (the ''parent'' enzyme) with a substitution of the amino acid at position 239 (serine), and having increased thermostability under specific conditions. The court noted that the specification includes a wide range of alpha amylase variants: deletions, substitutions and additions at 33 positions (out of 500) in seven parent enzymes, as well as combinations of those mutations.

The court also found important that the patent used two methods to identify the 33 positions that the patent stated would result in increased thermostability: 17 that were predicted using protein modelling and 16 that were found empirically using random mutagenesis and thermostability testing. The predicted variants had not been tested, and the evidence showed that mutations at some of these predicted positions would not result in any thermostable variants.

Specific to the claims, the specification describes a generic serine 239 (S239) variant and a specific replacement of serine 239 with tryptophan (S239W). It describes no thermostability data for any species within the genus, including the S239W species. And the S239W variant was later found to lack thermostability, along with all but six of the possible substitutions at that position. The court concluded: ''[T]he [] application lacks any indication that Novozymes had invented any thermostable alpha-amylase variants at amino acid position 239 by the time of filing, much less one specifically produced from a [*Bacillus stearothermophilus*] parent.'' Thus, according to the court, Novozymes did not possess the claimed subject matter at the time of filing.

To avoid *Novozymes*' written description problem when drafting a new application, consider including multiply-dependent claims with matching disclosure in the specification, such that many combinations of limitations are supported. And if possible, include sufficient blaze marks to specific nucleotide or amino acid substitutions. Upon filing a non-provisional, amend the claims if needed to reduce claim fees, to pursue the desired combination of limitations.

It may be difficult to avoid the *Novozymes* problem in existing applications. But it may be possible to file a continuation that includes multiply-dependent claims,

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those terms would have had a material, unpredictable effect on the operability of the claimed artificial spine disc.

[13] *In re Bimeda Research & Dev. Ltd.*, 724 F.3d 1320, 107 U.S.P.Q.2d 1619 (Fed. Cir. 2013) (86 PTCJ 684, 8/2/13). Compare with *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 104 U.S.P.Q.2d 1641 (Fed. Cir. 2012) (84 PTCJ 811, 9/14/12) (limitation ''contains no sucralfate'' adequately supported where specification described possible disadvantages of sucralfate).

[14] Other claims not at issue in the appeal expressly excluded either antibiotics or anti-infectives.

[15] Judge Rader filed a concurring opinion.

[16] *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 107 U.S.P.Q.2d 1457 (Fed. Cir. 2013) (86 PTCJ 630, 7/26/13).

[17] Judge Rader filed a dissenting opinion. In it, he argued that substantial evidence supports the jury's finding that the specification adequately describes the claimed invention.

as discussed above, and await restriction and election of species requirements. Then, elect the combination of limitations that is desired. Should the examiner agree that the multiply-dependent claims are supported, a court may agree that the elected invention/species is also supported.

Interplay of written description and incorporating disclosures by reference in Section 120 benefit applications:

Patent challengers may also challenge Section 120 benefit to an earlier application when the earlier application contains an insufficient incorporation by reference of disclosure relied on for written descriptive support for patent claims.

In *Hollmer v. Harari*,[18] the court held that an application (the '880 application) involved in an interference did not get the benefit of earlier Section 120 applications because the earlier applications did not properly incorporate by reference the disclosure of a related application (the '579 application). In this case, the first application in the benefit chain incorporated by reference the '579 application merely by referring to its inventors, its title, and stating that it was ''filed on the same day as the present application.'' It did not refer to the '579 application by serial (or application) number. Later child applications (to which the '880 application claimed benefit) also failed to provide the '579 application's serial (or application) number and filing date.

The court held that this identification was insufficient under the ''person of ordinary skill'' standard appropriate for Section 120 analysis because the '579 application was not filed on the same day as the intervening applications and more than two applications with the same inventorship and title as the '579 application were co-pending with one of them. Thus, the court found that the incorporation by reference in the intervening applications was ambiguous to a person of ordinary skill in the art.

To avoid this kind of benefit attack, applicants should file updated specifications in continuing applications or amend their continuing specifications as soon as possible after filing to adequately identify any disclosures that are incorporated by reference.[19]

Conclusion

In summary, patent applicants may take steps such as those described above to lessen the possibility of a successful written description attack during an AIA proceeding. Patentees and applicants should note two more points.

First, with the new, lower standards for indefiniteness expressed in *Nautilus*[20] (during district court litigation) and in *In re Packard*[21] (during examination), patent specification drafters may wish to include express definitions for key claim terms in a glossary, for example, including a definition for the term ''about.''

Second, patent challengers may use written description and obviousness as a dual attack on patentability. This strategy for invalidating a patent is to attack both written description support (or enablement) and obviousness. While defending against the Section 112 attack, e.g., arguing that the art is predictable, the patentee may inadvertently support the Section 103 attack.[23]

Patentees and applicants should consider the interplay of all of the above to avoid or minimize written description issues.

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[18] *Hollmer v. Harari*, 681 F.3d 1351, 102 U.S.P.Q.2d 1958 (Fed. Cir. 2012) (84 PTCJ 262, 6/15/12).

[19] *See also* 37 C.F.R. § 1.57; M.P.E.P. § 608.01(p).

[20] *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2014 BL 151635, 110 U.S.P.Q.2d 1688 (2014) (88 PTCJ 373, 6/6/14).

[21] *In re Packard*, 751 F.3d 1307, 110 U.S.P.Q.2d 1785 (Fed. Cir. 2014) (88 PTCJ 99, 5/9/14).

[23] Longsworth and Hammond, BNA Article, *supra* note 5.

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