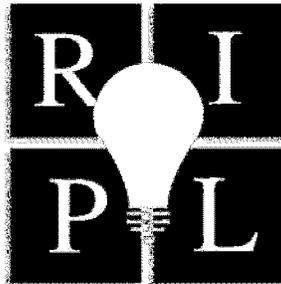


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



TO BE PRESUMED OR NOT TO BE PRESUMED . . . THAT IS THE  
ENABLEMENT QUESTION

KRISTINA A. WALKER

## ABSTRACT

In 2003, the Federal Circuit in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* placed the burden of proving a prior art patent's § 112 nonenablement on the patentee instead of the accused infringer. The patentee even bears this burden when the unclaimed subject matter is asserted to anticipate the patent at issue. This comment focuses on three questions that were created by the decision in *Amgen*. First, is material in a printed publication equivalent to unclaimed material in a patent? Second, is the holding in *Amgen* based on a false premise because it may accord a presumption of § 112 enablement to material that has never been examined by the USPTO for enablement? Third, did the court violate 35 U.S.C. § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee?

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## TO BE PRESUMED OR NOT TO BE PRESUMED . . . THAT IS THE ENABLEMENT QUESTION

KRISTINA A. WALKER\*

Even when laws have been written down, they ought not always to remain  
unaltered.<sup>1</sup>

### INTRODUCTION

As is well established, claimed subject matter in a patent application is examined by the United States Patent and Trademark Office (“USPTO”) for enablement,<sup>2</sup> and a patent is presumptively valid once issued by the USPTO.<sup>3</sup> To overcome this presumption of validity, a party challenging the patent bears the burden of proving the basis of invalidity due to anticipation by clear and convincing evidence.<sup>4</sup> Therefore, one would assume that a party who claims a prior art patent anticipates an invention would bear the burden of proving that the prior art patent is

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<sup>1</sup> Law Quotes—The Quotation Page, <http://www.quotationspage.com/subjects/laws/> (last visited Nov. 13, 2005) (quoting Aristotle (384 BC–322 BC)).

<sup>2</sup> U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.08 (8th ed., 2nd rev. 2004) [hereinafter MPEP].

All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims. The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually.

*Id.* “The ultimate goal of the enablement requirement is to put the public in ‘possession’ of the invention, by providing to persons of ordinary skill in the art a detailed description of how to make and use the invention.” JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 139 (Erwin Chemerinsky et al. eds., 2003). “The enabling disclosure . . . provides a type of blueprint that such persons can follow once the patent expires and they are free to make and use the invention without liability.” *Id.*

<sup>3</sup> 35 U.S.C. § 282 (2000). “A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim.” *Id.*

<sup>4</sup> *See* State Contracting & Eng’g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1067 (Fed. Cir. 2003) (“A party seeking to establish that particular claims are invalid must overcome the presumption of validity in 35 U.S.C. § 282 by clear and convincing evidence.”); Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 725 (Fed. Cir. 2002) (“Because of the presumption of validity, 35 U.S.C. § 282 (282), a defendant must show invalidity by facts supported by clear and convincing evidence.”); Innovative Scuba Concepts, Inc. v. Feder Indus., Inc., 26 F.3d 1112, 1115 (Fed. Cir. 1994) (stating the challenger of a patent’s validity bears the burden of proving invalidity by clear and convincing evidence).

§ 112 enabled.<sup>5</sup> In light of *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, however, this does not appear to be the situation.<sup>6</sup> In *Amgen*, the Federal Circuit placed the burden on the patentee to prove the prior art patent was invalid due to lack of § 112 enablement.<sup>7</sup> The patentee bears this burden even where unclaimed subject matter of the prior art patent's specification is asserted to anticipate the patent at issue.<sup>8</sup> Was this assignment of burden merely dictum or not?<sup>9</sup> Some courts have followed *Amgen* in this respect, while other courts have disregarded it.<sup>10</sup>

The result of *Amgen* creates three points that warrant discussion. First, is material in a printed publication equivalent to unclaimed material in a patent? Second, is the holding in *Amgen* based on a false premise because it may accord a presumption of § 112 enablement to material that has never been examined by the USPTO for enablement? Third, did the court violate 35 U.S.C. § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee?

The background section provides useful information to understand *Amgen's* ramifications. The analysis section discusses the three aforementioned topics that were created by the *Amgen* decision. The proposal section suggests solutions to the problems created by the court in *Amgen*. Lastly, the conclusion provides a summarization of significant points.

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<sup>5</sup> Cf. Robert A. Matthews, Jr., *A New Presumption Regarding Anticipatory Prior-Art Patents*, IP LITIGATOR, July/Aug. 2003, at para. 2 (“[L]ogic suggests that a party asserting that a prior-art reference anticipates a claimed invention bears the burden of proving . . . that the prior-art reference provides an enabling disclosure.”). For purposes of clarity in this article, the term § 112 enablement is used to describe a prior art patent and/or patent enabling itself, which is the enablement requirement of 35 U.S.C. § 112; the term anticipation is used to describe a prior art reference that enables a patent. “[T]he phrase prior art can be understood at a very basic level as the legally available technology and information with which the claimed invention will be compared, in order to determine whether that invention is patentable.” MUELLER, *supra* note 2, at 139. Examples of prior art documents are patents and printed publications. *See id.*

<sup>6</sup> *See generally* *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003) (placing the burden on the patentee to prove the prior art patent was not § 112 enabled).

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

[t]he requirement of 35 U.S.C. § 112, ¶ 1 that a patent applicant describe in the specification how to make and use the invention claimed therein in such “full, clear, and concise, and exact terms” as to permit any person skilled in the art of the invention to do so without undue experimentation.

MUELLER, *supra* note 2, at 372.

<sup>8</sup> *See* Matthews, *supra* note 5, at para. 3.

<sup>9</sup> Gale R. Peterson & Derrick A. Pizarro, *Recent Developments in Patent Law – Decisions by the U.S. Court of Appeals for the Federal Circuit*, 11 TEX. INTELL. PROP. L.J. 483, 505 (2003).

<sup>10</sup> *Compare* *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 581 (D.N.J. 2004) (“The patentee bears the burden of presenting evidence to convince the court that the prior art patent did not enable the invention, and thus, that it is not anticipating.”), *and* *Alza Corp. v. Mylan Labs., Inc.*, 310 F. Supp. 2d 610, 630 (D. Vt. 2004) (placing the burden on patentee to produce sufficient evidence of nonenablement to overcome the presumption of enablement), *with* *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1151 (Fed. Cir. 2003) (placing the burden of proving § 112 enablement and anticipation on the accused infringer).

## I. BACKGROUND

Part A of the background section explains the process of acquiring a patent and the shifting burden between the examiner and the applicant. Part B explains the process of challenging the validity of a patent due to anticipation. Part C discusses certain aspects of *Amgen* and the outcome of the case regarding the presumption of § 112 enablement.

### A. *The Process of Acquiring a Patent*

When an inventor files a complete patent application with the USPTO, the application is assigned to an examiner who performs the arduous task of determining whether the conditions of patentability and other formal requirements are met.<sup>11</sup> The requirements of patentability include that the claimed subject matter<sup>12</sup> be useful,<sup>13</sup> novel<sup>14</sup> and non-obvious<sup>15,16</sup>. In addition, the formal statutory requirements

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<sup>11</sup> 4 DONALD S. CHISUM, CHISUM ON PATENTS, § 11.01 (2004). The examiner conducts a search of prior art and determines compliance with, in addition to the formal requirements, the substantive and procedural requirements of patentability. See 1 *id.*, Glossary.

<sup>12</sup> An applicant for a patent must include in the specification accompanying the application for the patent “one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 3 *id.* § 8.01.

Patent claims serve two functions. First, they define the invention for the purpose of applying the conditions of patentability (eligible subject matter, originality, novelty, utility, and nonobviousness), the statutory bars, and the disclosure requirements. Second, they define the invention for the purpose of determining infringement, that is, what constitutes the ‘patented invention’ that persons cannot make, use or sell without the authority of the patent owner.

*Id.*

<sup>13</sup> See 35 U.S.C. § 101 (2000). “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” *Id.*

<sup>14</sup> See 35 U.S.C § 102 (2000).

A person shall be entitled to a patent unless—  
 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or  
 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

*Id.* § 102(a)–(b).

<sup>15</sup> See 35 U.S.C. § 103 (2000).

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

*Id.* § 103(a).

<sup>16</sup> 4 CHISUM, *supra* note 11, § 11.01 n.1.

must be satisfied before a patent can issue.<sup>17</sup> These include the requirement from 35 U.S.C. § 112 that the patent application must sufficiently describe, enable, and enumerate the best mode of operating the invention.<sup>18</sup> To be enabling, the patent's specification must include information regarding all aspects of the invention to teach persons skilled in the art<sup>19</sup> how to make and use the invention without "undue experimentation."<sup>20</sup>

To ensure the patent application complies with the enablement requirement of § 112, all claims are examined by the USPTO.<sup>21</sup> However, unclaimed subject matter

<sup>17</sup> 4 *id.* § 11.01, n.1. *See generally* 35 U.S.C. § 112 (2000) (stating the patent issuing requirements in addition to the conditions of patentability, which are 35 U.S.C. § 101–103).

<sup>18</sup> 35 U.S.C. § 112.

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

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

*Id.* The best mode requirement requires the inventor to disclose in the patent application "the best way known to the inventor on the application's filing date of carrying out the invention." MUELLER, *supra* note 2, at 368. The requirement that the specification include a written description is "separate and distinct from the enablement requirement." MPEP, *supra* note 2, § 2163. "The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term." *Id.* In addition "[t]his requirement for an adequate disclosure ensures that the public receives something in return for the exclusionary rights that are granted to the inventor of the patent." *Id.* § 2162.

<sup>19</sup> The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. Where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their specialty.

*Id.* § 2164.05(b).

<sup>20</sup> *See In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). "The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive.'" *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (quoting *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984)). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The following factors are to be considered in determining "whether a disclosure would require undue experimentation":

- (1) the quantity of experimentation necessary,
- (2) the amount of direction or guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the relative skill of those in the art,
- (7) the predictability or unpredictability of the art, and
- (8) the breadth of the claims.

*Id.* at 737.

<sup>21</sup> MPEP, *supra* note 2, § 2164.08. Regarding the examination inquiry, "the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims." *Id.* The examiner then "should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually." *Id.*

in the specification is not examined.<sup>22</sup> Moreover, this subject matter that is “disclosed but not claimed in a patent application is dedicated to the public.”<sup>23</sup>

When rejecting a claim under the § 112 enablement requirement, the USPTO bears the initial burden of asserting a prima facie case explaining why the scope of protection provided by that claim is not enabled by the specification.<sup>24</sup> If the USPTO meets this burden, the burden then shifts to the applicant to provide proof that the claim is § 112 enabled.<sup>25</sup> If the applicant fails to rebut § 112 nonenablement, the USPTO will reject the patent application.<sup>26</sup> However, if the applicant successfully rebuts this presumption and has met all the patent requirements, then the USPTO issues the claimed invention as a patent.<sup>27</sup> At this time, the patent is accorded a presumption of validity.<sup>28</sup> This presumption is partly derived from the USPTO’s presumed proficiency at performing its job.<sup>29</sup>

### *B. Challenging the Validity of a Patent Due to Anticipation Prior to Amgen*

Once the USPTO has issued the patent, a person having standing may challenge the patent’s validity.<sup>30</sup> A patent claim may be invalid due to anticipation if the

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<sup>22</sup> See *id.* § 2164.08. “All questions of enablement are evaluated against the claimed subject matter.” *Id.* Casual usage implies that the specification is distinct and separate from the claims; however, the specification is a superset of the claims. See 35 U.S.C. § 112; 4 CHISUM, *supra* note 11, § 11.02. “The written description portion of a patent encompasses all of the patent specification’s content other than the claims (i.e., the written description includes those sections of the patent specification that are typically labeled ‘Background of the Invention,’ ‘Summary of the Invention,’ and ‘Detailed Description of the Invention’).” MUELLER, *supra* note 2, at 82.

<sup>23</sup> Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1051 (Fed. Cir. 2002).

[W]hat is not claimed is public property. The presumption is, and such is generally the fact, that what is not claimed was not invented by the patentee, but was known and used before he made his invention. . . . The public has the undoubted right to use, and it is to be presumed does use, what is not specifically claimed in the patent.

*Id.* at 1053.

<sup>24</sup> *In re Wright*, 999 F.2d at 1561–62. This includes “providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.” *Id.* at 1562.

<sup>25</sup> *Id.* (stating that a rejection can be overcome by providing “suitable proofs indicating that the specification is indeed enabling”).

<sup>26</sup> See 35 U.S.C. § 112 (requiring that before the USPTO will issue a patent, the patent must enable a person skilled in the art to make and use the invention).

<sup>27</sup> See 4 CHISUM, *supra* note 11, § 11.01 n.1. The useful, novelty, and non-obviousness requirements of 35 U.S.C. §§ 101–103 must be satisfied. 4 *id.* “[T]he first paragraph of 35 U.S.C. § 112 requires that the patent specification describe, enable, and set forth the best mode of carrying out the invention.” 4 *id.* “[T]he second paragraph of section 112 requires that the claims set forth the subject matter that the applicant regards as his invention and that the claims particularly point out and distinctly define the invention.” 4 *id.*

<sup>28</sup> See 35 U.S.C. § 282 (2000).

<sup>29</sup> Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1992).

<sup>30</sup> See 35 U.S.C. § 282. “In accordance with § 282, each of these statutory criteria for patentability . . . also can serve as a basis for alleging invalidity of the issued patent.” MUELLER, *supra* note 2, at 297. These grounds include the failure to satisfy one or more of the statutory criteria set forth in 35 U.S.C. § 101 (statutory subject matter and utility), § 102 (novelty and no loss of right) and § 103 (nonobviousness). *Id.* at 297. An issued patent may also be held invalid based on a “failure to comply with any requirement of sections 112 or 251.” *Id.* at 297–98. Therefore, it “may

invention was patented or described in a printed publication before it was invented by the patentee,<sup>31</sup> or if the invention was patented or described in a printed publication more than one year prior to the filing date of the patent being challenged.<sup>32</sup> A reference is considered a printed publication once the reference is disseminated or at least made available to persons interested and ordinarily skilled in the art.<sup>33</sup> In order for the prior art reference to anticipate the patent claim, this single reference must disclose each and every element of the challenged claim, either expressly or inherently,<sup>34</sup> and the prior art must enable one skilled in the art to make and use the invention.<sup>35</sup>

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be held invalid under 35 U.S.C. § 112, ¶ 1 if the specification is nonenabling, does not provide a written description of the invention, or fails to disclose the best mode of carrying out the invention, or under 35 U.S.C. § 112, ¶ 2 if the claims are indefinite.” *Id.* at 298. “A patent reissued in accordance with 35 U.S.C. § 251 is subject to the same constraints.” *Id.* at 298. An accused infringer or an interested third-party may challenge the patent’s validity by raising an invalidity defense in an infringement suit or request a declaratory judgment. 4 CHISUM, *supra* note 11, § 11.03.

<sup>31</sup> 35 U.S.C. § 102(a) (2000). “When one or more of the novelty provisions of § 102 is triggered, patent attorneys say that the invention has been anticipated. When an invention has been anticipated, it is old, and thus unpatentable. In other words, anticipation is the opposite of or absence or negation of novelty.” MUELLER, *supra* note 2, at 94. In a patent case, “that which will [literally] infringe, if later, will anticipate, if earlier.” *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 726 (Fed. Cir. 2002).

<sup>32</sup> 35 U.S.C. § 102(b). “Section 102 uses the word ‘invention’ in two senses: to refer to the anticipatory *prior art invention*, and to the *applicant’s invention* for which a patent is being sought (or in federal district court litigation challenging validity, the invention of the patent in suit).” MUELLER, *supra* note 2, at 97.

<sup>33</sup> *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981) (footnote omitted).

“[P]rinted publication” should be approached as a unitary concept. The traditional dichotomy between “printing” and “publication” is no longer valued [sic]. Given the state of technology in document duplication, data storage, and data-retrieval systems, the “probability of dissemination” of an item very often has little to do with whether or not it is “printed” in the sense of that word when it was introduced into the patent statutes in 1836. In any event, interpretation of the words “printed” and “publication” to mean “probability of dissemination” and “public accessibility,” respectively, now seems to render their use in the phrase “printed publication” somewhat redundant.

*Id.* The reference’s dissemination or availability must be such that “to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate [the reference] and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.” *Id.*

<sup>34</sup> If a prior art reference fails to disclose even one element of the claimed invention, then that claimed invention is not anticipated. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574 (Fed. Cir. 1986); *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

To overcome the presumption of validity once a patent is issued, the party challenging the patent bears the burden of proving anticipation by clear and convincing evidence.<sup>36</sup> Clear and convincing evidence has been described as evidence that persuades the fact-finder that the factual contention is “highly probable.”<sup>37</sup> Considering the aforementioned, a party asserting a prior art reference as anticipatory to the patent in suit ought to bear the burden of proving that the prior art reference is § 112 enabled.<sup>38</sup> However, in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*,<sup>39</sup> the Federal Circuit ruled otherwise and placed the burden of proving the prior art’s lack of § 112 enablement on the patentee.<sup>40</sup>

### C. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*

Amgen Inc. (“Amgen”), the owner of several patents regarding the production of erythropoietin (“EPO”), filed a declaratory judgment action seeking to impede Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc. (hereinafter “TKT”) “from commercializing a competitive EPO product.”<sup>41</sup> Amgen, the patentee, alleged that TKT’s Investigational New Drug Application infringed several of Amgen’s patents.<sup>42</sup> TKT denied infringement and counterclaimed that Amgen’s patents were invalid.<sup>43</sup> To support TKT’s counterclaim, TKT relied on a prior art patent, the ’513 patent (hereinafter “Sugimoto”),<sup>44</sup> which had similar disclosures to the patents

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*Id.* at 43–44. A skilled artisan is not required “to recognize the inherent characteristic in the prior art that anticipates the claimed invention.” *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003).

<sup>35</sup> *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996). To constitute prior art, a printed publication’s disclosure of a claimed invention must be enabling. *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. and Research*, 346 F.3d 1051, 1055 (Fed. Cir. 2003). However, the claimed invention that was disclosed is not required to be physically made to satisfy the enablement requirement. *Id.*

<sup>36</sup> *See, e.g., State Contracting & Eng’g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1067 (Fed. Cir. 2003); *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 725 (Fed. Cir. 2002); *Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115 (Fed. Cir. 1994).

<sup>37</sup> *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

<sup>38</sup> *See Matthews, supra* note 5.

<sup>39</sup> *Hoechst Marion Roussel, Inc.* is now known as *Aventis Pharmaceuticals Inc.* *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1313 (Fed. Cir. 2003).

<sup>40</sup> *See Amgen*, 314 F.3d at 1355.

<sup>41</sup> *Id.* at 1319. Erythropoietin is “a naturally occurring hormone that controls the formation of red blood cells in bone marrow.” *Id.*

<sup>42</sup> *Id.* Amgen alleged that TKT infringed the following patents: Patent Nos. 5,547,933 (“the ’933 patent”); 5,618,698 (“the ’698 patent”); and 5,621,080 (“the ’080 patent”). *Id.* “The complaint was amended in October 1999 to include United States Patent Nos. 5,756,349 (“the ’349 patent”) and 5,955,422 (“the ’422 patent”), which issued after suit was filed.” *Id.*

<sup>43</sup> *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 77 (D. Mass. 2001).

<sup>44</sup> *See Amgen*, 314 F.3d at 1354. U.S. Patent No. 4,377,513 (filed August 1981) (“the ’513 patent”). *Id.* This patent “discloses a means for fusing lymphoblastoid cells with kidney cells and culturing them to produce EPO.” Randy Morin, *Legal Update: Recent Federal Circuit Decision Concerning Erythropoietin (EPO): Amgen v. TKT*, 9 B.U. J. SCI. & TECH. L. 490, 497 (2003) (discussing the Sugimoto reference).

asserted by Amgen.<sup>45</sup> TKT raised Sugimoto even though Sugimoto had been before the examiner during the prosecution of Amgen's patents.<sup>46</sup> Because TKT did not prove Sugimoto's § 112 enablement, the district court found that Sugimoto was not prior art.<sup>47</sup>

On appeal to the Federal Circuit, TKT contended that the district court committed error in placing the burden of proving Sugimoto's § 112 enablement on TKT.<sup>48</sup> TKT reasoned that patents issued by the United States, "even those only asserted as prior art in an invalidity defense, are presumed [§ 112] enabled under 35 U.S.C. § 282."<sup>49</sup> Amgen argued "there should be no presumption of [§ 112] enablement in this case because, under § 282, courts only presume the claimed subject matter in a patent is [§ 112] enabled."<sup>50</sup> Therefore, Amgen argued, "no presumption of [§ 112] enablement should apply" "because only the unclaimed disclosures of Sugimoto are at issue"; hence, the burden properly fell on TKT.<sup>51</sup>

The Federal Circuit agreed with TKT's argument that prior art patents are presumed § 112 enabled.<sup>52</sup> However, the Federal Circuit relied on authority going beyond § 282;<sup>53</sup> the court relied on its own precedent holding a presumption of § 112

<sup>45</sup> *Amgen*, 126 F. Supp. 2d at 108.

<sup>46</sup> *Amgen*, 314 F.3d at 1354.

[W]hen a party alleges that a claim is invalid based on the very same references that were before the examiner when the claim was allowed, that party assumes the following additional burden:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

*Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000). "While the presentation at trial of a reference that was not before the examiner does not change the presumption of validity, the alleged infringer's burden may be more easily carried because of this additional reference." *SIBIA Neurosciences, Inc. v. Cadus Pharms. Corp.*, 225 F.3d 1349, 1355–1356 (Fed. Cir. 2000).

During patent prosecution, Amgen did present Sugimoto's non-enablement to overcome a rejection. *Amgen*, 314 F.3d at 1356. However, Amgen used several arguments, and the examiner did not state whether he agreed with this argument when he allowed the patent. *Id.* The Federal Circuit concluded that because it "cannot assume the acceptance of every argument presented during prosecution, the mere fact this argument was made is only minimally probative of the enablement of Sugimoto." *Id.*

<sup>47</sup> *Id.* at 1354. After a three day *Markman* hearing, the district court:

(i) construed the disputed claims; (ii) held each of the patents enforceable; (iii) held the '080, '349, and '422 patents valid and infringed; (iv) held the '698 patent not infringed; and (v) held the '933 patent not infringed or, in the alternative, invalid for failure to satisfy 35 U.S.C. § 112.

*Id.* at 1320. The court reasoned that "In light of the intense competition that grew out of the race to make human EPO suitable for treatment of chronic anemia, one would imagine that if Sugimoto's invention were truly enabling, then he would have won that lucrative race." *Id.* at 1354 (quoting *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 108 (D. Mass. 2001)).

<sup>48</sup> *Amgen*, 314 F.3d at 1354.

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

<sup>50</sup> *Id.* at 1355.

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

<sup>52</sup> *Id.* at 1354.

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

enablement existed “in both the claimed and the unclaimed disclosures in a prior art patent.”<sup>54</sup> Furthermore, the Federal Circuit found that the burden of proving Sugimoto was invalid due to lack of § 112 enablement should have rested on Amgen.<sup>55</sup>

In *Amgen*, the Federal Circuit relied on its precedent, *In re Sasse*, which regarded patent prosecution.<sup>56</sup> The court reasoned that a presumption of § 112 enablement existed because during patent prosecution an examiner is allowed “to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether” the patent is § 112 enabled or whether “it is the [patent’s] claimed material (as opposed to the unclaimed disclosures)” that are alleged to anticipate the application claims.<sup>57</sup> Therefore, the Federal Circuit in *Amgen* held an accused infringer to be similarly entitled, as is the examiner in patent prosecution, to a presumption of § 112 enablement for the unclaimed material in the prior art patent asserted by the accused infringer.<sup>58</sup> The court stated that, also similar to the applicant in patent prosecution, the patentee could overcome the presumption of § 112 enablement by presenting persuasive evidence that the prior art’s relevant claimed material or unclaimed disclosures are not § 112 enabled and hence, cannot invalidate a claim.<sup>59</sup> The court noted its reasoning might also apply to prior art non-patent printed publications.<sup>60</sup> However, that issue was not reached because the prior art was a patent in this case.<sup>61</sup>

The court also noted a policy reason for its decision that Amgen, the patentee, bore the burden of proving § 112 nonenablement of Sugimoto.<sup>62</sup> Specifically, the court deemed it unwise “to force [the trial] court to conduct a mini-trial on the proper claim construction of a prior art patent every time an allegedly anticipating patent [was] challenged for lack of [§ 112] enablement.”<sup>63</sup> The court further noted that “because the presumption outlined [in *Amgen* did] not rely on § 282, [there was] no reason to impose these burdens on litigants and the [trial] courts.”<sup>64</sup>

The Federal Circuit concluded that the district court committed error by placing the burden of proving Sugimoto’s § 112 enablement on TKT.<sup>65</sup> However, the court

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<sup>54</sup> *Id.* at 1355. The Federal Circuit relied on its precedent, *In re Sasse*, 626 F.2d 675, 681 (C.C.P.A. 1980). See *Amgen*, 314 F.3d at 1355.

<sup>55</sup> *Amgen*, 314 F.3d at 1355.

<sup>56</sup> See *id.* (relying on *In re Sasse*, 626 F.2d 675, 681 (C.C.P.A. 1980), which arose in the context of *ex parte* prosecution).

<sup>57</sup> *Id.* “When the PTO cited a disclosure which expressly anticipated the present invention . . . the burden was shifted to the applicant. He had to rebut the presumption of the operability of [the prior patent] by a preponderance of the evidence.” *In re Sasse*, 626 F.2d 675, 681 (C.C.P.A. 1980) (citation omitted).

<sup>58</sup> *Amgen*, 314 F.3d at 1355.

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

<sup>60</sup> *Id.* at 1355 n.22.

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

<sup>62</sup> *Id.* at 1355 n.21.

<sup>63</sup> *Id.* The court only mentioned this policy reason in a footnote. See *id.* The Federal Circuit stated that because the court “frequently revisit[s] district courts’ determinations in matters of claim construction and validity, [it is] certainly aware that such a task [(mini-trials)] can occupy a great deal of a court’s resources.” *Id.*

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

<sup>65</sup> *Id.* at 1356.

held this error to be harmless for three of Amgen's patents.<sup>66</sup> But given the Federal Circuit's earlier holdings, it vacated and remanded the issue of Sugimoto's anticipation of one of the claims in another of Amgen's patents.<sup>67</sup>

On remand, the district court addressed the term "presumption" in the Federal Circuit's holding that an accused infringer should be entitled to a presumption of § 112 enablement for unclaimed material in the prior art patent.<sup>68</sup> The district court noted that often in patent law, "this is not a true presumption at all, but rather a burden shifting mechanism that places the burden of proving [§ 112] nonenablement on the patentee."<sup>69</sup> When a "true presumption" exists, the presumption disappears when the burden of production is met;<sup>70</sup> however, when a "burden shifting mechanism" exists, the patentee has the burden of production as well as the burden of persuasion to overcome the presumption.<sup>71</sup> The court concluded that Amgen could rebut the presumption of Sugimoto's § 112 enablement by proving Sugimoto lacked § 112 enablement by a fair preponderance of the evidence.<sup>72</sup>

The decision in *Amgen* produced a dramatic effect on how parties litigate. Was the assignment of the enablement presumption to a prior art disclosure merely dictum or not? This requires resolution; otherwise, confusion arises as to who bears the burden of proving whether the prior art patent is § 112 enabled. If the assignment is not dictum, and thus controlling, then the decision must be reversed because the court violated § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee.

## II. ANALYSIS

Three topics of discussion are created by the decision in *Amgen*. The first topic is whether material in a printed publication is equivalent to unclaimed material in a

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<sup>66</sup> *Id.* After the district court analyzed enablement and found "the relevant unclaimed disclosures of Sugimoto nonenabled, the court nevertheless conducted a full anticipation analysis." *Id.* The court found that "none of the cited references disclose [sic] each and every limitation of any of Amgen's individual claims." *Id.* (quoting *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 109 (D. Mass. 2001)).

<sup>67</sup> *Id.* Sugimoto did not anticipate claim 1 of the '422 patent. *Id.*; see *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 307 (D. Mass. 2004) (holding on remand that "Amgen has shown by a preponderance of the evidence that Sugimoto is not enabled—that is, that Sugimoto's specification does not teach skilled artisans how to make and use the entire scope of the claimed invention without undue experimentation").

<sup>68</sup> *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 305 (D. Mass. 2004).

<sup>69</sup> *Id.* at 305 n.124 (citation omitted); see *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126, 131–32 (D. Mass. 2003) (criticizing the recurrent imprecision of the term "presumption").

<sup>70</sup> *Amgen*, 287 F. Supp. 2d at 132. The burden of production is met when "the party with the burden presents evidence to rebut the presumed fact." *Id.*

<sup>71</sup> *Id.* at 131–32. For the burden of persuasion, the party must persuade the court of its fact. *Id.*

<sup>72</sup> *Amgen*, 339 F. Supp. 2d at 306 n.125. *But see* *Halliburton Energy Servs., Inc. v. Weatherford Int'l, Inc.*, No. 302CV1347-N, 2003 WL 22017187, at \*1–\*2 (N.D. Tex. Aug. 26, 2003) (interpreting the Federal Circuit's holding in *Amgen* "to teach that the patentee only has the burden of going forward to present some material evidence which places the enablement of the prior art in question, i.e., the burden of production").

patent. The second topic is whether *Amgen* is based on a false premise because it affords unclaimed material a presumption of § 112 enablement. The last topic is whether *Amgen* violated 35 U.S.C. § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee.

*A. Material in a Printed Publication Is Equivalent to Unclaimed Material in a Patent*

In *Amgen*, the Federal Circuit noted that the court's reasoning behind its holding that a prior art patent's unclaimed material is accorded a presumption of § 112 enablement might also logically extend to prior art non-patent printed publications.<sup>73</sup> Although the Federal Circuit did not decide this issue,<sup>74</sup> one could support the argument that material in a printed publication is equivalent to unclaimed material in a patent by comparing the examination and public aspect of the two.

The USPTO examines all claims to determine whether everything within the scope of the claim is § 112 enabled.<sup>75</sup> Considering that the claims define the patentee's scope of patent protection, the patent's claim requirement assumes that the invention is delineated in the claims, not in the specification.<sup>76</sup> Thus, when an applicant discloses subject matter but fails to claim it, the USPTO is deprived of the opportunity to consider whether the disclosures are § 112 enabled.<sup>77</sup>

Similar to unclaimed disclosures in a patent, material in a printed publication is not examined for enablement. Indeed, "[t]he statutory phrase 'printed publication' has been interpreted to mean that before the critical date the reference must have been sufficiently accessible to the public interested in the art."<sup>78</sup> Therefore, dissemination and public accessibility, not the reference's § 112 enablement, are the

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<sup>73</sup> *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 n.22 (Fed. Cir. 2003).

<sup>74</sup> *Id.* The Federal Circuit did not decide whether the presumption of enablement for the prior art patent's unclaimed material also applied to prior art printed publications because the prior art at issue, Sugimoto, was in fact a patent in this case. *Id.*

<sup>75</sup> MPEP, *supra* note 2, § 2164.08 ("All questions of enablement are evaluated against the claimed subject matter.").

<sup>76</sup> *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002).

<sup>77</sup> *See id.* at 1051. Where an applicant disclosed alternatives in her patent application but failed to claim them, the USPTO "was deprived of the opportunity to consider whether these alternatives were patentable." *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108 (Fed. Cir. 1996). Thus, the applicant dedicated the use of these alternatives to the public. *Id.* However, a patentee is not left without a remedy if the patentee unintentionally fails to claim disclosed subject matter. *Johnson & Johnston*, 285 F.3d at 1055. "Within two years from the grant of the original patent, a patentee may file a reissue application and attempt to enlarge the original scope of the claims to include the disclosed but unclaimed subject matter." *Id.*; *see* 35 U.S.C. § 251 (2000). "In addition, the patentee can file a separate application claiming the disclosed subject matter under 35 U.S.C. § 120 (2000)." *Johnson & Johnston*, 285 F.3d at 1055.

<sup>78</sup> *In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004) (quoting *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989). "Patent attorneys refer to the date that is one year prior to the application filing date as the *critical date* for § 102(b) purposes." MUELLER, *supra* note 2, at 103 (emphasis added).

indicators of whether a prior art reference is “published.”<sup>79</sup> Also, material in a printed publication is available to the public in the same way as a patent’s unclaimed subject matter.<sup>80</sup> Therefore, unclaimed material in a patent is equivalent to material in a printed publication because both are available to the public and neither was required to be analyzed to ensure the material is § 112 enabled.

### *B. The Amgen Holding Is Based on a False Premise*

Neither unclaimed material in a patent nor material in a printed publication is required to be examined for § 112 enablement. Consequently, the question is whether Amgen’s holding is based on a false premise as it affords a presumption of § 112 enablement to material that has never been examined for enablement.

The Federal Circuit held the accused infringer to be entitled to a presumption of § 112 enablement for both the claimed and unclaimed material in the prior art patent asserted by the accused infringer to challenge the validity of the patent in suit.<sup>81</sup> However, during patent prosecution, the examiner only inspects the claimed subject matter for § 112 enablement.<sup>82</sup> There is no requirement for the examiner to inspect the unclaimed disclosures.<sup>83</sup> Accordingly, the claims of a patent (as opposed to the unclaimed disclosures) enjoy the presumption of validity.<sup>84</sup> When Sugimoto was before the USPTO during the prosecution of Amgen’s patents, the examiner inspected its claims, not the unclaimed material for § 112 enablement. Therefore, *Amgen* based its holding on a false premise by giving a presumption of § 112 enablement to material that had never been required to be examined for enablement.

### *C. Can the Court Remove the Enablement Element of Anticipation Without Violating 35 U.S.C. § 282?*

A prior art reference can anticipate a claimed invention during patent prosecution and an issued patent during patent litigation.<sup>85</sup> However, in patent prosecution, § 282 does not apply as it does in patent litigation.<sup>86</sup> Accordingly, did the Federal Circuit in *Amgen* violate § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee?

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<sup>79</sup> *In re Klopfenstein*, 380 F.3d at 1348. “Public accessibility has been the criterion by which a prior art reference will be judged for the purposes of § 102(b).” *Id.* at 1350. Many times, courts find it useful to rely on distribution and indexing as alternatives for public accessibility. *Id.* However, these are not the only factors in determining whether the reference is a “printed publication.” *Id.*

<sup>80</sup> *See Johnson & Johnston*, 285 F.3d at 1051; *Maxwell*, 86 F.3d at 1106.

<sup>81</sup> *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003).

<sup>82</sup> MPEP, *supra* note 2, § 2164.08 (“All questions of enablement are evaluated against the claimed subject matter.”).

<sup>83</sup> *See id.*

<sup>84</sup> *See* 35 U.S.C. § 282 (2000) (“Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.”).

<sup>85</sup> *See* MUELLER, *supra* note 2, at 297 (stating the statutory criteria for patentability also can serve as a basis for alleging invalidity of the issued patent).

<sup>86</sup> *See generally* 35 U.S.C. § 282 (2000) (“A *patent* is presumed valid.”) (emphasis added).

After an anticipation rejection during patent prosecution, a shifting burden of proof exists.<sup>87</sup> Unfortunately, on account of a prior art patent's presumption of § 112 enablement in prosecution, the USPTO neither inquires whether the prior art patent is actually § 112 enabled nor distinguishes whether it is the prior art patent's claimed material (as opposed to the unclaimed disclosures) that allegedly anticipates the claimed invention at any point in the burden shifting analysis.<sup>88</sup> First, the USPTO satisfies its initial burden by citing a patent that expressly anticipates the claimed invention.<sup>89</sup> Subsequently, the burden shifts to the patent applicant to rebut the presumption that the prior art patent is § 112 enabled.<sup>90</sup> If the applicant successfully rebuts this presumption and has met all the patent requirements, the USPTO issues a patent.<sup>91</sup>

Only after a patent is issued by the USPTO may the patent enjoy a statutory presumption of validity under § 282.<sup>92</sup> In patent litigation, as opposed to prosecution, a party challenging the validity of a patent bears the burden of proving such invalidity.<sup>93</sup>

The distinction between patent prosecution and patent litigation becomes important when considering why the Federal Circuit in *Amgen* erroneously relied on its precedent, *In re Sasse*.<sup>94</sup> The *Amgen* court held the accused infringer to be similarly entitled, as is the USPTO in patent prosecution, to a presumption of § 112 enablement of the unclaimed material in the prior art patent asserted by the accused infringer.<sup>95</sup> However, the court used an erroneous analogy between patent prosecution and patent litigation. During patent prosecution, the claimed invention has not been issued by the USPTO as a valid patent; hence, the claimed invention is not entitled to a statutory presumption of validity under § 282.<sup>96</sup> At this time, § 282 is not being violated by shifting the burden of proving the prior art reference's lack of § 112 enablement because the claimed material is not afforded a presumption of validity. Therefore, the patent enjoys the presumption of validity only during patent

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<sup>87</sup> See *In re Sasse*, 626 F.2d 675, 681 (C.C.P.A. 1980).

<sup>88</sup> *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003).

<sup>89</sup> *In re Sasse*, 626 F.2d at 681.

<sup>90</sup> See *id.*

<sup>91</sup> See 4 CHISUM, *supra* note 11, § 11.01 n.1. The useful, novelty, and non-obviousness requirements of 35 U.S.C. §§ 101–103 must be satisfied. 4 *id.* Additionally, the requirements of 35 U.S.C. § 112 must be satisfied. 4 *id.*

<sup>92</sup> 35 U.S.C. § 282 (2000). "A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." *Id.*

<sup>93</sup> *Id.* "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.*

<sup>94</sup> See 1 CHISUM, *supra* note 11, § 3.04(1)(b)(v).

While numerous courts have stated that prior art references are entitled to a presumption of enablement, see, e.g., *Ciba Geigy Corp. v. Alza Corp.*, 864 F. Supp. 429, 438 (D.N.J. 1994), *aff'd* in pertinent part, vacated in part, 68 F.3d 487 (1995); *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 711 F. Supp. 759, 772 (D. Del. 1989); *Rockwell*, No. 93-542C, 1997 WL 50614, at \*28 (Ct. Cl. 1997), these courts have each relied incorrectly upon *In re Sasse* . . . .

1 *Id.*

<sup>95</sup> *Amgen*, 314 F.3d at 1355.

<sup>96</sup> See 35 U.S.C. § 282 ("A patent shall be presumed valid.") (emphasis added).

litigation.<sup>97</sup> Because the examiner only inspects the claimed subject matter (as opposed to the unclaimed disclosures) in the application for § 112 enablement,<sup>98</sup> after the patent issues, the presumption that the claims are § 112 enabled is encompassed in the presumption of validity.<sup>99</sup> As such, in patent litigation, because the party challenging the patent's validity bears the burden of proving such invalidity, the same party should also bear the burden of proving whether the prior art patent is § 112 enabled.<sup>100</sup> Therefore, *Amgen* incorrectly relied on *In re Sasse* because patent prosecution is not analogous to patent litigation in that § 282 does not apply in patent prosecution.

Considering *Amgen* improperly relied on its precedent, *In re Sasse*, the Federal Circuit violated § 282 by moving the burden of proving § 112 enablement from TKT to Amgen. The Federal Circuit glossed over this violation with the words "We agree that prior art patents are presumed enabled, but under authority going beyond § 282."<sup>101</sup> However, a finer distinction is required. While this presumption of § 112 enablement applies to the patent claims, the presumption does not apply to unclaimed disclosures.<sup>102</sup> There is no requirement for the examiner to inspect the unclaimed disclosures.<sup>103</sup>

Therefore, the *Amgen* court not only incorrectly moved the presumption of § 112 enablement to the wrong party, the court incorrectly afforded this presumption a broader scope than intended by § 282 without sufficient basis (an inapposite *In re Sasse*).

The Federal Circuit also grounded its decision that Amgen bore the burden of proving the prior art patent's (Sugimoto's) lack of § 112 enablement in policy considerations.<sup>104</sup> Cognizant that conducting mini-trials regarding proper claim construction diminishes a trial court's resources, the Federal Circuit thought it unwise to compel these courts to perform such a task for "a prior art patent every time an allegedly anticipating patent is challenged as lack[ing § 112] enablement."<sup>105</sup>

This policy consideration lacks substance. A trial court will not be required to perform claim construction on all prior art patents because the invalidity by anticipation analysis does not require it. Invalidity by anticipation analysis is a two step process.<sup>106</sup> The first step requires construction of the claims of the patent at issue.<sup>107</sup> The second step requires a "comparison of the properly construed claims to the prior art."<sup>108</sup> Thus, the at-issue patent's claims are construed, not the prior art

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<sup>97</sup> See 35 U.S.C. § 282 ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.").

<sup>98</sup> See MPEP, *supra* note 2, § 2164.08 ("All questions of enablement are evaluated against the claimed subject matter.").

<sup>99</sup> See 35 U.S.C. § 282.

<sup>100</sup> See *id.*

<sup>101</sup> *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003).

<sup>102</sup> See 35 U.S.C. § 282 ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims.").

<sup>103</sup> See MPEP, *supra* note 2, § 2164.08.

<sup>104</sup> *Amgen*, 314 F.3d at 1355 n.21.

<sup>105</sup> *Id.*

<sup>106</sup> *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003).

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

<sup>108</sup> *Id.* There is symmetry between the tests for infringement and invalidity by anticipation. See 1 CHISUM, *supra* note 11, § 3.02(1)(f).

patent's. This becomes clearer when one considers that anticipation involves any prior art reference, not only prior art patents. Generally, a prior art non-patent reference will not entail claims. Considering the aforementioned analysis is the same no matter what the prior art, it makes sense that the prior art patent's claims would not be construed. Thus, the Federal Circuit's conclusion that the courts would be burdened if there was no presumption of § 112 enablement for a prior art patent was improperly based.

### III. PROPOSAL

First, the proposal section discusses cases that have followed or ignored *Amgen*. Second, this section suggests solutions to the problems created by the court in *Amgen*.

*Amgen* held that an accused infringer should be entitled to a presumption of § 112 enablement for the unclaimed material in the prior art patent that the accused infringer asserts against the patent holder.<sup>109</sup> The Federal Circuit's decision was based on a false premise as it afforded a presumption of § 112 enablement to material that had never been examined for enablement. Also, the court violated § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee. Due to this false premise and violation of § 282, the assignment of burden of proof in *Amgen* must be reversed or otherwise treated as dictum.<sup>110</sup> However, if *Amgen* is found to be controlling on that issue, subsequent courts should not extend the § 112 enablement presumption to prior art non-patent printed publications.

Since the decision in *Amgen*, some courts have followed its reasoning, while other courts have disregarded it.<sup>111</sup> *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, which

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A simple example will illustrate the infringement test for anticipation. Assume that A invents and patents the ordinary lead pencil. Later, B invents and seeks a patent on a pencil with an attached eraser. Does A's prior device anticipate B's invention and hence preclude issuance of a valid patent? The classic infringement test requires a determination whether A's device (the pencil) would have infringed B's claim had it been made later in time. That determination *requires construction of B's claims*: does B claim only the improvement (combination of pencil and eraser) or the pencil itself—with or without eraser? If the former, A's device would not infringe and hence does not anticipate. If the latter, A's device would infringe and hence does anticipate.

1 *id.* (emphasis added).

<sup>109</sup> *Amgen*, 314 F.3d at 1355.

<sup>110</sup> Peterson, *supra* note 9, at 505.

In what is almost assuredly dicta in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, the court held, . . . , that "an accused infringer should be similarly entitled [as is the PTO during [patent] . . . prosecution] to have the district court presume the enablement of unclaimed (and claimed) material in a prior art patent defendant asserts against a plaintiff."

*Id.*

<sup>111</sup> *Compare* *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 581 (D.N.J. 2004) ("The patentee bears the burden of presenting evidence to convince the court that the prior art patent did not enable the invention, and thus, that it is not anticipating."), *and* *Alza Corp. v. Mylan Labs., Inc.*, 310 F. Supp. 2d 610, 630 (D. Vt. 2004) (placing the burden on patentee to produce sufficient evidence of nonenablement to overcome the presumption of enablement), *with* *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1151 (Fed. Cir. 2003).

was decided a year and a half after *Amgen*,<sup>112</sup> made no reference to the *Amgen* decision, thereby not even distinguishing *Koito* from *Amgen*.<sup>113</sup> Koito Manufacturing Company (“Koito”) brought a declaratory judgment action against Turn-Key-Tech (“Turn-Key”) “requesting that Turn-Key’s ’268 patent<sup>114</sup> be declared invalid” due to anticipation and lack of enablement.<sup>115</sup> Subsequently, Turn-Key counterclaimed for infringement.<sup>116</sup> The district court upheld the jury’s special verdict that the ’268 patent was invalid. Turn-Key appealed arguing “that Koito did not meet its burden of showing anticipation . . . by clear and convincing evidence.”<sup>117</sup> Koito cross-appealed seeking to invalidate all claims of the ’268 patent.<sup>118</sup> Turn-Key, the patentee, argued that the district court erred because Koito only submitted into evidence the allegedly anticipatory reference, which was an unexamined patent application (“JP ’082”).<sup>119</sup> The Federal Circuit concluded that Koito, the accused infringer, did not meet its burden because Koito failed to present testimony or other evidence demonstrating how the JP ’082 anticipated the ’268 patent or how the JP ’082 reference was § 112 enabled.<sup>120</sup> Thus, Koito had the burden of proving the JP ’082 was § 112 enabled and anticipated the ’268 patent.<sup>121</sup>

*Alza Corporation v. Mylan Laboratories, Inc.* is among the cases that have followed *Amgen*. The district court afforded a presumption of § 112 enablement to the prior art patent.<sup>122</sup> Thus, Alza Corporation, the patentee, bore the burden of proving the prior art patent’s lack of § 112 enablement.<sup>123</sup>

*Novo Nordisk Pharmaceuticals, Inc v. Bio-Technology General Corp.* is a case that originally followed *Amgen* in placing the burden on Novo Nordisk Pharmaceuticals, Inc. (“Novo Nordisk”), the patentee, to prove the prior art reference lacked § 112 enablement.<sup>124</sup> However, due to the subsequent appellate history, the case is now distinguishable. In the Federal Circuit’s interpretation of the district court’s opinion, the district court had not exclusively relied on the presumption in *Amgen* in determining that the Pavlakis 1981 article, a prior art non-patent

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<sup>112</sup> See *Koito*, 381 F.3d at 1142. *Koito* was decided on August 23, 2004. *Id.*

<sup>113</sup> See *id.* (citing no reference to *Amgen*).

<sup>114</sup> *Id.* at 1144. The ’268 patent is U.S. Patent No. 5,045,268. *Id.* at 1145.

<sup>115</sup> *Id.* at 1147. Koito is a manufacturer of taillights that are used by many Japanese automakers. *Id.* at 1147. Koito’s lenses, which are a component of the taillights, are at issue in this case. *Id.* At the time of this action, “Koito alleged that Turn-Key had accused Koito of infringement and already filed suit against some of Koito’s customers.” *Id.* For purposes of this section, anticipation is only being discussed for Koito’s grounds for declaring the ’268 patent invalid. See generally *Koito*, 381 F.3d 1142 (describing case in entirety).

<sup>116</sup> *Id.* at 1147.

<sup>117</sup> *Id.* at 1148.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at 1151. “JP ’082” is the Japanese Unexamined Application No. 148,082. *Id.* at 1145.

<sup>120</sup> See *id.* at 1151.

<sup>121</sup> See *id.* “Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses’ interpretation of the claim element, and explain in detail how each claim is disclosed in the prior art reference.” *Id.* at 1152. “General and conclusory testimony . . . does not suffice as substantial evidence of invalidity.” *Id.*

<sup>122</sup> *Alza Corp. v. Mylan Labs., Inc.*, 310 F. Supp. 2d 610, 630 (D. Vt. 2004).

<sup>123</sup> See *id.*

<sup>124</sup> *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, No. 02-332-SLR, 2004 U.S. Dist. LEXIS 14960, at \*73 (D. Del. Aug. 3, 2004).

publication, was § 112 enabled.<sup>125</sup> The district court had concluded that the Pavlakis 1981 article was § 112 enabled and anticipated the patent because Dr. Pavlakis, using the disclosures from his article, actually physically created the patent's subject matter.<sup>126</sup> Therefore, any presumption that can be inferred in this case is dictum because the finding of Pavlakis 1981 article's § 112 enablement was found on grounds beyond the *Amgen* presumption.

*Amgen*, *Koito*, and *Alza* were patent litigation cases. *Alza* followed *Amgen*, which incorrectly relied on a patent prosecution case for its holding. Accordingly, *Alza* was also based on a false premise, and the court in *Alza* also violated § 282 by moving the burden of proving § 112 enablement from the challenger to the patentee. However, in *Koito*, the party challenging the validity of the patent bore the burden of proving § 112 enablement. Thus, § 282 was not violated. Therefore, *Koito* is the better decision and should be the controlling case.

If *Amgen* is still the controlling case, subsequent courts should not extend the § 112 enablement presumption to prior art printed publications. Considering unclaimed material in a patent is equivalent to material in a printed publication, especially in the respect that neither is required to be scrutinized for § 112 enablement, *Amgen's* decision is based on a false premise. Subsequent courts do not need to expand the error of the Federal Circuit by giving even more material a presumption of § 112 enablement that has never been examined for enablement.

#### IV. CONCLUSION

The decision in *Amgen* has left patent litigants wondering which presumption controls. Is it the presumption of validity of the patentee's patent or the presumption of § 112 enablement of the prior art patent asserted by the accused infringer? Subsequent courts have not been consistent in applying *Amgen's* decision of allowing an accused infringer to be entitled to a presumption of § 112 enablement for both the claimed and unclaimed material in a prior art patent that the accused infringer asserts against the patent holder.<sup>127</sup> This inconsistency crystallizes the question of whether *Amgen's* assignment of the burden of proving § 112 nonenablement to the patent holder is merely dictum or not. The *Amgen* court not only incorrectly moved the presumption of § 112 enablement to the wrong party, the court incorrectly afforded this presumption a broader scope than intended by § 282 without sufficient basis. Therefore, though *Amgen* has been written down, it should not remain unaltered.

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<sup>125</sup> *Novo Nordisk Pharms., Inc. v. Bio-Technology Gen. Corp.*, No. 04-1581, 2005 U.S. App. LEXIS 21518, at \*22 (Fed. Cir. Oct. 5, 2005).

<sup>126</sup> *Id.* at 22-23.

<sup>127</sup> *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003) (regarding the holding in *Amgen*).