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## Patenting Antibodies: A Complication in Written Description Jurisprudence

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# Patenting Antibodies: A Complication in Written Description Jurisprudence

by

Krishna Yadav-Ranjan\*

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## Introduction

Antibodies are proteins that attach to specific molecular targets, or antigens, producing bodily responses. The immune system secretes antibodies to mark intruding viruses and bacteria for destruction to stop harmful species from replicating. Presence of antibodies is based on need: a high concentration can cause toxicities such as allergic reactions, yet at a therapeutic index, antibodies serve as the immune system's concerted orchestra of security.

Therapeutic Antibodies allow for better tailored treatments with more manageable and less impactful side effects than their small-molecule counterparts. Across every disease, therapeutic antibody treatments are better at targeting specific disease-causing mechanisms. Antibodies are programmed to act as a delivery vehicle for any treatment.<sup>1</sup> An example of the efficiency of these treatments is with metastatic neuroblastoma, a rare form of pediatric cancer that harms the nervous system. Before the advent of antibody treatments, the expected long-term survival rate for diagnosed individuals was nearly zero. Now, sixty percent of patients survive.<sup>2</sup>

Therapeutic antibody treatments have begun to dominate the biomedical industry, both in profits and in their R&D funding demands. In a single year, research and development for antibody therapies can cost upwards of \$500 million.<sup>3</sup> Antibody therapies are the future of medicine, and the investment in these solutions must be incentivized by patent protection.

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\* DePaul University College of Law, Juris Doctor Candidate 2020; University of California, at Davis, B.S. Environmental Toxicology, 2016. Special thanks to Professor Joshua Sarnoff, who has aided my passion for patent law and interest in research, as well as Professor Kevin Noonan for encouraging me to critically assess the issue central to this note.

<sup>1</sup> *Monoclonal antibody drugs for cancer: How they work*, MAYO CLINIC (Sept. 20, 2019), <https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/monoclonal-antibody/art-20047808>.

<sup>2</sup> *Monoclonal Antibody Drugs for Cancer Treatment*, MEMORIAL SLOAN KETTERING CANCER CTR. (Dec. 1, 2008), <https://www.mskcc.org/blog/monoclonal-antibody-drugs-treatment>.

<sup>3</sup> Carmela De Luca & Anastasia Trifonova, *Patent Disclosure Requirements for Therapeutic Antibody Patents*, 27 EXPERT OPINION ON THERAPEUTIC PATENTS, Mar. 9, 2017 (citing PHRMA, 2016 PROFILE: BIOPHARMACEUTICAL RESEARCH INDUSTRY 33 (2016)).

Patenting antibodies is complicated by the scientific characteristics of the art. Functionally, an antibody persists in an inactive form until the epitope of an antigen attaches to the antibody's antigen-binding sites, activating a cascade of cellular functions.<sup>4</sup> Structurally, the antigen-binding sites are located in the variable region of antibodies. Because of the great variety in structure, numerous permutations of antigens, each with different binding affinities, can cause varying activity in antibodies. Thus, claiming a single antibody with its highly specific structure and function does little to protect the invention. This decreases the marketability of the invention and harms the return on investment in the research and development needed to innovate. Instead, patentees must seek protection on an entire genus of antibodies capable of binding to the chosen target.

The Federal Circuit has articulated two approaches to satisfying 35 U.S.C. § 112's written description requirement for patenting antibody inventions through broad genus claims. The patentee can either disclose a representative number of species that fall within the scope of the genus to qualitatively represent the other types of antibodies encompassed by that genus or establish a correlative relationship between the structural and functional characteristics of the antibody. The former test relies on functional claiming and is referred to as the "representative number of species" test. The latter test, the "correlative standard," allows the patentee to disclose structural features common to the members of the genus, such that a person having ordinary skill in the art would be able to visualize the members of the genus.

This note considers what an inventor must disclose to the public to obtain a patent for an antibody invention.<sup>5</sup> The analysis of this note revolves around *Amgen v. Sanofi*, where the Federal Circuit delineated the modern disclosure requirement for claiming antibody inventions. This note argues that the Federal

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<sup>4</sup> Jose L. Sanchez-Trincado et al., *Fundamentals and Methods for T- and B-Cell Epitope Prediction*, J. IMMUNOLOGY RES., Dec. 28, 2017, at 2 (showing an "epitope," is "the antigen portion binding to the immunoglobulin or antibody.").

<sup>5</sup> Brief for Bristol-Myers Squibb Co., et al. as Amici Curiae Supporting Petitioners, *Amgen, Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), *cert. denied*, 586 U.S. \_\_ (U.S. Jan. 7, 2019) (No. 18–127).

Circuit's development of the written description doctrine for antibody genus claims creates an increasingly ambiguous burden of disclosure to obtain patent protection to the detriment of the public.

Part One details the relevant case history of the written description doctrine in the context of biotechnology. This section shows the development of the possession standard for satisfying written description. Part Two explores the USPTO's interim guidelines for compliance with the written description requirement. The Guidelines sought to cohesively represent existing written description jurisprudence, yet they have also influenced the CAFC's holdings in subsequent cases. Part Three explores the CAFC's contention with how to treat the scientific characteristics of antibodies complicating application of the possession standard. Part Four surveys modern disclosure requirement considering *Amgen v. Sanofi*, the most recent CAFC case, which upheld two avenues for satisfying the possession standard. Finally, Part Five concludes by discussing the policy considerations of the disclosure problem afflicting antibody inventions and offering suggestions to ameliorate the issue.

### **Part 1: History of Written Description for Biotechnology Patents**

Written description jurisprudence has been guided largely by case precedent before the Federal Circuit because disclosure is a question of fact. With the rapid rise in pace of biotechnological discoveries, this body of law has had to adapt to the growing complexity of the art. The more complex the field of art is, the less concrete the parameters are to satisfy the written description requirement<sup>6</sup>. It is for this reason that guidance applied to other fields of art like mechanical engineering and electrical engineering are not applicable to issues in the field of biotechnology. This section describes three landmark cases that changed written description jurisprudence for biotechnology arts, requiring the PTO to issue guidance in the form of interim guidelines directing prosecutors and examiners as to how to apply precedent.

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<sup>6</sup> 35 U.S.C. § 112 (1952).

### **A. Separating the Doctrines to let Written Description stand alone**

The current requirements for written description were set forth in 35 U.S.C. § 112(a) of the 1952 Patent Act.<sup>7</sup> For years, the written description requirement was circumscribed by the enablement requirement. Yet the distinction between these two requirements was introduced by the Federal Circuit in 1967 in the case *In Re Ruschig*. In this case, written description was mandated as a distinct requirement for patentability.<sup>8</sup> The patent application in *Ruschig* claimed a new benze sulfonyl urea, and the process for its preparation. The patent was invalidated for a lack of support in the specification because it did not name or identify the species of the compound. The *Ruschig* court construed the language of § 112(a) as separately demanding a ‘written description’ of the invention, and an ‘enabling’ disclosure as to how make and use the invention. This was later mandated by *Ariad* and is generally accepted as valid law. Thus, this area of the law is not contended in this note.

### **B. From “Conception” to “Possession”**

Given that the written description requirement is separate from enablement, the following case dealt with determining the standard of meeting the written description requirement. *Amgen* constituted the first time in the biological context that the “mental picture” argument, or the possession standard, is used to qualify the amount of information needed to satisfy the written description requirement.<sup>9</sup> The *Fiers* court stressed that conception of a DNA sequence requires description of the invention by characteristics other than its function.<sup>10</sup> Furthermore, the *Eli Lilly* court noted that description by function is insufficient because it is only a definition of a result rather than a definition of what achieved that result.<sup>11</sup>

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<sup>7</sup> *Id.*

<sup>8</sup> *In Re Ruschig*, 379 F.2d 990, 991 (CCPA 1967); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991).

<sup>9</sup> Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1255 (2000).

<sup>10</sup> *Id.* at 1207.

<sup>11</sup> *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

While the holding of *Amgen v. Chugai* largely impacts the enablement requirement of § 112, the court's reasoning applies to the written description doctrine and is used when determining the satisfaction of the written description of gene sequence claims.<sup>12</sup> The court related conception to written description as the inventor must establish that she possessed "a mental picture of the structure" or could define it by its distinguishing characteristics.<sup>13</sup> Simply describing the invention by its principal biological properties, or by its function, are not sufficient for the written description requirement.<sup>14</sup>

The court found Chugai's conception insufficient because the DNA sequence was merely described by its principal biological property, and was hence "no more than ... simply a wish to [claim] the identity of any biological material having that property."<sup>15</sup> The *Amgen* court's ruling began to chisel away at the overbroad written description requirement, narrowing the scope of the requirement by deeming description solely of its principal biological properties to be insufficient.

The *Fiers v. Revel* decision related conception to disclosure in stating, "if conception of DNA requires a precise definition, like structure, formula, chemical name or physical properties, then a description also requires that degree of specificity."<sup>16</sup> Ultimately, disclosing the full and accurate nucleotide sequence of the DNA was dispositive to the court that the inventor conceived of the invention at the time of filing.<sup>17</sup>

In *Regents of the Univ. of California v. Eli Lilly & Co.*, the Federal Circuit confined the scope of claims to only the disclosed embodiments of the invention.<sup>18</sup> *Eli Lilly* establishes a clear standard that "a written description of an invention involving a chemical genus, like a description of a chemical species 'requires a precise definition such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."<sup>19</sup> The invention at issue claimed cDNA sequences of PI

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<sup>12</sup> Sampson, *supra* note 9, at 1233; *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d at 1254.

<sup>13</sup> Sampson, *supra* note 9, at 1233.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Fiers v. Revel*, 984 F.2d 1164, 1166 (Fed. Cir. 1993).

<sup>17</sup> Sampson, *supra* note 9, at 1257.

<sup>18</sup> *Id.*

<sup>19</sup> *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

and PII insulin in rats.<sup>20</sup> The scope of the claims included more species than that in the scope of the specification. The court invalidated the claims to the undisclosed cDNA sequences.<sup>21</sup> The court upheld the possession standard that to fulfill the written description requirement, the specification must sufficiently describe the invention such that one skilled in the art can recognize that “the inventor invented the claimed invention.”<sup>22</sup> Until now, the written description standard centered around conception. Here, the Federal Circuit codified the public information purpose and “possession standard” of the written description requirement.<sup>23</sup>

These cases establish that not every species of a genus or embodiment needs to be noted to sufficiently describe a genus to comply with the written description requirement.<sup>24</sup> Merely describing the functional characteristics would not aid a person of skill in the art to identify the members of the genus. The *Eli Lilly* court noted that description by function is insufficient because it is only a definition of a result rather than a definition of what achieved that result. Many genes can cause the same result. Thus, the disclosure requirement demands a description of an invention, not a description of what one would achieve if they made that invention.

## **Part 2: The USPTO Guidelines**

After *Eli Lilly*, the PTO issued guidelines to assist patent examiners with administering the written description requirements when reviewing biotechnology patent applications. Scholars and commentators viewed the holdings from *Amgen*, *Fiers*, and *Lilly* as a departure from the traditional written description jurisprudence.<sup>25</sup> The PTO determined showing of sufficient written description requires the patent applicant

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<sup>20</sup> Sampson, *supra* note 9, at 1257; *see also Regents of the Univ. of Cal.*, 119 F.3d at 1568.

<sup>21</sup> *Regents of the Univ. of Cal.*, 119 F.3d at 1562.

<sup>22</sup> *Id.*

<sup>23</sup> Sampson, *supra* note 9, at 1259.

<sup>24</sup> *Utter v. Higura*, 845 F.2d 993, 998–99 (Fed. Cir. 1988).

<sup>25</sup> Lisa K. Karczewski, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043, 1066 (2000).

be in possession of the claimed invention at the time of filing; such that a person of skill in the art would be informed of the applicant's possession.<sup>26</sup>

The scope of the guidelines focused on articulating the prevailing law in a clear and technology neutral manner.<sup>27</sup> The review process set forth requires a strong initial presumption that the specification is a sufficient written description of the claimed invention as it is filed.<sup>28</sup> The patent examiner carries the initial burden of proof for a rejection for insufficient written description support.<sup>29</sup> Furthermore, compliance of written description requirements is a question of fact and is analyzed case-by-case.<sup>30</sup> In reviewing the sufficiency of the written description support of an application, the examiner *first* determines the scope of the claims.<sup>31</sup> *Second*, the examiner reviews the entire application to determine the invention. *Third*, each claimed species is reviewed for their sufficiency of written description support.<sup>32</sup> *Fourth*, each claimed genus is reviewed for sufficiency of written description support.<sup>33</sup> *Last* in the review process, is a complete determination of patentability from § 101-103 of the patent.<sup>34</sup>

#### **A. Determining the scope of the claims and claimed invention**

In determining the scope of the claims, the claims are held to the “broadest reasonable interpretation” standard.<sup>35</sup> In general, the claim must be adequately described in its entirety, including every limitation of the preamble, every transition, and the body of the claim.<sup>36</sup> To evaluate each separate claim, the examiner must determine whether “sufficient structures, acts or functions” are present.<sup>37</sup> Rejection on written

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<sup>26</sup> *Id.* at 1045.

<sup>27</sup> *Id.* at 1066.

<sup>28</sup> *Id.* at 1067.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> Revised Interim Guidelines, 64 Fed. Reg. 71427 (Dec. 21, 1999), *superseded by* Guidelines for Examination, 66 Fed. Reg. 3425 (Jan. 21, 2000).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*; *see also* Karczewski, *supra* note 25, at 1050.

<sup>34</sup> Karczewski, *supra* note 25, at 1050.

<sup>35</sup> Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005).

<sup>36</sup> Revised Interim Guidelines, 64 Fed. Reg. at 71427.

<sup>37</sup> *Id.*; *see also* Karczewski, *supra* note 25, at 1051.

description cannot be based on lack of definitions or details in the specification for well-established terms or procedures.<sup>38</sup>

Next, the examiner reviews the entire application to establish what the claimed invention is.<sup>39</sup> This includes complete review of the claims and the specification.<sup>40</sup> In this step, satisfying written description support requires determining the correlation between what the applicant has actually claimed and what the application identifies as possession.<sup>41</sup> As shown from *Lily*, there is an inverse correlation between the predictability level in the art and the amount of disclosure necessary to satisfy the written description requirement.<sup>42</sup>

The guidelines offer an example to illustrate this principle.<sup>43</sup> If the correlation between the functional and structural characteristics of the invention is well established, description of function alone may satisfy §112 because a person skilled in the art could reasonably predict the complete structure of the invention based on its function. As iterated in the cases, the specification does not require detailed description of commonly known information relevant in the art.

## **B. Examining Species Claims**

The examiner proceeds to review sufficiency of the written description support for each claimed species. Here the possession of the invention may be met by looking for dispositive evidence from three different avenues of factual analysis: (1) actual reduction to practice, (2) disclosure of sufficiently detailed drawings, or (3) disclosure of sufficiently detailed relevant identifying characteristics.<sup>44</sup> Any one of these facts will suggest satisfactory possession.<sup>45</sup> Yet, whether the specification shows that the applicant was in

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<sup>38</sup> Revised Interim Guidelines, 64 Fed. Reg. at 71427; *see also* Karczewski, *supra* note 25, at 1047.

<sup>39</sup> Karczewski, *supra* note 25, at 1050.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 1047.

<sup>42</sup> *Id.*

<sup>43</sup> Revised Interim Guidelines, 64 Fed. Reg. at 71427.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

possession of the claimed invention can also be determined by balancing or weighing factors rather than single factual determinations.<sup>46</sup>

If present, actual reduction to practice is dispositive of sufficient written description support for each claimed species.<sup>47</sup> This can be shown if the specification has evidence of an embodiment that was constructed, or a process was performed by the invention that satisfies all of the claim limitations. The invention must also work for its intended purpose to prove reduction to practice. Likewise, if the application discloses sufficiently detailed drawings, this fact may indicate that the patent applicant mentally possessed the invention and communicated that a person skilled in the art could also generate a mental picture of the invention.<sup>48</sup>

More complicated, however, is the third factual avenue for written description support: disclosure of sufficiently detailed relevant identifying characteristics. Two obstacles arise when proving possession through this standard, and at least one of these obstacles must be overcome to avoid rejection. One obstacle is whether the filed application describes the complete structure of the claimed invention in its entirety.<sup>49</sup> If this is not present, the examiner must look to whether the specification discloses other “relevant identifying characteristics” that may distinguish the invention, such that a person of skill in the art would be able to predict the complete invention.<sup>50</sup> Yet, if none of these affirmative indications of support are present when reviewing support for each claimed species, the examiner may still find sufficient support of each claimed species by a balancing test.<sup>51</sup>

Whether the specification indicates that the applicant was in possession of the claimed invention can be established by weighing the following four factors.<sup>52</sup> First, the level of skill and knowledge in the

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<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

art is evaluated to understand the level of predictability of the art and thereby the level of specificity required from the applicant.<sup>53</sup> Second, whether the applicant provides support showing the partial structure of the invention by offering physical and/or chemical properties that may distinguish the claimed species.<sup>54</sup> Third, the examiner may weigh evidence of the functional characteristics alone or depending on the certainty of the type of art, evidence coupled with known or disclosed correlation between structure and function.<sup>55</sup> Finally, the examiner can weigh evidence of the method of making the claimed invention to determine possession.<sup>56</sup> As shown from *Lilly*, emerging and unpredictable technologies such as those in the biotechnological arts require additional evidence to demonstrate possession.<sup>57</sup>

### **C. Examining Genus Claims**

After reviewing each claimed species for the sufficiency of written description support, the examiner is guided to review whether there is sufficient support for each claimed genus.<sup>58</sup> Each claim to a genus is subjected to the three-step possession test listed above. The PTO notes that possession of the claimed genus may be shown if the applicant provides sufficient description of a “representative number of species” under any one of the three steps.<sup>59</sup> Finally, analysis of the application’s written description requirement either invalidates the patent or the examiner proceeds to the other determinations of patentability for the application.<sup>60</sup>

The guidelines are consistent with the Federal Circuit’s holdings in *Amgen*, *Fiers*, and *Lilly*, and correctly reflect the prevailing law developing in the space of written description. The Revised Interim Guidelines do not constitute substantive rules and do not have a binding effect on the law.<sup>61</sup> The Guidelines

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1562 (Fed. Cir. 1997).

<sup>58</sup> Revised Interim Guidelines, 64 Fed. Reg. at 71427.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

further suggest that the stringency of written description requirements may ease with the increase of knowledge and skill in biotechnology. But more immediately, the PTO must be careful not to shy away from the heightened requirements as the downstream effects of granting broad claims will curb innovation in the future.

Yet, from 1999 to recently, the area of written description jurisprudence has been complicated by the cases leading up to *Ariad*. This string of cases ushered in a new phase of understanding or misunderstanding of the requirement.

### **Part 3: Proving Possession of Antibody Genus Claims**

#### **A. The *Enzo* Trilogy: Correlation of Structure and Function Test**

In the wake of the new written description guidelines, the Federal Circuit gave substantial weight to the PTO's compliance standards in the *Enzo* trilogy. In *Enzo*, the Federal Circuit visited application of the written description requirement to DNA sequences.<sup>62</sup> The invention at issue concerned nucleic acid probes that selectively hybridize to *Gonorrhoea* bacterial DNA but does not hybridize to common strains of *Meningitis*.<sup>63</sup> The case raised two main issues: (1) whether the deposit of a sample of the claimed probes constituted adequate written description to those sequences; and, (2) whether the deposits of a sample satisfy the written description requirement for broad genus claims.<sup>64</sup>

In a panel decision, the CAFC distinguished *Enzo* from *Lilly*, stating that the written description standard in *Lilly* incorrectly deemed functional descriptions of genetic material as presumptively inadequate.<sup>65</sup> Instead, the *Enzo* court integrated the PTO's Guidelines to set forth the "newly characterized antigen" test for written description of antibody and antigen materials.<sup>66</sup> Although the PTO's Guidelines

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<sup>62</sup> 3 Daniel Chisum, *Chisum on Patents* §§ 7.04 pt. 1, 34 (2018) (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 970 (Fed. Cir. 2002)).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

are not binding law, the CAFC gave judicial notice of it by adopting a standard from the guidelines on the written description requirements.

In *Lilly*, the Court looked to the PTO Guidelines in holding that written description may be satisfied by “functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”<sup>67</sup> This shows that the written description requirement can be met by functional description of the preferential binding characteristics of the probe to *N. gonorrhoea* over *N. meningitidis* when accompanied by disclosure of the correlation between those functions and disclosed or known structures.<sup>68</sup>

Per the first issue of whether deposits suffice for description of the claimed nucleotide sequence, the court spoke to public purpose of the written description requirement in evaluating this issue of first impression. Historically, depositing materials has satisfied the enablement requirement as it may instruct a person skilled in the art. However, here, in the context of written description and nucleic probes, the deposited samples are unlikely to provide any indication that the inventor possessed the claimed invention. The deposited probes represent an astronomical number of mutated variations that also fit within the scope of the claims of these numerous sequences; any number of them could meet the claimed hybridization ratio. The *Enzo* court settles this issue by remanding the inquiry as an issue of fact—not a matter of law as the district court held. Yet, in allowing deposits to qualify for the written description requirement, the *Enzo* court minimizes the public policy goals of the possession standard.<sup>69</sup>

Next, the *Enzo* court set forth precedent on description broad genus claims by deposited sequence in holding that compliance could be met in two disjunctive ways. If the deposited species of probes adequately represented the claimed genus, then those deposits sufficiently describe the invention for purpose of § 112. Otherwise, the *Enzo* court held that the written description requirement could be met if

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<sup>67</sup> *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

<sup>68</sup> 3 Daniel Chisum, *Chisum on Patents* §§ 7.04, 223, 160 pt. 1 (2018).

<sup>69</sup> Paula K. Davis, *Questioning the Requirement for Written Description: Enzo Biochem v. Gen-Probe and Overly Broad Patent Cases*, 37 IND. L. REV. 467, 488 (2004).

the claimed hybridization function was sufficiently associated with the deposited DNA samples. The *Enzo* trilogy of cases distinguished *Lilly* by opening the door for functional description of biological material to be satisfactory for the written description requirement in certain circumstances.

In dicta, the *Enzo* court cites the PTO Guidelines as the foundation of the “newly characterized antigen” test stating,

the PTO would find compliance with 112 ¶1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well-defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.<sup>70</sup>

The decision in *Enzo* was bolstered in *In re Wallach*, where the patent application disclosed only 5% of the amino acid sequence of the claimed protein and the molecular weight of the protein.<sup>71</sup> The Federal Circuit in *Wallach* ruled that functional description can be sufficient if the “structure-function relationship [is] known to those of skill in the art.”<sup>73</sup> The *Wallach* court’s ruling is referred to as the “full-characterization” requirement—codifying that functional characterization may satisfy description only if met with disclosure of a structural description.<sup>74</sup> Thus, from these two cases, functional description cannot serve as a basis to reject the patentability of the invention, so long as it is coupled with structural characterization.<sup>75</sup>

### **B. Rochester and Ariad: Codifying the Possession Standard**

The “full characterization” requirement gets revisited in *University of Rochester*.<sup>76</sup> The patent at issue disclosed a method to selectively inhibit cyclooxygenase (COX-2) activity in human hosts by administering a non-steroidal drug that would cap the activity of the gene that produced COX-2, PGHS-

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<sup>70</sup> *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (citing *Written Description Training Materials: Revision 1*, U.S. PAT. & TRADEMARK OFF. (Mar. 25, 2008), <https://www.uspto.gov/sites/default/files/web/menu/written.pdf>).

<sup>71</sup> *In Re Wallach*, 378 F.3d 1330, 1335 (Fed. Cir. 2004).

<sup>72</sup> Shengfend Chen, *Pathways to Patents: Applying the Written Description Requirement Doctrine to Patents on Biological Pathways*, 30 HASTINGS COMM. & ENT. L.J. 559, 570 (2008).

<sup>73</sup> *Id.*

<sup>74</sup> *In Re Wallach*, 378 F.3d at 1335.

<sup>75</sup> *Id.*; *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002).

<sup>76</sup> *Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1304 (Fed. Cir. 2004).

2.<sup>77</sup> Since the application failed to name any compound that actually could perform that claimed method, the Federal Circuit deemed the patent invalid on § 112 grounds.<sup>78</sup> The *Rochester* court did not seek to entirely eliminate functional description; instead, it suggested that because the claimed genus of compounds was so vague, functional description of the genus could not have met the written description requirement.<sup>79</sup>

The CAFC in *Ariad Pharmaceuticals v. Eli Lilly & Co.* laid out the foundation of the modern written description doctrine.<sup>80</sup> Being decided *en banc*, it harmonized the inconsistent precedents from cases including *Ruschig* and *Schriber-Schroth*.<sup>81</sup> Before the court were two main issues: whether claims must be evaluated under the written description requirement, separately from the enablement requirement, and whether the possession standard for written description compliance persists.<sup>82</sup> Ariad's patent claimed a method of negatively regulating the expression of a transcription factor called Nuclear Factor Kappa B ("NF-κB"). The specification hypothesizes three general types of molecules capable of down-regulating NF-κB.<sup>83</sup> At the time of filing, Ariad was the first to identify transcription factor NF-κB, and the first to chart the cellular mechanism by which the body's immune response to exotoxins activates expression of NF-κB.<sup>84</sup>

#### *i.* Separating Written Description from Enablement

The *Ariad* court based its holding on legislative intent, and case history in establishing that written description and enablement requirements are separate.<sup>85</sup> To determine the standard for adequate written description, the court spoke to the public policy of the requirement stating,

[a] description of the claimed invention allows the [PTO] to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the

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<sup>77</sup> *Id.* at 1306.

<sup>78</sup> *Id.* at 1305, 1307.

<sup>79</sup> 3 Daniel Chisum, *Chisum on Patents* §§ 7.04, 223, 175 pt. 1 (2018).

<sup>80</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1336 (Fed. Cir. 2010) (*en banc*).

<sup>81</sup> *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 56–57 (1938) (showing an instance where the Court's version of the purpose evoked in § 112 revolved solely around enablement).

<sup>82</sup> *Id.*

<sup>83</sup> *Ariad Pharm., Inc.*, 598 F.3d at 1336.

<sup>84</sup> *Id.* at 1349.

<sup>85</sup> *Id.* at 1342.

claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.<sup>86</sup>

The court added that having a separate written description requirement “does not conflict with the function of the claims” as notice of the boundaries of the property rights vested in the patent. While the claims contribute to description of the invention, the written description requirement achieves the teaching and disclosure functions of a patent. Ultimately the court relies on statutory language, case precedent, and the doctrine of *stare decisis* to uphold the distinction between the written description and enablement requirements. The court affirms *en banc* the written description doctrine crafted from *Eli Lilly, Fiers, Wallach*, and *Rochester*. Next, the CAFC seeks to unify the standard for complying with § 112.

#### *ii. Upholding the Possession Standard*

*Ariad* concerns an emerging and unpredictable field where there is very little prior art or knowledge, making this case the ideal circumstance for the Federal Circuit to examine criteria for compliance with the written description requirement.<sup>87</sup> This case summarizes the case law leading up to the decision and attempts to harmonize decisions about claiming antibody inventions.<sup>88</sup>

Similar to in *Rochester*, *Ariad* did not actually claim the molecules needed to achieve the claimed endpoint. Although the specification hypothesized the molecules, *Ariad* failed to include a term in the claims that would be associated with the molecules. Just as in *Rochester*, the ‘516 patent could not suggest, to a person of ordinary skill in the art, any compound that would match the claimed functional description. The *Ariad* court upholds the possession standard, stating

[to] satisfy the written description requirement for the asserted claims, the specification must demonstrate that *Ariad* possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF- $\kappa$ B activity so as to ‘satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.’

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<sup>86</sup> *Id.* at 1345.

<sup>87</sup> *Id.* at 1336.

<sup>88</sup> *Id.* at 1349.

Ariad fails to demonstrate a way of performing the claimed methods since it does not adequately describe the molecules necessary to the method. Further, the specification lacks detail about the how the hypothesized molecules accomplish the negative regulation of NF- $\kappa$ B.<sup>89</sup> The absence of working examples of the claimed methods and the vague description of what molecules can cause those methods could have been remedied if there were more prior art references to clarify the gaps in knowledge. Thus, the *Ariad* court found the claims invalid.<sup>90</sup>

From *Ariad*, the Federal Circuit codified the written description requirement as independent from enablement and upheld the possession standard as the measure of adequacy. So, the written description requirement is satisfied if a person of ordinary skill in the art can infer that the inventor possessed the claimed invention at the time of filing. Whether the patent tells the person of skill in the art about what the invention is, is irrelevant. The possession standard is problematic as it gives rise to circumstances where a pioneering patent broadly claims a genus and blocks a subsequent improvement patent claiming a species of that genus. This is referred to as “blocking conditions,” which often arise when the original inventor “failed to contemplate” an improvement later claimed by another patent.

The *Ariad* court established that the purpose of the written description requirement is to ensure “that the inventor actually invented the invention claimed.”<sup>91</sup> To satisfy this, the patentee must demonstrate it “had possession of the claimed subject matter as of the filing date.”<sup>92</sup> The standard for proving possession is “a precise definition” of the invention. When claiming a genus, precise definition requires the patentee to disclose “a representative number of species falling within the scope of the genus or structural features common to those members of the genus so that one of skill in the art can ‘visualize or recognize’ the

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<sup>89</sup> Negative regulation pertains to enzymatic degradation of a compound in the body.

<sup>90</sup> *Ariad Pharm., Inc.*, 598 F.3d at 1349.

<sup>91</sup> *Id.* at 1351.

<sup>92</sup> *Id.* at 1350.

members of the genus.”<sup>93</sup> Thus, written description depends on the state of prior art in the field at the time of priority. Likewise, the *Ariad* court is upholding the *Rochester* court’s perspective of a uniform written description requirement for all fields of art.<sup>94</sup>

#### **Part 4: Understanding the “Representativeness” Standard**

After *Ariad*, the larger doctrinal questions seemed answered. However, it was unclear how the decisions from *Enzo*, *Centocor*, and *Noelle*, which sought to develop the written description doctrine particular for antibody inventions, would persist until discussed in *Amgen v. Sanofi*.<sup>95</sup> The patent at issue in *Amgen* concerned antibodies capable of reducing LDL levels. The relevant claims covered the entire genus of antibodies with the disclosed functions: binding to amino acid residues on PCSK9, and blocking PCSK9 from binding to LDL-R’s.<sup>97</sup> The specification sought to adequately disclose the antibody invention in three different ways—showing the screening method used to find 85 antibodies capable of the blocking function; the three-dimensional structures of two antibodies; and the amino acid sequence of 22 antibodies that compete with the claimed antibodies for bind.<sup>98</sup>

##### *i. Amgen overturns the “Newly Characterized Antigen” test*

The CAFC contended with the trial court’s jury instruction as they edify use of the “newly characterized antigen” test for written description and misapplied the enablement standard to issues of written description adequacy. This test took root when the *Enzo* court integrated the PTO Guideline’s and was bolstered in *Noelle*. In *Noelle v. Lederman*, the Federal Circuit carved out an exception for broad, functional claiming if the antigen was novel and fully characterized.

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<sup>93</sup> *Id.*

<sup>94</sup> *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004) (noting “this statute applies to all types of inventions.”).

<sup>95</sup> *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017).

<sup>96</sup> *Abbott GmbH & Co., v. Centocor Ortho Biotech, Inc.*, 870 F.Supp. 2d 206, 246 (D.Mass. 2012).

<sup>97</sup> *Sanofi*, 872 F.3d at 1371.

<sup>98</sup> *Id.* at 1372.

The “newly characterized antigen” test served as an attempt to resolve the disclosure issue afflicting patentees inventing in the antibody space—because of the lack of prior art knowledge in the field, patentees could not rely on prior art to supplement gaps in disclosure needed to satisfy §112. This was rejected in *Amgen v. Sanofi* because this test is not correlative or dispositive enough of the antibody-antigen relationship. The CAFC reasoned this by reframing the *Centocor* court’s “lock and key” analogy as “a lock and a ring with a *million* keys.”<sup>99</sup>

The *Amgen* court noted that it could take judicial notice of the “newly characterized antigen” test if the underlying scientific premise supporting the test is “generally known” and “accurately and readily” ascertainable.<sup>100</sup> This would require the scientific premise that knowledge of the chemical structure of an antigen provides dispositive structure-identifying information about the corresponding antibody. Yet, currently, the science cannot support this premise to rise to the standard of being either “generally known” or “accurately and readily” obtainable to warrant judicial notice.<sup>101</sup> Further, the *Amgen* court noted the “newly characterized antigen” test “flouts basic legal principles of the written description requirement.”<sup>102</sup> It allows patent protection over antibodies by disclosing things that are not the invention—antigens.<sup>103</sup> In rejecting this test, the *Amgen* court synchronized the written description jurisprudence by treating the “newly characterized antigen” test as an inconsistent standard.

The *Amgen* court also addressed whether the trial court misapplied the law in excluding post-priority date evidence proving the patent’s failure to disclose representative species. The CAFC analogized *AbbVie* on its facts, and distinguished *Hogan* based on its application of the law.<sup>104</sup> *Hogan* speaks to using post-priority-date evidence to “illuminate” the state of prior art, which is an enablement argument. The trial court misapplied the holding in *Hogan* in light of *Ariad*. By using *Hogan*, it applies an enablement-founded

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<sup>99</sup> *Id.* at 1377.

<sup>100</sup> *Id.* at 1378.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1378 (Fed. Cir. 2017).

<sup>104</sup> *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014); *In re Hogan*, 559 F.2d 597, 607 (CCPA 1977).

argument to a written description challenge. Thus, post-priority date evidence may be offered to discredit a patent’s adherence to the “representative number of species” test. This holding serves as a safety valve for premature filing of under-developed antibody inventions.

In *MorphoSys*, the court reviewed the scope of the “newly characterized antigen” test since the claimed invention was highly unpredictable art, such that the functional characteristics of the variable antibodies were not sufficiently supported by structural characteristics. It is still widely common for patents covering antibodies to claim by function (called “binding claims”) instead of by structure (the protein’s sequence).<sup>105</sup> Binding claims characterize the antibody’s function by claiming the sites where it binds to the antigen.<sup>106</sup> Such were at issue in *MorphoSys*, where the court addresses the possession standard for antibody patents and affirms precedent on the requisite structural and functional information for §112.<sup>107</sup>

As a question of fact, the standard for determining whether a specification satisfies the written description requirement is a showing of possession, which must be established by disclosure of (1) a number of species representative of the genus, or (2) common structural features of the genus such that POSA can visualize the members of the genus.<sup>108</sup> With respect to the first inquiry, the court remanded the issue to settle whether peptide mapping may be regarded as a sufficiently reliable source of art to inform a POSA. Yet, this does not invalidate the second part of the inquiry in determining written description compliance, as evidence showing that the species are sufficiently represented may be submitted after the priority date.

In invalidating the “newly characterized antigen” test, the Federal Circuit has undone progress in developing the written description doctrine within biotechnology.<sup>109</sup> Because the state of art in the field is still underdeveloped, the burden rests on the inventor to invest significant time, money, and effort into

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<sup>105</sup> Zachary Silbersher, *District of Delaware Makes it Harder to Corner the Market on Antibody Patents in MorphoSys v. Janssen*, IPWATCHDOG (Jan. 31, 2019), <https://www.ipwatchdog.com/2019/01/31/morphosys-v-janssen-antibody-patents/id=105841/>.

<sup>106</sup> *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F.Supp. 3d 354, 369 (D.Del. 2019).

<sup>107</sup> *Id.*

<sup>108</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 967 (Fed. Cir. 2002); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

<sup>109</sup> *MorphoSys AG*, 358 F.Supp. 3d at 354.

characterizing their invention. While this would normally tend to bolster the goals of the patent regime, in the context of antibody patents, this disclosure requirement complicates innovation simply because the science is not predictable, so the requirement is essentially forcing inventors to predict the unpredictable.

Currently, the broader, overarching standard for written description compliance requires a showing of possession. Within the context of antibodies, the only metric of written description adequacy for functionally claimed antibody inventions is either by: (1) affirming a correlation between structure and function per *Eli Lilly*, or (2) disclosing “a number” of species representative of the entire genus per *Enzo*. Remaining uncertain is factual question of “representativeness,” and by what standard the Federal Circuit will find sufficient representativeness. It seems the question of “how many disclosed representative species is satisfactory” is an impossible task for the scientific world to tackle and a precarious one for a patent holder. Per *Amgen*, obtaining patent protection over a genus of antibodies under the representativeness standard is coupled with the danger of post-priority species invalidating the patent. As such, the current written description jurisprudence poses numerous legal tradeoffs.

### **Part 5: Policy Considerations of the Antibody-Disclosure Problem**

In the interest of promoting innovation, patents for biotechnical inventions surged at the risk of granting overinclusive patent rights. This section inspects the policy considerations surrounding compliance with the written description doctrine in the antibody inventions field of art. This section argues that *Amgen* court failed to weigh the implications of its precedent. Finally, this section advises patentees on ways to navigate the possession standard when claiming broad genera.

At contention with the law is determining the appropriate scope of broad genus antibody claims. The possession standard requires a showing that the inventor understood the full depth and range of the claimed invention to the extent that a person of skill in the art could ascertain so.<sup>110</sup> This standard is applied

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<sup>110</sup> *Ariad Pharm., Inc.*, 598 F.3d at 1345.

uniformly to all sciences under *Rochester*; however, a separate written description requirement is needed for antibody patents.

Such a task should either be taken on by the courts or by Congress. Congress is better suited to enact this change, as attempting to shape the written description jurisprudence through the courts has proven problematic. The Federal Circuit may decide to use *MorphoSys* as an opportunity to determine *en banc* the written description adequacy standard for antibody patents. This would be instrumental as the *Amgen* court's decision led to an inability to rely on earlier precedents, which allowed for less developed genus claims.

Alternatively, the Supreme Court may grant certiorari on such a case. However, unless the amici can persuade the Court to view this issue as paramount, it is unlikely the Court will expend time and resources towards settling this niche of patent law. Most recently, the Supreme Court refused to examine the written description requirement developed by the Federal Circuit by declining to grant certiorari for *Amgen v. Sanofi*.<sup>111</sup> In terms of administering the 112 requirement, the Supreme Court's refusal to consider a nuanced possession standard for antibody patents causes those patents to be subject to the same-size-fits-all possession standard. Unfortunately, doing so curbed the market potential and regulatory momentum of the antibody space, causing inventors to consider an alternative route of protection over the costly IP.<sup>112</sup>

More practical is for the legislature to address this issue by enacting a new provision to Title 35 of the U.S. Code to carve out a special exception for written description of antibody patents as it has done for plant patents.<sup>113</sup> With plant patents, Congress recognized that a uniform written description standard for every field of biotechnology is ill-fitting to the serve that field of art. The same rationale is valid for antibody patents: the possession standard of written description, and it's two common law tests for antibody patents

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<sup>111</sup> Patrick Wingrove, SCOTUS antibody case refusal raises Section 112 uncertainty, PATENT STRATEGY (May 29, 2019), <https://patentstrategy.managingip.com/articles/50/scotus-antibody-case-refusal-raises-section-112-uncertainty>.

<sup>112</sup> *Id.*

<sup>113</sup> See 35 U.S.C. § 162 (2011) (exempting plant patents from § 112 “if the description is as complete as is reasonably possible.”).

can lead to inconsistent application of the law. Despite being an issue of fact, written description jurisprudence must alleviate the burden on courts to determine compliance. Additional instruction should be offered as to how many disclosed species satisfy “representation” of the entire genus.

Further, obtaining patent protection over broad genera of antibodies poses industry-wide competition concerns regarding the appropriate scope of inventions. Broader patent claims are favored over narrow claims, as they allow for more variations of the invention to fall within the scope of the patent.<sup>114</sup> However, claim scope breadth is directly correlative to the amount of competition and potential infringement the patent will face.<sup>115</sup> This tension between awarding broad claim scope and avoiding the problem of blocking patents is especially timely for the field of antibody patents. By granting broad genus claims, inventors can bring inventions to patentability more rapidly, and hence reach market returns much more quickly than if not for the written description speed bumps.

Likewise, having too narrow of a disclosure principle would allow imitators to use the same doctrine as a defense against the patentee enforcing their patent. This would be the demise of patent law and cease to render patents useless.<sup>116</sup> On one hand, the disclosure requirement protects granting broad genus patents over antibody classes that they have not fully invented to reach the level of actual “possession.” The tension between granting over-broad patent rights and narrowing disclosure requirements at the detriment of innovation and the patent system itself is particularly nuanced when considering pioneering inventions.<sup>117</sup> Narrowing claim scope may be the clearest way to meet the disclosure requirement; however, the Federal Circuit risks enacting an over-restrictive standard by doing so.

The social and economic costs of an over-restrictive disclosure doctrine will result in delayed innovation biomedical technology. With the rise in costs of life-saving small-molecule cancer therapies, it

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<sup>114</sup> Lauren Matlock-Colangelo, *Broadly Unpatentable: How Broad Method Claims have Limited Patentability of Diagnostic Inventions*, 119 COLUM. L. REV. 797, 810 (2019).

<sup>115</sup> See generally Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1998).

<sup>116</sup> *Id.* at 875.

<sup>117</sup> *Id.* at 854.

is important that patients have alternative avenues of care available to them. By codifying clear and concrete disclosure standards, inventors can reduce the transaction costs associated with patent prosecution, allowing for speedier commercialization of the invention. As a result, investors have greater assurance in the value of their return, causing the prices of these therapies to be driven down at the benefit of everyday patients.

In conclusion, the tension between the written description doctrine and antibody inventions can be remedied by either an adaptation of the law or prosecution practice. Patentees may delay filing nonprovisional applications until there is greater representation of the claimed genus. Doing so allows patentees to mitigate risks of litigation and *inter partes* review, which can be anticipated on the grounds of overbroad claim scope or lack of written description.