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## A TOUGH PILL TO SWALLOW: INCREASING COMPLEXITY FOR DRUG DEVELOPERS IN THE FEDERAL CIRCUIT

*Jacob T. Michalakes\**

### I. INTRODUCTION

Society, as a whole, benefits from the increased public health capabilities that result from a consistent, streamlined and cost effective-drug development process.<sup>1</sup> The FDA notes, “speeding the availability of drugs that treat serious diseases are in everyone’s interest.”<sup>2</sup> It is essential that the regulatory, legislative and judicial mechanisms in place work in sync so that drug developers have a predictable journey when bringing a drug to market.<sup>3</sup> The need for a reliable system is increasingly important

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U.S. Food & Drug Admin., *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review* (Feb. 23, 2018), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm20041766.htm>.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

with how the diversity of therapeutics is rapidly expanding.<sup>4</sup> The focus of this discussion will be on the recent development of antibody patents and the challenges that drug developers are facing in light of recent Federal Circuit holdings.<sup>5</sup>

Antibody treatments that involve the use of the patient's own immune systems are inherently complicated but extremely lucrative.<sup>6</sup> "These immune-system molecules form the basis of drugs that rake in about US\$100 billion per year."<sup>7</sup> A major player in this market is Amgen Inc., who in early 2005 began developing an antibody therapy to treat high cholesterol.<sup>8</sup> The result of Amgen's research and development was a drug named Repatha, which was approved by the FDA in 2015.<sup>9</sup> Amgen obtained two different patents involving Repatha that were later challenged by Sanofi, another major pharmaceutical developer.<sup>10</sup> The result of this litigation had profound effects on the drug development process as a whole.<sup>11</sup>

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<sup>4</sup> Charlotte Harrison, *Patent Challenges to Antibody and Gene-Therapy Firms on the Rise*, NATURE BIOTECHNOLOGY, (May 9, 2018), <https://www.nature.com/articles/nbt0518-382>.

<sup>5</sup> Biosimilar Development, *Patent Eligibility of Biologic & Biosimilar Patents — A Primer* (Jan. 2, 2018), <https://www.biosimilardevelopment.com/doc/patent-eligibility-of-biologic-biosimilar-patents-a-primer-0001>.

<sup>6</sup> *Id.*

<sup>7</sup> Hedi Ledford, *Rush to Protect Lucrative Antibody Patents Kicks Into Gear* (May 25, 2018), <https://www.nature.com/articles/d41586-018-05273-z>.

<sup>8</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017).

<sup>9</sup> *Id.* at 1371.

<sup>10</sup> *Id.* at 1372.

<sup>11</sup> Dani Kass, *Fed. Circ. Created Disclosure 'Anarchy,' Amgen Tells Justices*. (Aug. 7, 2018), <https://www-law360-com.ezproxy.depaul.edu/articles/1070997/fed-circ-created-disclosure-anarchy-amgen-tells-justices>.

In *Amgen Inc., et al., v. Sanofi, et al.*, the Federal Circuit held Amgen's patents to a different standard than that required by the Patent Act in regard to the written description and enablement requirements.<sup>12</sup> The court made an already complicated landscape even more challenging and unpredictable.<sup>13</sup>

Part II of this note, will discuss the Court's deviation from the Patent Act and the implications it has on Amgen's prospects of clearing their patents<sup>14</sup> Part III, will discuss the larger ramifications this holding has on the drug development process.<sup>15</sup> It will also analyze the complexity of the new standard the Federal Circuit is creating.<sup>16</sup> Finally, Part V will conclude the overall discussion.<sup>17</sup>

## II. BACKGROUND

Patent law in the United States traces its roots back to the constitution.<sup>18</sup> Article 1, Section 8, Clause 8 states: [Congress shall have power] "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."<sup>19</sup> This clause did not create an automatic right for inventors to receive

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<sup>12</sup> *Supra* note 4.

<sup>13</sup> *Supra* note 7.

<sup>14</sup> See *infra* note 18 – 35 and accompanying text.

<sup>15</sup> See *infra* notes 36 – 92 and accompanying text.

<sup>16</sup> *Id.*

<sup>17</sup> See *infra* notes 93 – 105 and accompanying text.

<sup>18</sup> U.S. Const. art. I, §8, cl. 8.

<sup>19</sup> *Id.*

patents, but rather, enabled Congress to create a patent system through subsequent legislation.<sup>20</sup>

Wide sweeping legislative action in the realm of patent law occurred in 1952 with the passing of the Patent Act of 1952.<sup>21</sup> The act, codified at Title 35 of the United States Code, modernized and simplified patent law in the United States.<sup>22</sup> The most recent amendments to the Patent Act occurred in 2011 with the passing of the Leahy-Smith America Invents Act (AIA).<sup>23</sup>

#### A. *Written Description*

Section 112 of the Patent Act states that “[t]he specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . .”<sup>24</sup> The purpose of this requirement is for the inventor to prove that they, “had possession of the claimed subject matter as of the filing date.”<sup>25</sup> Proving possession requires, “a precise definition of the invention.”<sup>26</sup>

Proving possession becomes more difficult when an inventor attempts to claim a generic group of inventions instead of

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<sup>20</sup> Ladas & Perry, LLP, *A Brief History of the Patent Law of the United States*, (May 7, 2014), <https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2/>.

<sup>21</sup> *Id.*

<sup>22</sup> *supra*.

<sup>23</sup> *supra*.

<sup>24</sup> 35 U.S.C. § 112(a).

<sup>25</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed.Cir. 2010) (en banc).

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

a specific single entity.<sup>27</sup> For the inventor to give a precise definition of the generic group, the *Ariad* court requires: “a patentee must disclose a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”<sup>28</sup>

Proving possession is uniquely challenging when the invention is a molecule or antibody.<sup>29</sup> The court in *Enzo*, created a mechanism for inventors to prove possession of antibodies.<sup>30</sup> The Federal Circuit held “as long as an applicant has disclosed a ‘fully characterized antigen,’ either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.”<sup>31</sup>

### B. Enablement

The Enablement requirement of a patent application has the same statutory roots as the written description requirement.<sup>32</sup> Section 112 of the Patent Act reads “[t]he specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.”<sup>33</sup>

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<sup>27</sup> See generally Brief for Bristol-Meyer Squib Company as Amici Curiae Supporting Petitioner, *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017) (No. 17-1480) [hereinafter Brief for Bristol-Meyer Squib].

<sup>28</sup> *Ariad Pharm., Inc.* at 1351.

<sup>29</sup> Brief for Bristol-Meyer Squib at 7.

<sup>30</sup> *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 965 (Fed.Cir. 2002).

<sup>31</sup> *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed.Cir. 2004).

<sup>32</sup> 35 U.S.C. § 112(a).

<sup>33</sup> *Id.*

Determination of whether the written description is enabling turns on the question, “is the experimentation needed to practice the invention undue or unreasonable?” Even though the words “undue experimentation” aren’t found in the Patent Act itself, this has become the standard adopted by the Federal Circuit.<sup>34</sup>

### III. ANALYSIS

#### A. *Amgen Inc., et al. v. Sanofi, et al*

The district court held that Amgen’s patents, U.S. Patent No. 8,829,165 (‘165 Patent) and No. 8,859,741 (‘741 patent), were valid and granted a permanent injunction enjoining the sale of Sanofi’s product.<sup>35</sup> Sanofi appealed that judgment claiming the district court improperly excluded post-priority date evidence regarding written description and enablement that proffered to show that written description and enablement were inadequate.<sup>36</sup> The Federal Circuit held that the district court erred by excluding Sanofi’s evidence regarding written description and enablement and reversed and remanded the case.

Sanofi sought to introduce evidence to show that Amgen’s patents did not disclose a representative number of species and therefore the written description not proving possession.<sup>37</sup> However, Amgen claims the “Possession Standard,” which the Federal Circuit used to gage the sufficiency of the written description, has no statutory basis and defies court precedent.<sup>38</sup>

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<sup>34</sup> *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

<sup>35</sup> *Amgen Inc.*, 872 F.3d at 1371.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 1374.

<sup>38</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480).

### B. *Written Description of the '165 Patent*

At the heart of the written description requirement is the “quid pro quo” of patent law.<sup>39</sup> The patent applicant, in exchange for describing and disclosing their invention to the public (quid), receives a right to exclude others (quo) from using their invention.

<sup>40</sup> The exchange of sufficient description of invention for the right to exclude is the ultimate purpose of the patent system and more specifically, the goal of §112(a).<sup>41</sup> The following theme has been woven through case law for decades, “the object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent.”<sup>42</sup> Amgen has upheld its side of the bargain in the written description of its ‘165 patent and is consistent with the object and purpose of §112(a).<sup>43</sup> However, the Federal Circuit has ruled Amgen’s ‘165 patent invalid because it does not comply with the extra-statutory standard the court has created.<sup>44</sup>

Amgen’s ‘165 patent disclosed the active ingredients in their drug Repatha™.<sup>45</sup> Claim of patent ‘165 states:

An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least

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<sup>39</sup> *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944).

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

<sup>41</sup> Brief for Bristol-Meyer Squib, p. 7, *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017).

<sup>42</sup> *Schriber-Schroth Co. v. Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938).

<sup>43</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480) at 3.

<sup>44</sup> *Id.* at 5.

<sup>45</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367, 1372 (Fed. Cir. 2017).

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 LDL [-]R.<sup>46</sup>

Under the standard created by the Federal Circuit, in order for Amgen to adequately prove they have actually invented their claimed invention, Amgen must show in its disclosure that it had “possession” of the subject matter that they are claiming at the time they filed the patent application.<sup>47</sup> The crux of the matter is that showing possession becomes extremely difficult when the subject matter of the patent is a drug or biologic.<sup>48</sup> Showing possession of an antibody that ligates a certain residue on a protein is immensely more complicated to show possession as compared to possessing a mechanical device that can be physically held.<sup>49</sup>

The Federal Circuit created another rule that attempts to address this issue.<sup>50</sup> In doing so, the court only made the uphill battle for drug developers even steeper.<sup>51</sup> When a patentee is claiming a general group of molecules that achieve the same goal, they are claiming a genus patent.<sup>52</sup> A patent claiming a genus must disclose: “a representative number of species falling within the scope of the genus or structural features common to the members

<sup>46</sup> U.S. Patent No. 8,829,165 (Simon M. Jackson).

<sup>47</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

<sup>48</sup> Brief for Bristol-Meyer Squib, p. 15, *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017).

<sup>49</sup> *Supra* note 31.

<sup>50</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480) at 11.

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

<sup>52</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367, 1374 (Fed. Cir. 2017).

of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”<sup>53</sup>

In Amgen’s ‘165 patent, they are claiming a genus patent.<sup>54</sup> Here, Amgen is claiming “An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues,” followed by a list of potential residues on the protein, which could potentially serve as an antigen for the antibody to ligate to.<sup>55</sup> The genus is any antibody that binds to one of listed residues and performs the function of destroying LDL-receptor cells.<sup>56</sup> Additionally, Amgen provided in the specification of the ‘165 patent: “the three-dimensional structures, obtained via x-ray crystallography, of two of the antibodies known to bind the residues recited.”<sup>57</sup> This information was put forward to satisfy the extra-statutory rule of requiring a patent to disclose “a representative number of species falling within the scope of the genus or structural features common to the members of the genus.”<sup>58</sup>

The information that Amgen submitted to satisfy the “possession” standard to the Federal Circuit goes above and beyond what other patent applicants must disclose in order to receive patent protection.<sup>59</sup> Referring back to the “quid pro quo” argument, the Federal Circuit is requiring Amgen to give “quid

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<sup>53</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

<sup>54</sup> *Amgen* at 1372.

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

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

<sup>57</sup> *Id.*

<sup>58</sup> *Amgen* 872 F.3d 1372 (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 958 F.3d 1336, 1351 (Fed. Cir. 2010)).

<sup>59</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367, 1373 (Fed. Cir. 2017).

plus” in order to receive the quo of patent protection.<sup>60</sup> This is both in contravention of the plain letter and spirit of the patent code in §112(a).<sup>61</sup> To make matters even more complicated, the Court in *Amgen* allowed Sanofi to enter post-priority-date evidence to show that Amgen’s patent does not disclose a representative number of species of a claimed genus and therefore does not have possession of the invention for written description sake.<sup>62</sup> The Federal Circuit has been silent as to whether this type of evidence can be offered up until the decision in *Amgen*.<sup>63</sup> Unless, the Supreme Court grants certiorari and reverses this decision, drug developers not only have to prove more to receive a patent, but also additional evidence can be used against them to prove they are not entitled to patent protection.<sup>64</sup> This further adds to the complexity and unpredictability that results from *Amgen*’s holding.<sup>65</sup>

### C. Enablement of the ‘165 Patent

Similar to the written description requirement, the enablement requirement is a mechanism to ensure the inventor knows the extent of what they have invented before they receive a

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<sup>60</sup> *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944) (explaining the “quid pro quo” of patent law, here the concept is taken beyond its intended scope).

<sup>61</sup> Brief for Bristol-Meyer Squib at 7.

<sup>62</sup> *Amgen* 872 F.3d at 1370.

<sup>63</sup> *Amgen* at 1374 (Citing *In re Hogan* 559 F.2d 595 (CCPA 1977)).

<sup>64</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017), petition for cert. filed, (U.S. Jul. 23, 2017) (No. 2017-1480) at 2.

<sup>65</sup> *Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc., v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC*, 2017 WL 6760911 \*6 (C.A.Fed.).

right to exclude.<sup>66</sup> The specification of the patent is sufficiently enabling, according to § 112(a) of the patent statute, if the written description is clear and concise enough to enable a person ordinarily skilled in the art to actually use the invention.<sup>67</sup> The enablement requirement also serves the purpose of being the middleman in the “quid pro quo” of patent law.<sup>68</sup> Whatever the patent applicant is disclosing is only of value to the public if it clearly and concisely enables a person ordinarily skilled in the art to use the invention without undue experimentation.<sup>69</sup>

The Federal Circuit bifurcated its analysis of the sufficiency of Amgen’s ‘165 patent specification.<sup>70</sup> It first analyzed whether evidence submitted after the patent application was filed was allowed to be submitted to prove that the written description was insufficient.<sup>71</sup> The Court went on to analyze whether post-priority date evidence could be entered to show that undue experimentation was needed to determine how to use Amgen’s patent, therefore causing the specification to not be enabling.<sup>72</sup>

The Federal Circuit separating the analysis into two different inquiries goes directly against the purpose of the patent act. “The Act sets forth a single standard for the written description: It must be “in such full, clear, concise, and exact terms as to enable any person skilled in the art... to make and use” the

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

<sup>67</sup> 35 U.S.C. § 112(a) (2012).

<sup>68</sup> *Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc., v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC*, 2017 WL 6760911 \*7 (C.A.Fed.).

<sup>69</sup> *In re Wands* at 858 F.2d 731.

<sup>70</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367, 1375 (Fed. Cir. 2017).

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

invention.<sup>73</sup> Allowing Sanofi to submit evidence to prove lack of enablement separate from allowing evidence to show lack of possession, adds to the lack of consistency and another layer of complexity to an already complicated process.<sup>74</sup>

#### *D. Impact on the Pharmaceutical Company*

In both Amgen's petition for Writ of Certiorari<sup>75</sup> and Bristol-Meyers Amicus Curiae Brief<sup>76</sup>, the extent of the adverse effects of the holding in *Amgen* cannot be understated. The single most dispositive variable that determines whether a drug will be developed and eventually made available to patients is the cost to bring the drug to market.<sup>77</sup> Drug developers spend gargantuan amounts of money researching and developing cutting-edge therapies for patients with medical needs that have no remedy yet.<sup>78</sup> Return on investment is primarily secured through drug developers receiving patent protection on their innovations.<sup>79</sup>

A unique issue presents itself when the patent being sought is a genus patent, similar to the Amgen '165 patent.<sup>80</sup> Because of the relative ease to develop a drug similar to one already patented without infringing it, drug developers need to be able to claim

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<sup>73</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480) at 11.

<sup>74</sup>*Id.* at 12.

<sup>75</sup>*Id.* at 4.

<sup>76</sup> *Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc., v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC*, 2017 WL 6760911 \*7 (C.A.Fed.).

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

<sup>78</sup> *Id.* at \*1.

<sup>79</sup> *Id.* at \*5.

<sup>80</sup> *Amgen Inc., et al., v. Sanofi, et al.*, 872 F.3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480) at 20.

genus patents and have confidence that the application process will be similar to any other patent application.<sup>81</sup> The only way to ensure that drug developers are rewarded for their expenditure of resources and the risk taken to develop the breakthrough discoveries is through robust patent protection on an entire group (or “genus”) of antibodies that bind to the desired target.<sup>82</sup> Without the ability to patent the entire genus, the drug developer would be spending time and money developing a drug that could potentially be worthless because a competitor circumvented their patent.<sup>83</sup> This goes to show that the Federal Circuit ignored market realities when they decided to create their own standard to review written description and enablement of patent applications.<sup>84</sup>

The secondary impact that results from drug developers’ lack of certainty about obtaining patent protection for their breakthroughs is felt by patients and society as a whole.<sup>85</sup> Patients and society’s overall health and wellness is dependent on pharmaceutical companies investing in research and eventually developing drugs to meet the unmet medical needs of society.<sup>86</sup> Because of the extensive knowledge and capital necessary to develop new therapies, drug companies are best situated to do so.<sup>87</sup> Society, although maybe not most efficiently, places this enormous responsibility in the hands of pharmaceutical companies.<sup>88</sup> It is farsighted and prudent for courts to interpret

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<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 6.

<sup>83</sup> See generally *Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc., v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC*, 2017 WL 6760911 \*5 (C.A.Fed.).

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

<sup>85</sup> *Id.* at \*1.

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

<sup>87</sup> *Id.* at \*2.

<sup>88</sup> *Id.* at \*5.

laws in a way that reduces the complexity and cost of drug development.<sup>89</sup> This will encourage drug development and result in an overall net benefit for society.<sup>90</sup> The holding in *Amgen* is diametrically opposed to this thought process and, for that reason, stifles drug research and development.<sup>91</sup>

#### IV. CONCLUSION

The Federal Circuit's holding in *Amgen* incorrectly bifurcated the written description requirement of 35 USC § 112(a)<sup>92</sup> into two separate requirements each held to a different standard. The Federal Circuit now requires the specification to be sufficiently described as to "enable a person of skill to make and use the invention."<sup>93</sup> Additionally, the written description must show "possession" of the invention.<sup>94</sup> The Federal Circuit cleaved the unitary standard of §112(a) into two separate requirements – "enablement" and "written description."<sup>95</sup> This departs from a

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<sup>89</sup>See generally *Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc., Plaintiffs-Appellees, v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC, Defendants-Appellants.*, 2017 WL 6760911, at \*5 (C.A.Fed.).

<sup>90</sup> *Id.*

<sup>91</sup> See generally *Amgen Inc. v. Sanofi*, , 872 F. 3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480 ).

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

<sup>93</sup> *Id.* at \*4.

<sup>94</sup> *Id.* at \*7.

<sup>95</sup> *AMGEN INC., Amgen Manufacturing Limited, Amgen USA, Inc., Plaintiffs-Appellees, v. SANOFI, AVENTISUB LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC, Defendants-Appellants.*, 2017 WL 6760911, at \*4 (C.A.Fed.).

foundation of precedent and conflates the purpose and plain meaning of §112(a).<sup>96</sup>

Bristol-Myers Squibb states: The Federal Circuit's approach makes it exceedingly difficult to obtain robust patent protection for biopharmaceutical innovations and consequently impedes progress in this field.<sup>97</sup> Additionally, Bristol-Meyers reminds the court that pharmaceutical companies such as Amgen, spend enormous amounts of money to research and develop new therapies for patients with unmet medical needs.<sup>98</sup> If growth in the field of pharmaceutical development is impeded or made more complex because of arbitrary application of laws, then society as a whole will suffer because therapies will be unavailable to patients.<sup>99</sup> Complicating the process for drug developers to bring their inventions to market has larger implications than any other segment of the market because these inventions alleviate human suffering and cure diseases the public suffers from.<sup>100</sup>

On July 23<sup>rd</sup>, 2018, Amgen, Inc. filed its Petition for a Writ of Certiorari to the Supreme Court of the United States.<sup>101</sup> Amgen is presenting this question: should the standard for determining the adequacy of the "written description of the invention" be as the statute says or should court-created standards control instead?<sup>102</sup> Optimistically, the Supreme Court will grant Amgen's petition of Certiorari and return written description jurisprudence back within

<sup>96</sup> *Id.* at \*1.

<sup>97</sup> *Id.* at 3.

<sup>98</sup> *Id.* at 1.

<sup>99</sup> *Id.* at 2.

<sup>100</sup> *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review*, U.S. FOOD & DRUG ADMIN., (Feb. 23, 2018), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm20041766.htm>.

<sup>101</sup> *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017), *petition for cert. filed*, (U.S. Jul. 23, 2017) (No. 2017-1480) at 1.

<sup>102</sup> *Id.* at 7.

the confines of 35 U.S.C. § 112 where it belongs.<sup>103</sup> This can be done by abolishing the conflated standard the Federal Circuit is constructing on their own before its adverse effects are felt by society as a whole.<sup>104</sup>

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<sup>103</sup> *Id.* at 5.

<sup>104</sup> See generally *Amgen Inc., Amgen Manufacturing Limited, Amgen USA, Inc., Plaintiffs-Appellees, v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., Sanofi-Aventis U.S., LLC, Defendants-Appellants.*, 2017 WL 6760911, at \*5 (C.A.Fed.).