



## Deference Overcome: Courts' Invalidation of Patent Claims as Anticipated by Art Considered by the PTO

J. MICHAEL BUCHANAN, PH.D., J.D.\*

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### I. INTRODUCTION

¶1 Courts accord varying degrees of deference to administrative decisions. In the context of patent law, an issued patent is entitled to a statutory presumption of validity that places the burden on the challenger to prove by clear and convincing evidence that the patent's claims are invalid. The presumption of validity is based, at least in part, on the patent examiner's consideration of references, including earlier patents and publications, in determining whether the claimed invention is new.

¶2 To what extent should a court's degree of deference depend on whether the challenger relies on references that were not considered by the Patent Office before it granted the patent? Should the fact that a challenger relies only on references already considered by the patent examiner be held against him? This article is a partial exploration of those questions through analysis of cases in which courts invalidated patent claims based solely on prior art that had already been considered by the examiner.

¶3 To be patented, an invention should be new, useful, and nonobvious.<sup>1</sup> Accordingly, when applying for a patent, the applicant has a duty to disclose to the United States Patent and Trademark Office ("PTO") any information pertinent to these issues.<sup>2</sup> Such information, often referred to as "prior art," may be in many forms, including United States patents and published patent applications, patents and publications from other countries, technical publications, and product brochures.<sup>3</sup> The prior art disclosed by the applicant is considered by the patent examiner, who also conducts her own searches to discover additional prior art pertinent to patentability.<sup>4</sup> The examiner then determines the patentability of the invention, as specifically defined by the patent application's claims,<sup>5</sup> relative to the prior art submitted by the applicant and found in the examiner's own searches. If the patent application is allowed by the examiner and issued as a patent, it is entitled to a presumption of validity<sup>6</sup> that is based, at least in part, on the presumed expertise of the PTO in issuing the patent.<sup>7</sup>

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\* Spring 2005 graduate of Western New England College School of Law and patent attorney at Cantor Colburn LLP. I would like to thank Professors Amy Cohen and William Childs for their guidance and insightful comments. I also thank my wife Alison and daughters Isabelle and Rosemary for their love and encouragement. The opinions herein are those of the author and should not be attributed to Cantor Colburn LLP or its clients.

<sup>1</sup> 35 U.S.C. §§ 101-03 (2000).

<sup>2</sup> The duty of disclosure applies not only to the inventor, but also to her patent agent or attorney, and to anyone else "substantively involved in the preparation or prosecution of the application." 37 C.F.R. § 1.56 (2004).

<sup>3</sup> See, e.g., MANUAL OF PATENT EXAMINING PROCEDURE §§ 901.03 (pending applications), 901.04 (U.S. Patents), 901.05 (Foreign Patent Documents), 901.06 (Nonpatent Publications) (8th ed. 2001, revised 2004).

<sup>4</sup> *Id.* § 904.

<sup>5</sup> "The [patent application] shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 (2000).

<sup>6</sup> "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." 35 U.S.C. § 282 (2000).

One consequence of this presumption is that a party asserting the invalidity of a claim (a “challenger”) carries the full burden of establishing invalidity.<sup>8</sup> A challenger must prove this burden by clear and convincing evidence.<sup>9</sup>

¶4 The presumption of validity applies whether or not the challenger is relying on prior art that was considered by the examiner.<sup>10</sup> Yet, the Court of Appeals for the Federal Circuit (“the Federal Circuit”) has stated that a challenger’s burden of clear and convincing evidence may be more easily carried when relying on prior art that was not considered by the examiner during patent prosecution (“PTO-unconsidered art”).<sup>11</sup> Similarly, the Federal Circuit has stated that the challenger’s burden may be more difficult to carry when relying on prior art that was considered by the examiner (“PTO-considered art”).<sup>12</sup> The question thus arises, do district courts account for the factor of whether the challenger is relying on “PTO-considered art” or “PTO-unconsidered art”? If so, how?

¶5 To begin answering that question, this Paper examines six decisions in which district courts have held patent claims invalid based on PTO-considered art. Specifically, it looks at decisions in which patent claims were held “anticipated” by the PTO-considered art; i.e., decisions in which a court determined that the claimed invention was not new because all of the limitations of the claim were found in a single prior art reference that had been considered by the PTO examiner. These cases at once represent situations in which the PTO arguably should have been accorded the greatest deference, and situations in which that deference was overcome by the challenger. They therefore offer an instructive window on the limits of courts’ deference to the PTO as an expert agency. The cases suggest that when courts have held that patent claims are anticipated by PTO-considered art, deference to the PTO is limited to the use of the clear and convincing evidentiary standard. Since this evidentiary standard applies to all patent challengers, whether relying on PTO-considered or PTO-unconsidered art, challengers successfully alleging anticipation by PTO-considered art thus seem not to have been specifically disadvantaged by their reliance on PTO-considered art.

¶6 The remainder of the Paper is divided into five Parts. Part II describes the origin and limitations of the methodology used to select and analyze particular cases. Part III summarizes the pertinent law relating to the presumption of validity and anticipation, and it briefly considers the PTO’s inter partes patent reexamination process as an administrative analog of patent validity litigation. It ends with a summary of the factors weighing for and against the challenger. Part IV explores a few policy reasons that challengers should not be discouraged from relying on PTO-considered art, including the limited inquiry of patent examination, the PTO’s admission that it issues invalid claims, and the economic efficiency of relying on PTO-considered art to invalidate patent claims. In Part V, the cases are described in terms of how the courts analyzed the issue of anticipation and how they addressed, if at all, the issue of deference to the PTO. Finally, conclusions and opportunities for further research are presented in Part VI.

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<sup>7</sup> Although the presumption of validity reflects the presumed expertise of the PTO, the PTO itself does not regard an examiner’s allowance of an application and the PTO’s subsequent issuance of a patent as tantamount to a PTO judgment that its claims are valid. Rather, the PTO’s own policy manual states that, except for validity determinations necessary to carry out reissue, reexamination, or interference proceedings, “[t]he question of validity or invalidity is otherwise exclusively a matter to be determined by a court.” MANUAL OF PATENT EXAMINING PROCEDURE, *supra* note 3, § 1701.

<sup>8</sup> The validity of a patent is judged claim-by-claim, so a court may invalidate one or more claims of a patent, but it does not, strictly speaking, invalidate the patent itself. 35 U.S.C. § 282 (2000).

<sup>9</sup> See, e.g., *High Concrete Structures, Inc. v. New Enter. Stone And Lime Co.*, 377 F.3d 1379, 1382 (Fed. Cir. 2004); *Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115 (Fed. Cir. 1994); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984), *cert. denied* 469 U.S. 821 (1984).

<sup>10</sup> See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1984).

<sup>11</sup> See, e.g., *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988); *Atlas*, 750 F.2d at 1569 (noting that the use of PTO-unconsidered art may facilitate meeting burden on invalidity); *Am. Hoist*, 725 F.2d at 1350 (explaining why no deference is due to PTO for PTO-unconsidered art).

<sup>12</sup> See, e.g., *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990) (reiterating that meeting the clear and convincing evidence standard is especially difficult when relying on PTO-considered art); *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1359 (Fed. Cir. 1983) (finding that challenger’s burden is less easily carried when relying only on PTO-considered art).

## II. METHODOLOGY

¶7 This work began as a search for cases in which courts had invalidated claims based on PTO-considered art. A statistical analysis by Professors John Allison and Mark Lemley of 299 patent validity decisions from early 1989 through 1996 indicated the existence of such cases.<sup>13</sup> The analysis considered factors including whether claims were ultimately held invalid,<sup>14</sup> whether claims were invalidated as anticipated by prior art,<sup>15</sup> and whether the decision was made on the basis of PTO-considered art, PTO-unconsidered art, or both.<sup>16</sup> The study found that when the validity issue was anticipation by prior art, 40.7% of the decisions held claims invalid.<sup>17</sup> Although it did not separate decisions based on anticipation and obviousness, the study also found that in decisions finding claims anticipated by or obvious over prior art, challengers relied primarily on PTO-unconsidered art and utilized no PTO-considered art in over half of the cases.<sup>18</sup> The type of prior art relied on by challengers appeared to be a marginally significant factor in predicting the outcome of validity decisions. Challengers who relied on PTO-unconsidered art were more likely to obtain an invalidity decision than those who relied on PTO-considered art.<sup>19</sup> The authors characterized this result as “confirm[ing] the conventional wisdom . . . that [PTO-unconsidered art] is a more effective tool for invalidating patents than [PTO-considered] prior art.”<sup>20</sup>

¶8 Professors Allison and Lemley graciously shared their “raw data.” The raw data was offered in the form of a spreadsheet that included case names (although no case citations), associated patent numbers, outcomes (e.g., valid or invalid), issues (e.g., anticipation by prior art), and other factors (e.g., number of PTO-considered and PTO-unconsidered references relied on by challengers). Using this information, it was possible to identify three cases in which courts held claims to be anticipated by PTO-considered art.<sup>21</sup> The three cases identified via the Lemley and Allison study were used to search retrospectively and prospectively,<sup>22</sup> leading to the identification of two more decisions in which claims were held anticipated by PTO-considered art.<sup>23</sup> One additional case<sup>24</sup> was identified with the help of the editors of <http://www.patstats.org>, who graciously provided a list of anticipation decisions in 2003.<sup>25</sup>

¶9 The six cases analyzed thus span 1989 to 2004, but they are based primarily on a study of cases from 1989 to 1996 and do not reflect any systematic effort to identify similar cases from 1997 to 2002. While acknowledging that a comprehensive survey of cases from 1983 (the year the Federal Circuit began issuing decisions) to the present would have been preferable, the author is not aware of any post-1996 decisions of the Federal Circuit or the Supreme Court that affect the validity of the

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<sup>13</sup> John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185 (1998).

<sup>14</sup> *Id.* at 198.

<sup>15</sup> *Id.* at 199.

<sup>16</sup> *Id.* at 201.

<sup>17</sup> *Id.* at 209.

<sup>18</sup> *Id.* at 232-33. In cases where claims were held invalid as anticipated by or obvious over prior art, challengers relied on an average of 2.8 PTO-unconsidered references and 0.9 PTO-considered references. The median number of PTO-considered references relied on by challengers was zero, indicating that in over half of the cases, challengers utilized no PTO-considered references.

<sup>19</sup> *Id.* Statistically speaking, the hypothesis that a court was just as likely to hold a claim anticipated by PTO-considered art as by PTO-unconsidered art could be rejected with 90% confidence, but not 95% confidence.

<sup>20</sup> *Id.*

<sup>21</sup> *Clements Indus., Inc. v. A. Meyers & Sons Corp.*, 712 F. Supp. 317 (S.D.N.Y. 1989), *aff'd*, 899 F.2d 1227, 1990 WL 21272 (Fed. Cir. 1990); *Gen. Elec. Co. v. Hoechst Celanese Corp.*, 740 F. Supp. 305 (D. Del. 1990); *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 711 F. Supp. 759 (D. Del. 1989).

<sup>22</sup> “Retrospective” searching refers to analysis of cases cited within the three cases identified via the Allison and Lemley study. “Prospective” searching refers to analysis of subsequent cases that cite those three cases.

<sup>23</sup> *Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp.*, 86 F. Supp. 2d 433 (D.N.J. 2000), *aff'd sub nom. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.2d 1368 (Fed. Cir. 2001) (rehearing and rehearing en banc denied); *Tyler Refrigeration Corp. v. Kysor Indus. Corp.*, 601 F. Supp. 590, 225 U.S.P.Q. 492 (D. Del. 1985), *aff'd*, 777 F.2d 687, 227 U.S.P.Q. 845 (Fed. Cir. 1985).

<sup>24</sup> *Upsher-Smith Labs., Inc. v. Pan Am. Labs., Inc.*, 2004 U.S. Dist. LEXIS 7274 (D. Minn. 2004).

<sup>25</sup> The editors of <http://www.patstats.org> have also compiled patent statistics for the years 2000 to 2002.

selected cases on the issue of courts' deference to the PTO as a function of whether the allegedly anticipating art was or was not considered by the PTO.<sup>26</sup>

¶10 The term "PTO-considered art" was described above as prior art considered by the PTO during prosecution of a patent application, whether provided by the applicant or discovered in the examiner's own search.<sup>27</sup> PTO-considered art is typically (but not always) listed on the face of an issued patent.<sup>28</sup> The authoritative source for determining whether a reference is PTO-considered art is the PTO file history for the patent, where references submitted by the applicant or discovered by the examiner are listed on standard forms<sup>29</sup> and individually initialed by the examiner as they are considered. Even though not listed on a standard form, a reference is considered PTO-cited art if it is relied on by the examiner in a rejection of claims or otherwise acknowledged by the examiner in the file history. However, it is important to note that a reference need *not* have been cited by the examiner in a rejection of claims to be called PTO-considered art.<sup>30</sup>

### III. REVIEW OF PERTINENT LAW

¶11 This section reviews the law of presumption of validity and anticipation as they relate to a court's deference to the PTO's decision to issue a patent. It also briefly reviews the PTO's inter partes reexamination procedure, which is an administrative analog to a judicial challenge to patent validity. The section concludes with a summary of the reasons that a court may defer to the PTO's decision to issue a patent when deciding the validity of claims that have been challenged as anticipated by PTO-considered art.

#### *A. The Presumption of Validity and the Clear and Convincing Evidence Standard*

¶12 Since 1952, an issued patent has carried a statutory presumption of validity.<sup>31</sup> The only express procedural requirement of the statutory presumption of validity is that the challenger bears the burden of establishing invalidity.<sup>32</sup> The statute specifies no particular evidentiary burden.

¶13 Although the Federal Circuit now imposes a "clear and convincing evidence" standard on the challenger<sup>33</sup> and views that standard as having arisen from the statutory presumption of validity,<sup>34</sup>

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<sup>26</sup> While it might be argued that district courts' deference to the PTO might have been increased by *Dickinson v. Zurko*, 527 U.S. 150 (1999) (holding that the Federal Circuit must review factual findings of the PTO's Board of Patent Appeals and Interferences under the APA standards of review, which are more deferential than the "clearly erroneous" standard previously used), there remains considerable controversy about the breadth of that case's holding. It is not yet clear whether district courts are relying on *Zurko* generally to accord greater deference to all PTO decisions. See the discussion of *Zurko*, *infra*. See 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.06[2], 5-757 (2003) ("A question of interest is whether courts will interpret *Zurko* as requiring that greater deference be accorded to the PTO's fact findings made in the course of allowing an applicant's claims and issuing, reissuing, or confirming on reexamination a patent.")

<sup>27</sup> Although PTO-considered art most commonly originates from the inventor or the examiner, third parties may also submit it at any time during the pendency of an application or the enforceability of a patent. 35 U.S.C. § 301 (2000); 37 C.F.R. § 1.501 (2004).

<sup>28</sup> There are a number of ways in which PTO-considered art may be omitted from the front page of the patent. For example, even though it was listed on a PTO standard form by either the inventor or the examiner, and subsequently initialed by the examiner, the PTO may inadvertently omit it from the front-page listing. It may also have been considered by the PTO because of an obligation to consider art from a parent application, MANUAL OF PATENT EXAMINING PROCEDURE, *supra* note 3, § 609, but not listed on a standard form by either the inventor or the examiner. To the extent that the printing office relies on standard forms to list PTO-considered art, such references may not be listed on the face of the patent.

<sup>29</sup> See, e.g., Form PTO-1449 (listing references submitted by an applicant); Form PTO-892 (listing references discovered in an examiner's search).

<sup>30</sup> In order to avoid this possible confusion, the more succinct nomenclature of Lemley and Allison, which refers to references as "PTO-cited" or "PTO-uncited," has not been used.

<sup>31</sup> "A patent shall be presumed valid." 35 U.S.C. § 282 (2000).

<sup>32</sup> "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.*

<sup>33</sup> See, e.g., *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036 (Fed. Cir. 2001); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1984); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 821 (1984).

<sup>34</sup> *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1258 (Fed. Cir. 2004) ("[T]he presumption of validity and heightened burden of proving invalidity 'are static and in reality different expressions of the same thing—a single hurdle to be cleared.'" (quoting *Am. Hoist*, 725 F.2d at 1360)).

earlier decisions of the Courts of Appeals reveal remarkably varying treatments of the presumption of validity and the proper evidentiary standard to impose on challengers.<sup>35</sup> For example, some cases predating the creation of the Federal Circuit in 1982 treated the presumption of validity as weakened or destroyed when a challenger relied on PTO-unconsidered art.<sup>36</sup> Other cases treated the presumption as having been strengthened when the challenger relied only on art considered by the PTO.<sup>37</sup> With respect to the burden of proof imposed on the challenger, the Supreme Court in 1934 summarized the standard as “convincing evidence of error” and acknowledged that lower courts had used varying descriptions of the burden, including “every reasonable doubt shall be resolved against [challenger]” and “clearest proof perhaps beyond reasonable doubt.”<sup>38</sup> Although a consensus was forming around the “clear and convincing evidence” standard, substantially varying expressions of the evidentiary standard persisted through the 1970s and included “clear and cogent showing,”<sup>39</sup> “substantial evidence,”<sup>40</sup> and “a preponderance of evidence.”<sup>41</sup> In 1980, the Federal Circuit’s predecessor court, the Court of Customs and Patent Appeals, adopted the “clear and convincing evidence” standard.<sup>42</sup> Soon after its creation in 1982, the Federal Circuit also chose to adopt the “clear and convincing” standard.<sup>43</sup> It has since applied that standard consistently.<sup>44</sup>

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It is thus currently well established that a challenger always bears the evidentiary burden of proving invalidity and that the burden is a constant one of clear and convincing evidence. These burdens faced by a patent challenger do not depend on the type of prior art on which she relied. However, the Federal Circuit has indicated that the challenger’s ability to meet the evidentiary burden

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<sup>35</sup> See generally CHISUM, *supra* note 26, § 5.06[2].

<sup>36</sup> See, e.g., *Mfg. Research Corp. v. Graybar Elec. Co., Inc.*, 679 F.2d 1355, 1360-61 (11th Cir. 1982) (noting presumption of validity “severely weakened” by challenger’s use of PTO-unconsidered art); *Globe Linings, Inc. v. City of Corvallis*, 555 F.2d 727, 729 (9th Cir. 1981) (“Even one prior art reference not considered by the patent office may be sufficient to overcome the presumption.”); *Republic Indus., Inc. v. Schlage Lock Co.*, 592 F.2d 963, 972 (7th Cir. 1979) (stating that the presumption “does not exist against evidence of [PTO-unconsidered art]”); *Futorian Mfg. Corp. v. Dual Mfg. & Eng’g, Inc.*, 528 F.2d 941, 943 (1st Cir. 1976) (applying a weakened presumption of validity); *Foster v. Newport News Shipbuilding & Dry Dock Co.*, 531 F.2d 1243, 1245 (4th Cir. 1975) (finding presumption of validity “at least weakened” by challenger’s use of PTO-unconsidered art); *George A. Rolfes Co.*, 363 F.2d 57, 60 n.4 (8th Cir. 1966) (finding presumption of validity “substantially weakened” by challenger’s use of PTO-unconsidered art).

<sup>37</sup> See, e.g., *Ortho Pharm. Corp. v. Am. Hosp. Supply Corp.*, 534 F.2d 89, 93 (7th Cir. 1976) (“the usual presumption of validity under 35 U.S.C. § 282 is strengthened when the Patent Office specifically considered the prior art which is urged to invalidate the patent by an accused infringer”); *LaSalle St. Press, Inc. v. McCormick & Henderson*, 445 F.2d 84, 93 (7th Cir. 1971) (“The presumption of validity is strengthened where the prior art asserted against validity is no better than that considered and rejected by the Patent Office.”).

<sup>38</sup> *Radio Corp. v. Radio Eng’g Lab.*, 293 U.S. 1, 7-8 (1934).

<sup>39</sup> *Chicago Rawhide Mfg. Co. v. Crane Packing Co.*, 523 F.2d 452 (7th Cir. 1974) (Stevens, J.) (describing as a “clear and cogent showing” the burden imposed on challenger who relies on PTO-considered art).

<sup>40</sup> *Clark Equip. v. Keller*, 570 F.2d 778, 794 (8th Cir. 1978) (upholding district court’s use of “substantial evidence” standard while acknowledging that most Circuits used clear and convincing evidence standard).

<sup>41</sup> *Dickstein v. Seventy Corp.*, 552 F.2d 1294, 1297 (6th Cir. 1975) (applying preponderance standard in finding claims invalid as obvious, thereby reversing district court, which has used “clear and convincing evidence” standard).

<sup>42</sup> *Astra-Sjuco, A.B. v. U.S. Int’l Trade Comm’n*, 629 F.2d 682, 688 (C.C.P.A. 1980).

<sup>43</sup> *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983).

<sup>44</sup> See, e.g., *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1357 (Fed. Cir. 2004); *Apotex, USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036 (Fed. Cir. 2001); *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1070 (Fed. Cir. 1997); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467, (Fed. Cir. 1990); *Am. Hoist, & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360. (Fed. Cir. 1984).

There has been some debate about the origin of the clear and convincing evidence standard. One commentator has argued that it is best thought of as based on the presumption of administrative correctness, rather than the presumption of validity. Charles F. Phipps, *The Presumption of Administrative Correctness: The Proper Basis for the Clear and Convincing Evidence Standard*, 10 FED. CIR. B.J. 143 (2000). The argument has some logical appeal because the statutory basis of the presumption of validity, 35 U.S.C. § 282, allocates the burden of proof but does not mention an evidentiary standard, Phipps, *supra* at 145-46, and because some cases have distinguished the presumption of validity from the presumption of administrative correctness (although the cases, collectively, do not clarify the relationship between the two presumptions), *id.* at 150-51. The weakness of this argument follows from its corollary: the clear and convincing evidence standard should apply only when an underlying fact has been the subject of a PTO finding. *Id.* at 151. Phipps’s conclusion is contrary to Federal Circuit case law holding that the clear and convincing evidence standard always applies to a challenger, even, for example, when a challenger relies on PTO-unconsidered art. In short, Phipps’s argument that the presumption of administrative correctness is the proper basis for the clear and convincing evidence standard is appealing for its logical clarity, but ultimately inconsistent with Federal Circuit case law. Phipps’s response to this acknowledged inconsistency is to suggest that the Federal Circuit should apply a preponderance standard when the presumption of administrative correctness does not attach. *Id.* at 162.

of clear and convincing evidence may be influenced by whether or not the prior art relied on by the challenger was considered by the PTO.<sup>45</sup> For example, the Federal Circuit has repeatedly held that the challenger's burden may be more easily carried by using PTO-unconsidered art.<sup>46</sup> Similarly, the Federal Circuit has stated that a challenger's ability to meet its burden may be particularly difficult when relying only on PTO-considered art.<sup>47</sup> These cases, although providing little guidance on how a district court is supposed to weigh the factor of PTO-considered versus PTO-unconsidered art, expressly permit the factor to be considered.

In addition to the presumption of validity and the evidentiary burden of clear and convincing evidence, the challenger in a jury trial faces the related issue of a jury instruction on the presumption, the evidentiary burden, or both.<sup>48</sup> The content of these instructions and their recitation by the judge may lead a jury to be more reluctant than a judge to find claims invalid. For example, the District Court for the Northern District of California has published model jury instructions for patent cases<sup>49</sup> that include an instruction on burden of proof that reads, in part,

I will now instruct you on the rules you must follow in deciding whether [alleged infringer] has proven that claims [ ] of the [ ] patent are invalid. To prove invalidity of any patent claim, [alleged infringer] must persuade you that it is highly probable that the claim is invalid.<sup>50</sup>

The "highly probable" standard in this jury instruction reflects courts' use of that term to explain the "clear and convincing" standard.<sup>51</sup> It is noteworthy that the committee drafting these model jury instructions could not agree on whether to include a sentence mentioning the presumption of validity within a lengthy jury instruction titled "What a Patent Is and How One Is Obtained."<sup>52</sup> Opponents argued that a validity instruction would be redundant to a burden of proof instruction and potentially confusing given that the presumption of validity merely allocates the burden of proof and is not entitled to evidentiary weight.<sup>53</sup> Proponents pointed to the statutory nature of the provision and argued that an instruction on the presumption explains to jurors why the clear and convincing standard is used.<sup>54</sup> In the end, the controversial sentence mentioning the presumption of validity was included within brackets and accompanied by an explanatory footnote.<sup>55</sup> That this is a contentious

<sup>45</sup> See generally CHISUM, *supra* note 26, § 5.06[2][d].

<sup>46</sup> See, e.g., *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355-56 (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."); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988) ("reliance on [PTO-unconsidered art] when that art is more pertinent than the art considered by the PTO may facilitate meeting the burden of proving invalidity"); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1984) ("prior art not before the PTO may facilitate meeting the challenger's ability to meet the burden of proof on invalidity"); *Am. Hoist*, 725 F.2d at 1360 ("What the production of new prior art or other invalidating evidence not before the PTO does is to eliminate, or at least reduce, the element of deference due the PTO, thereby partially, if not wholly, *discharging* the attacker's burden, but neither shifting nor lightening it or changing the standard of proof." (emphasis in original)).

<sup>47</sup> See, e.g., *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339 (Fed. Cir. 2001) ("When no prior art other than that which was considered by the PTO 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 . . ." (quoting *Am. Hoist*, 725 F.2d at 1359)); *Hewlett-Packard*, 909 F.2d at 1467 (finding challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application"); *Hughes Aircraft Co. v. United States*, 717 F.2d 1351 (Fed. Cir. 1983) (holding that burden is less easily carried when challenger relies only on cited art).

<sup>48</sup> Philippe Signore, *On the Role of Juries in Patent Litigation (Part 1)*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 791, 815 (2001).

<sup>49</sup> MARTIN FLIESLER ET AL., MODEL PATENT JURY INSTRUCTIONS FOR THE NORTHERN DISTRICT OF CALIFORNIA (2004), available at <http://www.cand.uscourts.gov>.

<sup>50</sup> *Id.* at 23.

<sup>51</sup> See *Buldex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988) ("clear and convincing" evidence has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of [the] factual contentions are 'highly probable'" (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

<sup>52</sup> FLIESLER, *supra* note 49, at 1. The model jury instruction reads, in part, "The fact that the PTO grants a patent does not necessarily mean that any invention claimed in the patent, in fact, deserves the protection of a patent. [The patent, when granted by the PTO, is presumed to be valid but its validity can be challenged by others.] A person accused of infringement has the right to argue here in federal court that a claimed invention in the patent is invalid because it does not meet the requirements for a patent." *Id.* at 2 (brackets in original).

<sup>53</sup> *Id.* at 2 n.1.

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

<sup>55</sup> *Id.* at 2.

issue suggests that jury instructions have a significant effect on the ultimate disposition of the case, in addition to the validity presumption and the burden of proof themselves. Perhaps this is because the instructions are delivered by a neutral authority figure—the judge.<sup>56</sup> In other words, jury instructions may be important not just because of their message, but because of the messenger who delivers them. And jury instructions that mention both the presumption of validity and the clear and convincing evidence standard might influence a jury to be more deferential to the PTO than a judge would be in applying the same substantive law.

*B. Should Dickinson v. Zurko Increase District Courts' Deference to the PTO in Validity Challenges?*

¶16 Although the Supreme Court's 1999 decision in *Dickinson v. Zurko*<sup>57</sup> related directly to the issue of courts' deference to PTO findings of fact, there are several reasons to believe that it is unlikely to have significantly increased district courts' deference to PTO decisions to grant patents. In *Zurko*, applicants Mary Zurko et al. had applied for a patent related to computer security. After it was finally rejected by the examiner as obvious in light of prior art,<sup>58</sup> applicants filed an administrative appeal to the PTO's Board of Patent Appeals and Interferences ("the Board"). The Board upheld the examiner's decision to reject the claims as obvious.<sup>59</sup> Applicants appealed directly to the Federal Circuit,<sup>60</sup> which held that the Board's findings of fact on the prior art teachings were "clearly erroneous."<sup>61</sup> Amid controversy over whether the Federal Circuit should review PTO findings of fact under the less strict (more deferential) standard of the Administrative Procedures Act<sup>62</sup> rather than the "clearly erroneous" standard that typically had been used in such cases, the Federal Circuit reheard the case en banc.<sup>63</sup> The Federal Circuit unanimously decided that the stricter "clearly erroneous" standard was warranted and permitted by a provision in the Administrative Procedures Act<sup>64</sup> that did not "limit or repeal additional requirements . . . recognized by law."<sup>65</sup> The Supreme Court reversed, holding that the Federal Circuit, when reviewing fact findings of the PTO, should employ the less strict review standard of the Administrative Procedures Act rather than the "clearly erroneous" standard that had long been used.<sup>66</sup>

¶17 Based solely on the Supreme Court's ruling, there are several reasons to believe it would not lead to greater deference to the PTO by district courts deciding challenges to claim validity. First, the procedural posture in *Zurko* is different from that of a district court deciding a challenge to the validity of issued claims. In *Zurko*, the claims had been *rejected* by an examiner, and their rejection had been administratively appealed to the Board, which affirmed the rejection. Applicants then sought judicial review directly in the Federal Circuit. The Supreme Court accordingly framed the question in *Zurko* as "whether [APA standard of review] § 706 applies when the *Federal Circuit* reviews findings of fact made by the [PTO]."<sup>67</sup> In contrast, district courts decide the validity of claims only after the claims are *allowed* by the PTO and subsequently challenged by an accused infringer. It therefore follows that the decision in *Zurko* does not necessarily extend to *district court* reviews of PTO findings of fact. It is also true that the PTO's decision to allow claims is usually made by the examiner rather

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<sup>56</sup> William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO But Not to the FDA?*, 5 MINN. INTELL. PROP. REV. 155, 172 (2004).

<sup>57</sup> *Dickinson v. Zurko (Zurko III)*, 527 U.S. 150 (1999).

<sup>58</sup> *Id.* at 153.

<sup>59</sup> *Ex parte Zurko*, No. 94-3967 (B.P.A.I. 1995).

<sup>60</sup> Patent statutes provide for two paths of appeal when an applicant is unsatisfied with a ruling of the Board. The first is appeal to the U.S. District Court of the District of Columbia. 35 U.S.C. § 145 (2000). The second is direct appeal to the Federal Circuit. 35 U.S.C. § 141 (2000).

<sup>61</sup> *In re Zurko (Zurko I)*, 111 F.3d 887, 889 (Fed. Cir. 1997).

<sup>62</sup> 5 U.S.C. § 706 (2000).

<sup>63</sup> *In re Zurko (Zurko II)*, 142 F.3d 1447 (Fed. Cir. 1998).

<sup>64</sup> 5 U.S.C. § 559 (2000).

<sup>65</sup> *Zurko II*, 142 F.3d at 1452.

<sup>66</sup> *Dickinson v. Zurko (Zurko III)*, 527 U.S. 150, 165 (1999).

<sup>67</sup> *Id.* at 152 (emphasis added).

than the Board,<sup>68</sup> whereas, to be reviewed directly by the Federal Circuit, a PTO decision to reject claims is always made by the Board.<sup>69</sup> Arguably, federal courts should accord greater deference to the highest administrative appeal board of an agency than to a first-level adjudicator of that agency. A district court therefore should owe less deference to a patent examiner's allowance of claims than the Federal Circuit owes to the Board's affirmance of claim rejection.<sup>70</sup> Moreover, the challenger's burden of clear and convincing evidence in a patent validity dispute may be thought of as already incorporating a high degree of deference to the PTO's fact findings. Even if there were some impact of *Zurko* on district court patent validity decisions, that impact would be no greater than the impact on Federal Circuit review of Board factfinding in the rejection of claims, which was acknowledged by the Supreme Court to be very subtle. The Court noted that the difference between the Federal Circuit's "clearly erroneous" standard and the APA standards of "arbitrary, capricious, [or] an abuse of discretion, or . . . unsupported by substantial evidence" is "so fine that (apart from the present case) we have failed to uncover a single instance in which a reviewing court conceded that use of one standard rather than the other would in fact have produced a different outcome."<sup>71</sup> Finally, the Court stressed the limits of deference by reiterating "the importance of not simply rubber-stamping agency factfinding."<sup>72</sup> For all of the above reasons, it is unlikely that the Supreme Court's decision in *Zurko* would cause a district court to give increased deference to PTO factfinding when deciding the issue of claim validity.

¶18

That *Zurko* does not affect district court determinations of validity is further supported by the Federal Circuit's own post-*Zurko* case law. In *Purdue Pharma L.P. v. Faulding, Inc.*, patentee Purdue sued Faulding for patent infringement, and Faulding asserted the affirmative defense that the disputed claims were invalid.<sup>73</sup> The district court held that the claims at issue were invalid.<sup>74</sup> On appeal, Purdue argued, relying on *Zurko*, that the district court should have deferred to the examiner's finding that the claims were valid.<sup>75</sup> The Federal Circuit rejected that argument, distinguishing Federal Circuit review of a decision of the Board from a district court validity determination and stating that

[t]he Administrative Procedure Act standard of review adopted in *Zurko* . . . has no application here. To be sure, as we have noted, the decision of the Patent and Trademark Office with respect to patentability is accorded deference in district court litigation, deference that takes the form of the presumption of validity that is accorded to issued patents under 35 U.S.C. § 282. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 USPQ 26, 31 (Fed.Cir.1985). The court, however, was not bound by the examiner's finding in the *ex parte* application proceeding that the new claims were supported by the specification, particularly in light of the fact that the court heard extensive evidence on the issue in an adversary hearing, none of which was before the patent examiner.<sup>76</sup>

The Federal Circuit thus strongly rejected the applicability of *Zurko* to district court validity determinations, but, based on the last phrase in the quoted section above, the Court seemed to leave a small opening for a patentee to argue that *Zurko* might be more applicable when a challenger is relying solely on references that were considered by the examiner. On the whole, however, such an argument is unlikely to be successful because of the Federal Circuit's clear statement that the

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<sup>68</sup> The vast majority of decisions to allow claims are made by examiners. Only in a small minority of cases does the Board effectively decide the issue by directing an examiner to allow claims.

<sup>69</sup> A rejection of claims by an examiner must be affirmed by the Board before it can be judicially appealed. *See* 35 U.S.C. §§ 141, 145 (2002).

<sup>70</sup> The Board's position as an administrative appellate arbiter of examiner rejections may be considered one of "those factors which give [an administrative judgment] power to persuade, if lacking power to control." *Skidmore v. Swift*, 323 U.S. 134, 140 (1944).

<sup>71</sup> *Dickinson v. Zurko (Zurko III)*, 527 U.S. 150, 163 (1999).

<sup>72</sup> *Id.* at 162.

<sup>73</sup> *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1322 (Fed. Cir. 2000).

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

<sup>75</sup> *Id.* at 1329.

<sup>76</sup> *Id.*

difference in procedural posture between Federal Circuit review of Board rejections and district court review of examiner allowances is sufficient to preclude the extension of *Zurko* to district court validity decisions.<sup>77</sup>

### C. Law of Anticipation

¶19 A review of the law of anticipation is necessary to understand cases in which a challenger asserts that patent claims are anticipated by PTO-considered prior art. To be granted a U.S. patent, an applicant must show that her invention is new, useful, and nonobvious. The newness or “novelty” requirement is codified in 35 U.S.C. § 102, which lists seven circumstances that would preclude a PTO finding of novelty. Among these circumstances are (1) if the claimed invention was already publicly known or publicly used in the United States before applicant conceived of it;<sup>78</sup> (2) if the claimed invention was already patented or described in a printed publication anywhere in the world before the applicant conceived of it;<sup>79</sup> and (3) if the claimed invention was already patented or described in a printed publication anywhere in the world more than one year before the applicant filed her patent application.<sup>80</sup>

¶20 The first step of an anticipation analysis is to determine the limitations of the disputed claims.<sup>81</sup> This exercise, which is conducted by the district court judge, is referred to as “claim construction.”<sup>82</sup> It focuses on a review of so-called “intrinsic evidence,” which includes the language of the claims themselves, as well the rest of the patent application (usually called the “written description”) and any arguments made by the applicant during prosecution that may affect interpretation of the claim language.<sup>83</sup> Although entitled to less evidentiary weight, the court may also consult so-called “extrinsic evidence,” such as dictionary definitions, to interpret claim terms.<sup>84</sup>

¶21 After the district court construes a disputed claim to determine its limitations, the claim is compared to the allegedly anticipating prior art reference. For a claimed invention to be anticipated by a prior art reference, the prior art reference must teach all the limitations of the claim.<sup>85</sup> In other words, “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.”<sup>86</sup> Courts analyze the all-elements prong of anticipation as a question of fact.<sup>87</sup> Even if one or more claim limitations are not *expressly* taught by the prior art reference, it will still anticipate if those limitations are *inherently* taught by the reference.<sup>88</sup> The concept of an inherently taught limitation is illustrated by *In re Cruciferous Sprout*, where the patentee claimed “A method of preparing a food product rich in glucosinolates, comprising germinating cruciferous seeds, . . . and harvesting sprouts prior to the 2-leaf stage, to

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<sup>77</sup> At least one district court had come to the same conclusion before the Federal Circuit issued its opinion in *Purdue Pharma. See U.S. Filter Corp. v. Ionics, Inc.*, 68 F. Supp. 2d 48, 52 (D. Mass. 1999) (rejecting patentee’s argument that *Zurko* requires a district court to review the PTO’s determination of validity under the APA’s standards of review).

<sup>78</sup> 35 U.S.C. § 102(a) (2002).

<sup>79</sup> *Id.*

<sup>80</sup> 35 U.S.C. § 102(b) (2002).

<sup>81</sup> *See, e.g., Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

<sup>82</sup> *See, e.g., id.*; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384-90 (1996).

<sup>83</sup> *Phillips v. AWH Corp.*, 415 F.3d 1303, 1311-19 (Fed. Cir. 2005) (en banc).

<sup>84</sup> *Id.* at 1317-19.

<sup>85</sup> *See, e.g., Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986).

<sup>86</sup> *See, e.g., Scripps Clinic*, 927 F.2d at 1576.

<sup>87</sup> *See, e.g., Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp.*, 86 F. Supp. 2d 433, 436-37 (D.N.J. 2000) (“Claim anticipation in prior art is a finding of fact.”); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 863 F. Supp. 1165, 1179 (C.D. Cal. 1994), *aff’d in part, rev’d in part*, 91 F.3d 169 (Fed. Cir. 1996) (“Whether a reference discloses each element of the claim is a question of fact.”); *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed. Cir. 1992) (“Identity of invention is a question of fact . . . .”); *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) (“[A]nticipation is a finding of fact, reviewable under the ‘clearly erroneous’ standard.”).

<sup>88</sup> *See, e.g., In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999); *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985).

form a food product comprising a plurality of sprouts.”<sup>89</sup> The patentee conceded that the prior art taught growing and eating sprouts, but argued that the prior art did not teach the limitation of “preparing a food rich in glucosinates.”<sup>90</sup> However, the district court held, and the Federal Circuit affirmed, that the limitation was inherently taught by the prior art, because “the [glucosinate] content . . . of sprouts necessarily . . . existed as long as sprouts themselves, which is certainly more than one year before the date of application at issue here.”<sup>91</sup> In affirming that the claim limitation was inherently taught by the prior art, the Federal Circuit noted that the inherent characteristics of the prior art need not have been recognized by those of ordinary skill in the art.<sup>92</sup> In other words, even though people may not have recognized that the sprouts were rich in glucosinates, that property was inherent in the sprouts themselves. The doctrine of inherency makes intuitive sense and good public policy, because without it someone who discovered a previously unrecognized property of a known composition would be able to patent the known composition and remove it from the public domain.<sup>93</sup> The court in *Cruciferous Sprout* thus concluded, “[w]hile [patentee] may have recognized something quite interesting about those sprouts, it simply has not invented anything new.”<sup>94</sup>

¶22 There is also a procedural aspect of the doctrine of inherency that is relevant to some of the cases discussed below. If, during prosecution of the patent application, the examiner provides a rationale or evidence that a claim limitation is inherently taught by a reference, the burden shifts to the applicant to rebut the assertion of inherency.<sup>95</sup> In contrast, if a claim is allowed by the examiner and later challenged as anticipated by a reference that inherently teaches one or more claim limitations, the inherent teaching is part of what the challenger must prove by clear and convincing evidence. The challenger bears this burden whether or not the examiner even recognized the question of inherency during prosecution. As discussed below, an examiner’s failure to recognize a question of inherent teaching may be an important reason justifying district courts’ apparent lack of deference as they invalidate claims as anticipated by PTO-considered art.

¶23 In addition to teaching, expressly or inherently, all limitations of a disputed claim, a prior art reference must also enable one of ordinary skill in the art to make or use the claimed invention.<sup>96</sup> The question of enablement is “whether one skilled in the art to which the ‘invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought.”<sup>97</sup> In other words, the ability to practice the invention may be derived not only from the teachings of the reference, but also from the general skill level of those who practice the technology to which the invention contributes.

¶24 To summarize the law of anticipation, the three steps in a district court’s analysis of anticipation are construction of the claims to determine their limitations, comparison of the claim limitations with the prior art reference to determine whether all limitations are expressly or inherently taught, and determination of whether the prior art reference enables the claimed invention.

#### *D. Inter Partes Reexamination—An Administrative Procedure Analogous to a Judicial Determination of Validity*

¶25 A challenger seeking a determination that a claim is invalid as anticipated by prior art need not sue or be sued in federal court. There exists an alternative administrative procedure known as “inter

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<sup>89</sup> *Cruciferous Sprout*, 301 F.3d 1343, 1345 (Fed. Cir. 2002).

<sup>90</sup> *Id.* at 1345.

<sup>91</sup> *Id.* at 1350.

<sup>92</sup> *Id.* at 1349.

<sup>93</sup> *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir.1985).

<sup>94</sup> *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1351 (Fed. Cir. 2002).

<sup>95</sup> MANUAL OF PATENT EXAMINING PROCEDURE § 2112 (8th ed., rev. 2 2005).

<sup>96</sup> *See, e.g., Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp.*, 86 F. Supp. 2d 433, 437 (D.N.J. 2000).; *PPG Indus. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

<sup>97</sup> *Bristol-Myers*, 86 F. Supp. 2d at 441 (quoting *In re Sasse*, 629 F.2d 675 (C.C.P.A. 1980)).

partes reexamination.”<sup>98</sup> That procedure expressly permits a challenger to argue to the PTO examiner handling the reexamination that a claim is anticipated by PTO-considered art.<sup>99</sup> This provision raises the following questions. First, how much deference does the PTO accord prior determinations of anticipation by its examiners? Second, is there any reason that a court should accord an examiner’s finding of no anticipation more deference than the PTO accords the same determination in inter partes reexamination? This section briefly outlines the inter partes reexamination procedure and examines how that procedure treats prior examiner findings of no anticipation.

¶26 Since 1981, a patentee has been able to have a patent “reexamined” by a PTO examiner if a substantial new question of patentability based on a prior art patent or publication arises after the patent is issued.<sup>100</sup> For example, a patentee might become aware of a material reference that was not considered by the examiner during prosecution. By having the claims reexamined in view of the new reference, the patentee may be able to blunt any subsequent litigation challenging the validity of the claims as anticipated by the new reference. The reexamination procedure was thus intended to “(i) settle validity disputes more quickly and less expensively than litigation, (ii) allow courts to refer patent validity questions to an agency with expertise in both the patent law and technology, and (iii) reinforce investor confidence in the certainty of patent rights by affording an opportunity to review patents of doubtful validity.”<sup>101</sup> In 1999, Congress created inter partes reexamination, giving third parties a greater, though still limited, opportunity to initiate and participate in reexamination of a patent.<sup>102</sup> A 2002 amendment expanded the procedural rights of third-party initiators of inter partes reexamination.<sup>103</sup> Comparisons of ex parte and inter partes reexaminations<sup>104</sup> and discussions of the advantages and disadvantages to a challenger of reexamination versus litigation<sup>105</sup> have been reviewed elsewhere and are beyond the scope of this paper. The focus here is on the particular issue of how reexamination treats prior art that had been considered by the examiner during prosecution.

¶27 A threshold issue in reexamination is whether there exists a substantial new question of patentability. Whether the reexamination is ex parte or inter partes, the requestor must “point out each substantial new question of patentability based on the cited patents and printed publications,”<sup>106</sup> and the PTO Director must determine within three months “whether a substantial new question of patentability affecting any claim of the patent” is raised by the request.<sup>107</sup>

¶28 Prior to the amendment of the inter partes reexamination statute in 2002, a substantial new question of patentability could not be based on the same statutory ground (e.g., anticipation or obviousness) and the same reference considered by the examiner during prosecution.<sup>108</sup> For example, in *In re Portola Packaging*, some of applicant Bullock’s claims were rejected during prosecution as obvious over the Hunter patent, while others were rejected as obvious over the combined teachings

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<sup>98</sup> 35 U.S.C. §§ 311-18 (2000).

<sup>99</sup> 35 U.S.C. § 303 (2000).

<sup>100</sup> 35 U.S.C. §§ 301-07 (2000).

<sup>101</sup> *In re Portola Packaging, Inc.*, 110 F.3d 786, 789 (Fed. Cir. 1997).

<sup>102</sup> 35 U.S.C. §§ 311-18 (2000).

<sup>103</sup> Pub. L. No. 107-273, 116 Stat. 1758 (2002). *See also, e.g.*, 37 C.F.R. § 1.983 (2004) (providing right of third-party requester to appeal decision of inter partes reexamination to Federal Circuit after unsuccessful administrative appeal to the Board of Patent Appeals and Interferences).

<sup>104</sup> *See, e.g.*, Kenneth L. Cage & Lawrence T. Cullen, *An Overview of Inter Partes Reexamination Procedures*, 85 J. PAT. & TRADEMARK OFF. SOC’Y 931 (2003); Joseph D. Cohen, *What’s Really Happening in Inter Partes Reexamination*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 207 (2005).

<sup>105</sup> *See, e.g.*, Sherry M. Knowles, Thomas E. Vanderbloemen & Charles E. Peeler, *Inter Partes Patent Reexamination in the United States*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 611 (2004); Paul Morgan & Bruce Stoner, *Reexamination vs. Litigation—Making Intelligent Decisions in Challenging Patent Validity*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 441 (2004); Qin Shi, *Reexamination, Opposition, or Litigation?—Legislative Efforts to Create a Post-Grant Patent Quality Control System*, 31 AIPLA Q.J. 433 (2003).

<sup>106</sup> 37 C.F.R. § 1.915(b)(3) (2004).

<sup>107</sup> 35 U.S.C. § 312 (2000).

<sup>108</sup> *In re Portola Packaging, Inc.*, 110 F.3d 786, 788 (Fed. Cir. 1997); *In re Recreative Techs. Corp.*, 83 F.3d 1394, 1396 (Fed. Cir. 1996).

of the Faulstich patent and two other references.<sup>109</sup> Bullock amended his claims, and his patent issued.<sup>110</sup> During reexamination, some claims were rejected as obvious over the combination of the Hunter and Faulstich patents, and the Board affirmed the rejection.<sup>111</sup> Bullock appealed to the Federal Circuit, which reversed, holding that “the rejection based on the same prior art reference and the same statutory ground that was overcome during the original examination was barred during reexamination because the question of patentability raised by that rejection was previously considered by the PTO.”<sup>112</sup> The opinion went on to emphasize the presumption that the earlier examination was conducted properly, stating “[w]hether the earlier examination was correct or not, reexamination of the same claims in light of the same references does not raise a substantial new question of patentability, which is the statutory criterion for reexamination.”<sup>113</sup> Five years later, *Portola Packaging* was overturned by a congressional amendment to section 303, which added the sentence, “The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.”<sup>114</sup> The legislative history of the amendment is brief, saying little more than that the amendment was intended to overturn the “overly strict” limits placed on reexamination by *Portola Packaging*.<sup>115</sup> Congress thus made clear that the examiner’s previous use of the same reference and the same statutory ground of rejection does not preclude a new question of patentability.

¶29 If Congress so limited the PTO’s ability to defer to its own prior determination of patentability, why should a court accord greater deference to an examiner’s determination of patentability by discriminating against a challenger who relies on PTO-considered art? If the basis of a court’s deference is a presumption of administrative regularity, a court should accord no greater deference to an examiner’s decision than the PTO Board does. If, on the other hand, the basis of a court’s deference to the examiner’s decision is grounded in the statutory presumption of validity, Congress may have intended the separate and distinct standards of deference reflected in section 282 (for courts) and section 303 (for the Board). In other words, one can argue that Congress intended courts to accord greater deference to an examiner’s decision to grant a patent than it intended the Board to accord the same decision. From this perspective, one can think of the amendment to section 303 as an incentive encouraging challengers to use inter partes reexamination rather than litigation.

¶30 Ultimately, the best reason not to defer to the PTO’s prior consideration of a reference may not be related to any theory of congressional intent, but may instead be based on the reality that the examination procedure is a limited inquiry with a significant error rate, and something approaching a de novo determination of the factual issues underlying validity is necessary for a just legal determination of validity. These issues are explored below.

#### *E. Summary of Factors for and Against Deference to the PTO*

¶31 One way to summarize the foregoing discussion of law pertinent to the issue of deference is to consider a hypothetical challenger alleging claim anticipation by PTO-considered art and list the factors weighing for and against deference to the PTO’s decision to issue the disputed claims.

¶32 Four main factors weigh in favor of court deference to the PTO determination of patentability. First is the statutory presumption of validity, with its express requirement that the challenger bears the burden of proving invalidity and its court-construed requirement that the standard of proof is one of clear and convincing evidence. Second is the closely related but arguably distinct influence of a jury instruction on the presumption of validity and/or the burden of proof. Although a patentee is not strictly entitled to such a jury instruction, most courts grant them in one form or another, and

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<sup>109</sup> *Portola Packaging*, 110 F.3d at 787.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *Id.* at 788.

<sup>113</sup> *Id.* at 790 (emphasis added).

<sup>114</sup> 35 U.S.C. § 303(a) (2004).

<sup>115</sup> H.R. REP. NO. 107-120 at 1 (2001).

litigators believe that they can have a significant influence on juries.<sup>116</sup> Obviously, the second factor is relevant only in jury trials where the issue is not decided on summary judgment. Third is the presumption of administrative regularity, which applies to the examiner's finding of fact that none of the considered references taught all elements of the claimed invention.<sup>117</sup> At least one commentator's analysis suggests that the presumption of administrative regularity is un rebutted when a challenger relies on PTO-considered art.<sup>118</sup> Fourth is the Federal Circuit's repeated statement that, although a challenger's burden of proof does not change as a function of whether or not the prior art relied on was considered by the PTO, a challenger relying only on PTO-considered art may have greater difficulty discharging that burden than would a challenger relying on PTO-unconsidered art.<sup>119</sup> Of these four factors, only the fourth is unique to challengers relying on PTO-considered art.

¶33

Three main factors limit court deference to the PTO determination of patentability where a challenger asserts anticipation by PTO-considered art. First, a challenger has a statutory entitlement to assert invalidity as a defense to infringement.<sup>120</sup> And a challenger, though not yet sued for infringement, may sue for a declaratory judgment of claim invalidity if it has a reasonable apprehension that it may be sued.<sup>121</sup> Second, the Federal Circuit has held that a district court must consider all references relied on by a challenger, including PTO-considered references.<sup>122</sup> Third, the Federal Circuit's decisions may be interpreted as supporting the proposition that a district court may invalidate claims over PTO-considered art,<sup>123</sup> and the Federal Circuit has implicitly reinforced this proposition by affirming district court decisions doing just that.<sup>124</sup> None of the factors represents a distinct advantage for the challenger relying on PTO-considered art. They merely preserve the possibility, however slim, that such a challenger may prevail on the merits.

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<sup>116</sup> See William G. Childs, *The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO But Not to the FDA?*, 5 MINN. INTELL. PROP. REV. 155, 172 (2004).

<sup>117</sup> Charles F. Phipps, *The Presumption of Administrative Correctness: The Proper Basis for the Clear and Convincing Evidence Standard*, 10 FED. CIR. B.J. 143, 155. Most courts do not expressly account for the presumption of administrative regularity, considering it ancillary to the presumption of validity. It is doubtful that it is a significant and independent factor in the outcome of many patent cases. Even Phipps sees the primary effect of the presumption of administrative regularity as justifying the use of the clear and convincing evidence standard, a standard uniformly imposed on challengers. *But see* Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984), *cert. denied* 469 U.S. 821 (1984) ("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 . . .").

<sup>118</sup> See Phipps, *supra* note 117, at 155. ("[T]he discovery of material evidence that was not considered by the PTO removes the basis for the clear and convincing evidence standard.")

<sup>119</sup> See, e.g., *Ultra-Tex Surfaces Inc. v. Hill Brothers Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000) ("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 . . .") (quoting *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984)); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990) (noting that the challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application"); *Hughes Aircraft Co. v. United States* (Fed. Cir. 1983) (noting that the burden is less easily carried when challenger relies only on cited art).

<sup>120</sup> 35 U.S.C. § 282 (2000).

<sup>121</sup> 28 U.S.C. § 2201 (2000). See also *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002); *BP Chems., Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 977-78 (Fed. Cir. 1993).

<sup>122</sup> *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984).

<sup>123</sup> See, e.g., *Upsher-Smith Corp. v. Optical Radiation Corp.*, 10 U.S.P.Q.2d 1292, 1294 (Fed. Cir. 1989) ("The issue before this court is whether the GPCL brochure and the Fertig article, whether or not considered by the examiner, are sufficiently probative of obviousness to overcome the presumption of validity."); *Surface Tech., Inc. v. U.S. Int'l Trade Comm'n*, 801 F.2d 1336, 1339-40 (Fed. Cir. 1986) ("The fact that the basis for holding the method claims invalid did not include different or additional references is not dispositive. Although the prior art considered by the ALJ was essentially the same as that considered by the examiner, this alone is an insufficient basis for reversing the decision of the Commission."); *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555 (Fed. Cir. 1985) ("The Examiner's decision, on an original or reissue application, is never binding on a court.")

<sup>124</sup> See, e.g., *Upsher-Smith Labs., Inc. v. PamLab, L.L.C.*, 412 F.3d 1319 (Fed. Cir. 2005); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001) (rehearing and rehearing en banc denied 2001); *Clements Indus., Inc. v. A. Meyers & Sons Corp.*, 899 F.2d 1227 (table), 1990 WL 21272 (Fed. Cir. 1990); *Tyler Refrigeration Corp. v. Kysor Indus. Corp.*, 777 F.2d 687 (Fed. Cir. 1985).

#### IV. POLICY CONSIDERATIONS

¶34 When the realities of patent examination are taken into account, the PTO's decision to issue a patent is presently accorded greater deference by courts than it deserves. This statement is based both on aspects of patent examination that tend to allow errors and on evidence of actual errors in the allowance of claims.

¶35 Two characteristics of the patent examination procedure tend to favor improper allowance of claims: the limited time dedicated to examination of each application and incentives for examiners to allow applications rather than to continue rejecting them. A conscientious examination of a patent application initially requires an examiner to read the application,<sup>125</sup> review any prior art submitted by applicant, search for other pertinent prior art, identify the most pertinent prior art, and consider whether any claims should be rejected on grounds including lack of novelty, obviousness, lack of utility, lack of enablement, or indefiniteness.<sup>126</sup> Assuming, as is true for the majority of applications, that this initial examination does not lead to the immediate allowance of all claims, the results of these efforts are then summarized in a first office action, which includes one or more claim rejections and is mailed to applicant.<sup>127</sup> At this point, the applicant has a right to submit claim amendments and/or arguments to overcome the claim rejections.<sup>128</sup> The applicant will often discuss the rejection with the examiner by phone or in person.<sup>129</sup> The examiner then considers the applicant's response and issues either a notice of allowance or another (typically final) office action. Even when a final rejection is issued, the applicant may exercise a limited right to submit additional amendments and/or arguments, and, if the applicant's response is submitted within two months of the date of final rejection, the examiner is required to consider the submission and respond in turn.<sup>130</sup> The total time that examiners actually take to perform these tasks does not appear to have been authoritatively documented, but Lemley<sup>131</sup> reported various estimates of eight hours,<sup>132</sup> sixteen to seventeen hours,<sup>133</sup> and eighteen hours of examination per application.<sup>134</sup> A then-acting Director of the PTO, who might be presumed to have reliable information, told Lemley in 2000 that the average examination time ranged from eight hours to thirty-two hours, depending on the technology involved.<sup>135</sup> No matter which of these estimates one accepts, the time dedicated to examination is small compared to the task at hand.

¶36 The PTO also provides examiners with incentives that provide a bias toward allowing claims rather than continuing to reject them. An examiner's productivity is measured, in part, in units of "disposal counts."<sup>136</sup> A disposal count is accumulated when an examiner issues a first office action on the merits, allows an application, or when the application goes abandoned (e.g., the applicant simply gives up and the pendency clock runs out).<sup>137</sup> No count is accumulated when claims are rejected after the first office action.<sup>138</sup> There is therefore a significant incentive for examiners to allow applications rather than to continue to reject them. Allowance is also favored over rejection by

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<sup>125</sup> At a minimum, an examiner must read the claims. The author's personal experience in four years of chemical patent prosecution suggests that some examiners do not read the entire application, but instead read only the claims.

<sup>126</sup> Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 (2001).

<sup>127</sup> *Id.*

<sup>128</sup> 37 C.F.R. § 1.112 (2004).

<sup>129</sup> Lemley, *supra* note 126, at 1500.

<sup>130</sup> MANUAL OF PATENT EXAMINING PROCEDURE, *supra* note 3, § 714.13.

<sup>131</sup> Lemley, *supra* note 126, at 1500 n.19.

<sup>132</sup> Anonymous, *Patent Nonsense: The Knowledge Monopolies*, THE ECONOMIST, Apr. 8, 2000.

<sup>133</sup> John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314 (2001).

<sup>134</sup> Brenda Sandburg, *Speed Over Substance?*, INTELL. PROP. MAG., Mar. 1999.

<sup>135</sup> Lemley, *supra* note 126, at 1500, n.19.

<sup>136</sup> Thomas, *supra* note 133, at 324.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

examination procedures that require examiners to explain reasons for rejection but not reasons for allowance.<sup>139</sup> Patent Office productivity metrics and examination procedures thus favor allowance over continued rejection.

¶37 That the PTO erroneously grants some claims is admitted by the PTO, reflected in high rates of allowance of applications, and, most importantly, supported by high rates of claim invalidation by courts. The PTO's own review procedures indicate a significant error rate in allowance of claims. A 2002 PTO "Performance and Accountability Report" concluded that 4.2% to 6.6% of issued patents from 1999 to 2002 had at least one claim that would be held invalid if considered by a court.<sup>140</sup>

¶38 Although it is far less direct evidence of erroneously allowed claims, the rate of allowance of patent applications may also be circumstantially relevant. The probability that an application will be allowed has been hotly debated by scholars. Quillen and Webster touched off the debate by asserting that the rate of allowance might be as high as 97%.<sup>141</sup> Subsequent work by Quillen, Webster, and Eichmann applied a different estimation technique and came up with an allowance rate of 85%.<sup>142</sup> Clarke used a different method to estimate an allowance rate of 75%.<sup>143</sup> Other commentators have weighed in in favor of either the later Quillen study<sup>144</sup> or the Clarke study.<sup>145</sup> The debate seems to have focused the disputed range of allowance rates to 75-85%. Any figure in this range is significantly higher than the allowance rates in Europe (60-68%) or Japan (57-65%) as estimated by the original Quillen et al. method.<sup>146</sup> These studies thus suggest that patent examination may be less rigorous in the United States than in Europe or Japan, and that the United States may therefore issue more invalid claims.

¶39 The best evidence of erroneously issued claims is the high rate at which issued claims are found invalid by federal courts. The Allison and Lemley study of 300 patent validity decisions from 1989 to 1996 found that claims were held invalid in 46% of decisions.<sup>147</sup> Statistics compiled by the editors of <http://www.patstats.org> for each of the years from 2000 to 2003 indicate that the rate at which claims were held invalid bounced from 53% to 29% to 41% to 58% in those years.<sup>148</sup> So, in rough aggregate, nearly half of all court decisions on validity hold claims invalid. These figures are viewed by some as scandalous,<sup>149</sup> and by others as simply representative of a rational economic choice to conduct a limited review during examination of hundreds of thousands of applications and a more thorough review of the relatively small percentage of patents that are disputed in litigation.<sup>150</sup> In

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<sup>139</sup> *Id.* at 324-25.

<sup>140</sup> U.S. PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT 18, <http://www.uspto.gov/web/offices/com/annual/2002/1-58.pdf> (last visited Oct. 9, 2004). The statistics are based on random quality reviews of issued patents.

<sup>141</sup> Cecil D. Quillen & Ogden D. Webster, *Continuing Patent Applications and Performance at the U.S. Patent and Trademark Office*, 11 FED. CIR. B.J. 1, 3 (2001-2002) ("The Grant Rate for the PTO in fiscal years 1993-1998, corrected for continuing applications, ranges from 80% to 97%, depending on the extent to which prosecution of abandoned applications was prolonged in continuing applications.").

<sup>142</sup> Cecil D. Quillen, Ogden D. Webster & Richard Eichmann, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office—Extended*, 12 FED. CIR. B.J. 35, 38 (2002).

<sup>143</sup> Robert A. Clarke, *U.S. Continuity Law and Its Impact on the Comparative Patenting Rates of the U.S., Japan, and the European Patent Office*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 335, 335 (2003).

<sup>144</sup> Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 69 n.22 (2004).

<sup>145</sup> Lawrence B. Ebert, *Patent Grant Rates at the United States Patent and Trademark Office*, 4 CHI.-KENT J. INTELL. PROP. 108, 113-14 (2004).

<sup>146</sup> Quillen & Webster, *supra* note 141, at 10-11.

<sup>147</sup> John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998).

<sup>148</sup> University of Houston Law Center, Institute for Intellectual Property & Information Law, <http://www.patstats.org> (last visited Oct. 9, 2004).

<sup>149</sup> See, e.g., Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999) (discussing erroneously issued patents in the context of claims to business methods).

<sup>150</sup> See Mark A. Lemley, *Rational Ignorance*, *supra* note 126. Although Lemley sees limited review of application during examination as rational, he advocates limiting application of the clear and convincing evidence standard to situations in which prior art references and associated arguments were considered by the examiner. *Id.* at 1528-29.

either case, the figures indicate that for a small<sup>151</sup> but economically important subset of patents, courts disagree nearly half the time with the PTO's decision to allow claims.

¶40 The cost of erroneously issued claims is substantial. Lemley estimates that about half the annual cost of patent litigation—about \$1.05 billion—is attributable to validity disputes,<sup>152</sup> and that \$263 million is attributable to validity determinations related to patent licensing independent of litigation (as, for example, when a potential licensee seeks a validity opinion before paying to license a patent).<sup>153</sup> There might be a small but significant reduction in these costs if challengers were able to rely on PTO-considered art without risking being viewed by a court as thereby bearing a burden that is more difficult to carry than that of a challenger relying on PTO-unconsidered art. Specifically, if deference were limited to the imposition on the challenger of the burden of proof by clear and convincing evidence, without regard to the type of art relied on, a challenger who believed PTO-considered art to be sufficient to invalidate the disputed claims would not feel compelled to incur the costs associated with additional searching, analysis, and argument.

## V. ANALYSIS OF CASES INVALIDATING CLAIMS AS ANTICIPATED BY CITED ART

¶41 Following are descriptions and analyses of six cases in which courts have invalidated claims as anticipated by PTO-considered art. Although there is considerable variation in the ways the courts discuss (or do not discuss) deference to the PTO, the cases all include detailed analyses of the validity questions and properly apply the clear and convincing evidence standard imposed on challengers.

### *A. Clements Industries, Inc. v. A. Meyers & Sons Corp.—The Garment Tag Case*

¶42 *Clements Industries*<sup>154</sup> concerned a dispute over so-called “tag pins,” which are familiar to consumers as those annoying little strands of plastic inserted through the fabric of a garment or other textile item to attach a tag with price or product information. Tag pins generally consist of a head portion that is inserted through the fabric, a tail portion that prevents the pin from passing completely through the fabric and also secures the tag with price or product information, and a thin filament that connects the head and tail portions. Tag pins are inserted through the textile article using a gun, which uses a strip of joined tag pins as ammunition. Patentee Clements Industries, Inc. (“Clements”) sued defendant A. Meyers & Sons Corp. (“Meyers”), claiming infringement of multiple claims in Clements’ U.S. Patent No. 4,347,932 to Furutu (“the ’932 Patent”). After a bench trial, the trial court held, *inter alia*, that claim 7 of the ’932 Patent was anticipated by the PTO-considered references U.S. Patent No. 3,765,110 to Olsen (“Olsen”) and British Patent No. 950,402 to Merser (“Merser”).<sup>155</sup> The Federal Circuit summarily affirmed in an unpublished opinion.<sup>156</sup>

¶43 Claim 7 of the ’932 Patent is a so-called multiple dependent claim, which adds a limitation to any of the three broader claims, 1, 5, or 6. All four claims are reproduced below.

1. A tag pin group comprised of a plurality of integrally molded tag pins formed from a synthetic resin and lying in an aligned row, each said tag pin comprising:

a solid head portion, said head portion including a transverse bar-like projection,

said transverse bar-like projection being positioned approximately mid-way of the longitudinal height of said head portion and coinciding with the largest head width, thereby assuring that the head portion maintains its maximum width, and permitting the use of a

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<sup>151</sup> Lemley estimates that 2% of patents are litigated, and that 0.2% reach trial. *Id.* at 1501. So, while it is true that claims are held invalid in roughly half the cases in which they are challenged, the percentage of all patent claims held invalid by courts is very small.

<sup>152</sup> *Id.* at 1502-03.

<sup>153</sup> *Id.* at 1507-08.

<sup>154</sup> *Clements Indus., Inc. v. A. Meyers & Sons Corp.*, 712 F. Supp. 317 (S.D.N.Y. 1989), *aff'd*, 899 F.2d 1227 (Fed. Cir. 1990) (unpublished table decision).

<sup>155</sup> *Id.* at 325.

<sup>156</sup> *Clements Indus., Inc. v. A. Meyers & Sons Corp.*, 899 F.2d 1227 (Fed. Cir. 1990) (unpublished table decision).

relatively thin head portion while preventing deformation of the head portion;  
an elongate transverse bar portion having a uniform cross-section;  
a filament portion interconnecting said head and transverse bar portions to form a tag pin having a generally H-shape;  
a connecting portion extending from said transverse bar portion in a direction away from said filament portion;  
a connecting bar connecting each of said connecting portions of said tag pins, wherein said connecting portion and said connecting bar cooperate to form said tag pin group, said head portion and said transverse bar portion of each tag pin being substantially coplanar and the head and transverse bar portion of each tag pin of said tag pin group lying in substantially parallel planes; and  
said solid head portion further including an edge opposite said transverse bar portion, said edge being formed so as to continuously arcuately slope away from said transverse bar portion as it spreads out from the center of the head portion to its outer periphery, the arcuately sloped edge portion forming an obtuse angle with said filament, thus forming a convex release means facing said transverse bar portion permitting easy removal of a single tag pin or group of tag pins from an intermixed group of tag pins.

5. An assembly of tag pins comprising

a plurality of integrally molded tag pins formed from a synthetic resin and lying in an aligned row, each of said tag pins including a solid head portion, an elongate transverse bar portion having a uniform cross-section, and a filament portion interconnecting said head and transverse bar portions to form a tag pin having a generally H-shape;

a connecting portion extending from the transverse bar portion of each of said tag pins in a direction away from the filament portion thereof;

and a connecting bar connecting each of said connecting portions, wherein said connecting portions and said connecting bar cooperate to form said assembly, said head portion and said transverse bar portion of each tag pin being substantially coplanar and the head and transverse bar portions of each tag pin of said assembly lying in substantially parallel planes;

said head portion being free of attachment to an adjacent head portion and further including an edge opposite said transverse bar portion, said edge being formed to slope away continuously from said transverse bar portion as it spreads out from the center of the head portion to its outer periphery, the sloped edge portion forming an obtuse angle with said filament for forming a release means facing said transverse bar portion permitting easy removal of a single tag pin from the assembly and removal of an assembly of tag pins from an intermixed group of assemblies of tag pins.

6. The assembly of claim 5, wherein said slope of said edge of said head portion is a continuously arcuate slope.

7. The assembly of claims 1, 5 or 6, wherein said filament is flexible.<sup>157</sup>

¶44

The main point of dispute regarding the novelty of claim 7 was whether the prior art tag pins disclosed in Olsen and Merser included flexible filaments.<sup>158</sup> The trial court, in conducting the “all elements” step of anticipation analysis, found that both Olsen and Merser expressly disclosed flexible filaments. The court concluded that “[t]hrough the actual degree of flexibility in these prior art references and in Clements’ filament may differ, these prior art references clearly disclose flexibility as part of their inventions.”<sup>159</sup> Thus, although the examiner considered the Olsen and Merser references, the court’s decision suggests that critical, express teachings of those references were not appreciated.

<sup>157</sup> U.S. Patent No. 4,347,932 (filed Oct. 24, 1979).

<sup>158</sup> *Clements Indus.*, 712 F. Supp. at 325.

<sup>159</sup> *Id.*

¶45 The trial court acknowledged the statutory presumption of validity but found it to be “significantly undercut because the applicant erroneously advised the Patent Examiner that certain prior art did not involve clips but rather, contained only single attachments.”<sup>160</sup> This statement may be criticized as contrary to the Federal Circuit’s holdings that the presumption of validity is constant and neither voided nor weakened by the circumstances of a given case.<sup>161</sup> At the very least, the patentee’s conduct during prosecution is not a pertinent consideration in determining whether the prior art references teach all elements of claim 7. In any case, the Federal Circuit’s affirmation of the judgment suggests that it did not view the district court’s approach as constituting reversible error. Having determined that the claims at issue were invalid, the court did not reach the issue of whether the patents in suit were unenforceable for inequitable conduct by Clements during prosecution of the application leading to the ’932 Patent. Nevertheless, the quoted statement about the presumption of validity, above, suggests that the court’s holding on the validity issue may have been influenced by evidence that Clements may have intentionally misled the examiner about the content of the prior art.<sup>162</sup>

¶46 In sum, *Clements Industries* illustrates a district court critically reexamining PTO-considered references and finding that they anticipated an allowed claim. The court’s opinion suggests that the claims may have been mistakenly allowed because of the applicant’s mischaracterization of the prior art to the examiner. An examiner’s mistaken reliance on an applicant’s characterization of the prior art may therefore be considered one type of PTO error that may be detected and corrected when a challenger argues that claims are invalid as anticipated by PTO-considered art. Although the district court’s decision in *Clements Industries* arguably mischaracterized the presumption of validity as having been undercut by applicant’s misleading description of prior art to the PTO, the Federal Circuit’s summary affirmation of the district court decision suggests that any such mischaracterization did not constitute reversible error.

#### B. *General Electric Co. v. Hoechst Celanese Corp.—The Polymer Blend Case*

¶47 Among the cases considered here, *General Electric*<sup>163</sup> arguably represents the least deference shown by a court to PTO decisions. The claims at issue had been allowed by an examiner, and they were subsequently subjected to reexamination, where they were narrowed to avoid the PTO-considered art. The patentability of the claims was thus considered twice by the PTO, and during the second consideration, the PTO grappled with the same issues and references facing the district court. Nevertheless, the district court, on summary judgment, held the claims invalid as anticipated by the same art that had been considered during reexamination.

¶48 The disputed claims related to blends of two types of polymers (plastics) called polyethylene terephthalate (“PET”) and polybutylene terephthalate (“PBT”). PET is commonly encountered in soft drink bottles, and PBT is used in such applications as computer keyboards. The patent at issue,

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<sup>160</sup> *Id.* at 320.

<sup>161</sup> See, e.g., *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359-60 (Fed. Cir. 1984).

<sup>162</sup> The district court’s statement about the presumption of validity having been undercut by applicant’s erroneous statement to the examiner is not its only questionable application of patent law. Although the court’s decision that claim 1 was invalid was not based on PTO-considered art, it does raise a question about the court’s agility with the law of anticipation. Claim 7 was held anticipated by each of three prior art references, two PTO-considered and one PTO-unconsidered. Since claim 7 depends on and further limits claim 1, it is axiomatic that the anticipating references also taught all the limitations of claim 1 and therefore anticipated claim 1. However, the court did not hold claim 1 anticipated by any reference. Instead, claim 1 was held invalid as obvious, apparently over each of three references, including *Merser*. *Clements Indus.*, 712 F. Supp. at 324. The court apparently used the grounds of obviousness rather than anticipation because, “[a]lthough Clements’ patent describes its transverse bar with language not present in the prior art references, the bars still appear precisely the same as [those in the prior art patents]. They clearly would have been obvious to someone skilled in the art.” *Id.* If the claimed transverse bar was pictured in the prior art references, then that limitation of claim 1 was expressly taught by the references, and an anticipation rejection of claim 1 would have been appropriate. Conversely, if the transverse bar was not expressly taught, then the rejection of claim 1 as obvious raises the question of whether claim 7 should have been held invalid as obvious rather than anticipated.

<sup>163</sup> *Gen. Elec. Co. v. Hoechst Celanese Corp.*, 740 F. Supp. 305 (D. Del. 1990) (invalidating, on summary judgment, claims 1-4 and 38 as anticipated by Kurashiki); *Gen. Elec. Co. v. Hoechst Celanese Corp.*, 698 F. Supp. 1181 (D. Del. 1988) (invalidating, on summary judgment, claims 31-37, 39 and 40 as anticipated by Kurashiki).

U.S. Patent No. 3,953,394 to Fox et al. (“the ’394 Patent”), describes blends of PET and PBT as useful to overcome processing disadvantages associated with the use of either material alone.<sup>164</sup> The blends are also described as having property advantages compared to the individual plastics.<sup>165</sup> PET contains only repeating ethylene terephthalate (“ET”) units, and PBT contains only repeating butylene terephthalate (“BT”) units. The disputed issue in the district court’s first validity determination was whether the PET and PBT in General Electric’s blend reacted to form a hybrid polymer (called “PET/PBT” by the court) that contained both ET and BT repeating units.<sup>166</sup> The prior art considered during reexamination and relied on by challengers taught blends containing PET, PBT, and PET/PBT copolymer.<sup>167</sup> During reexamination, General Electric attempted to limit their claims to blends of PET and PBT that were free of PET/PBT copolymer, thereby distinguishing from the blends of prior art references that appeared to require the presence of the PET/PBT copolymer.<sup>168</sup>

¶49 In a first decision on summary judgment motions, the trial court held that claims 31-37, 39, and 40 of the ’394 Patent were anticipated by each of the PTO-considered prior art references: British Patent No. 1,060,401 issued to inventor Kurashiki (“Kurashiki”) and Belgian Patent No. 747,243 assigned to Fiber Industries (“Fiber”). Kurashiki and Fiber both taught blends of PET, PBT, and the copolymer PET/PBT. Although General Electric had tried to amend all of its claims to exclude PET/PBT and thereby distinguish the references, this effort was unsuccessful for claims 31-37, 39, and 40.<sup>169</sup> These claims encompassed blends of PET, PBT, and the PET/PBT copolymer, and they were therefore anticipated by Kurashiki and Fiber. In essence, the PTO’s decision to issue the amended claims after reexamination was overruled because the examiner had failed to notice that the narrowing amendments during reexamination did not achieve their purpose of excluding the PET/PBT copolymer.

¶50 The second decision on summary judgment related to claims 1-4 and 38, for which General Electric’s amendments during reexamination had successfully excluded the PET/PBT copolymer.<sup>170</sup> The question presented was whether Kurashiki taught compositions containing PET and PBT, but essentially no PET/PBT copolymer.<sup>171</sup> The court answered in the affirmative based on Kurashiki’s specific teaching of blends containing PET, PBT, and a small amount of a compound added to prevent copolymer formation.<sup>172</sup> In essence, the PTO’s decision to issue claims after reexamination was overruled because it had failed to notice a key teaching in Kurashiki.

¶51 The net result of the two summary judgment decisions was that two groups of claims were held anticipated by PTO-considered references. In its summary of the applicable law of anticipation, the court expressly considered the issue of deference to the PTO decision on reexamination:

The Examiner’s determination that the GE patent is valid is evidence of the claims’ validity, but is not binding on the court. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555 (Fed. Cir. 1985). As evidence of validity, the Examiner’s decision increases defendants’ burden on summary judgment. *See Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1359 (Fed. Cir. 1983). Yet defendants’ burden can be met. *See, e.g., Surface Technology, Inc. v. United States International Trade Commission*, 801 F.2d 1366, 1340 (Fed. Cir. 1986) (Claims in a patent may be found invalid even though no prior art more pertinent than that considered by the PTO is presented.); *Tyler Refrigeration*, 777 F.2d at 690 (“The trial court did not err in finding

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<sup>164</sup> U.S. Patent No. 3,953,394, col.1 l.63 to col.2 l.3 (filed Nov. 15, 1971).

<sup>165</sup> *Id.* at col.2 l.4-7.

<sup>166</sup> *Gen. Elec.*, 698 F. Supp. at 1188.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 1183.

<sup>169</sup> Specifically, General Electric amended its claims to substitute the term “comprising,” which allows additional components such as copolymer, with the term “consisting essentially of,” which would exclude the copolymer. However, the term “comprising” occurred twice in the original claims, and the amendment left one of these occurrences intact. The court therefore construed the claim to allow the presence of PET/PBT in the composition. *Id.* at 1188.

<sup>170</sup> *Gen. Elec. Co. v. Hoechst Celanese Corp.*, 740 F. Supp. 305, 313 (D. Del. 1990).

<sup>171</sup> *Id.* at 314.

<sup>172</sup> *Id.*

the patent claims invalid as anticipated by a prior art reference even though the PTO examiner had considered that reference during the prosecution of the patent.”<sup>173</sup>

Although the other cases cited in this excerpt are correctly characterized,<sup>174</sup> the court slightly misstates the proposition from *Hughes Aircraft*. Rather than stating that “the Examiner’s decision increases defendants’ burden on summary judgment,” *Hughes Aircraft* states that the challenger’s “burden is less easily carried when the evidence relied upon consists only of the prior art considered by the examiner.”<sup>175</sup> The distinction between an “increased burden” and an “increased difficulty in carrying a constant burden” is a slim one. In any case, the authorities cited in the above passage collectively support the proposition that the presumption of validity leaves room for a court to invalidate a claim over art considered by the PTO. *General Electric* thus illustrates that a court, while mindful of the deference that should be accorded the PTO, can—even on summary judgment—find that deference overcome by the challenger’s reliance on a PTO-considered reference. *General Electric* is an extraordinary decision because the claims at issue had been examined and reexamined by the PTO before they were challenged in litigation.

¶52 General Electric did not appeal the district court’s decisions, so they were not reviewed by the Federal Circuit.

### C. *Procter & Gamble Co. v. Nabisco Brands, Inc.—The Cookie Case*

¶53 The dispute in *Procter & Gamble*<sup>176</sup> dates from the early days of soft-baked store-bought cookies. It relates to claims to cookies that have both crispy and soft textures, as well as to the cookie dough itself and methods of forming the dough.<sup>177</sup> The district court held on summary judgment that claim 35, relating to “[a] method of making a laminated dough structure,” was anticipated by a published cookie recipe that had been considered by the examiner.<sup>178</sup>

Early in the opinion, the court squarely addressed the issue of deference to the PTO:

P & G’s view that the PTO’s decision to issue the ‘333 Patent must be given controlling weight is mistated [*sic*]. Instead, the Federal Circuit has opined that “the examination procedure and result should be given appropriate consideration and due weight by the [district] court.” *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139, 227 U.S.P.Q. (BNA) 543 (Fed.Cir. 1985). As stated in *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, 225 U.S.P.Q. (BNA) 26 (Fed.Cir. 1985), “the Examiner’s decision, on an original or reissue application, is never binding on a [district] court. It is, however, evidence the [district] court must consider in determining whether the party asserting invalidity has met its statutory burden by clear and convincing evidence.”<sup>179</sup>

Although it correctly noted that the PTO’s decision was not binding, the court did not expressly consider case law suggesting that a challenger’s burden may be more difficult to carry when the challenger relies on PTO-considered art. However, the court’s reasons for not deferring to the examiner’s assessment of the key prior art reference were extensively discussed in the context of its factual determination of whether the reference taught all elements of the disputed claim.

¶54 Disputed claim 35 is reproduced below:<sup>180</sup>

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<sup>173</sup> *Id.* at 312-13.

<sup>174</sup> Note, however, that although *Fromson* supports the proposition that “[t]he Examiner’s determination that the GE patent is valid is evidence of the claims’ validity . . .,” *id.*, that proposition is contradicted by other Federal Circuit cases. *See, e.g.*, *Avia Group Int’l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988) (“the presumption [of validity] is one of law, not fact, and does not constitute ‘evidence’ to be weighed against a challenger’s evidence.”); *SSIH Equip. S.A. v. U.S. Int’l Trade Comm’n*, 718 F.2d 365, 375 (Fed. Cir. 1983) (“The presumption of validity afforded by 35 U.S.C. § 282 does not have independent evidentiary value.”).

<sup>175</sup> *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1359 (Fed. Cir. 1983).

<sup>176</sup> *Procter & Gamble Co. v. Nabisco Brands, Inc.*, 711 F. Supp. 759 (D. Del. 1989).

<sup>177</sup> *See* U.S. Patent No. 4,455,333 (filed Mar. 3, 1981).

<sup>178</sup> *Procter & Gamble*, 711 F. Supp. at 773.

<sup>179</sup> *Id.* at 766.

<sup>180</sup> Though presented as one long sentence in the patent, the claim has been parsed here to facilitate an understanding of the

35. A method for making a laminated dough structure comprising:  
 preparing a first cookie dough from cookie ingredients comprising  
 a crystallization resistant sugar component comprising a mono- or di-saccharide or mixture thereof that crystallizes substantially more slowly than sucrose at the water content and water activity conditions encountered in semi-moist cookies of the home-baked type; and flour and shortening;  
 preparing a second cookie dough comprising  
 a readily crystallizable sugar component comprising a mono- or di-saccharide or moisture thereof which readily and spontaneously crystallizes, at the water content and water activity encountered in semi-moist cookies of the home-baked type, and flour and shortening and  
 applying a layer of said second dough to said first dough, thereby forming a laminated dough structure.<sup>181</sup>

In layman's terms, the method relates to forming two doughs (a first dough that that will form the soft part of the cookie and second dough that will form the crispy part of the cookie), and layering the two doughs. The factual dispute in the case centered on whether the PTO-considered, published recipe for Rigglevake Kucha (Railroad Cookies)<sup>182</sup> necessarily included a first dough that would form the soft part of the cookie. The Railroad Cookie recipe is reproduced below:

RIGGLEVAKE KUCHA (Railroad Cookie)	
Light [crispy] Part:	Dark [soft] part:
4 cups sugar	1 cup sugar, brown
1 egg	1 cup butter
1 cup butter	1 cup molasses
1/2 cup milk	1/2 cup water
2 teaspoons baking powder	2 teaspoons soda
1/2 teaspoon vanilla	1/2 teaspoon vanilla

Enough flour in each part to make dough easy to handle.

Mix the light and dark parts in separate bowls. Blend the sugar and butter for both parts. For the light part beat in the egg then alternately add the milk, vanilla and baking powder sifted with flour. For the dark part add to the butter-sugar mixture the molasses, water and vanilla alternately with enough flour.

Break off pieces of dough from both dark and light parts, shape them into rounds and roll them separately about 1/8 inch thick. Put one on top of the other, roll up like a jelly roll and slice off the pieces as thinly as you can. Place on greased cookie sheets and bake at 350 degrees till done.<sup>183</sup>

In anticipation law terms, the issue was whether the use of molasses in the Railroad Cookie recipe inherently satisfied the claim's requirement for a "crystallization resistant sugar"; that is, whether the use of molasses *necessarily* satisfied the claim's requirement for a crystallization resistant sugar. During prosecution of the application leading to the '333 Patent, Procter & Gamble ("P&G") was aware of the opinion of inventor Hong that the claims would be anticipated by the Railroad Cookie recipe if the molasses used in the recipe contained more than 15% crystallization resistant sugar in the dark dough.<sup>184</sup> Inventor Hong's opinion was relevant because of his duty, as an inventor, to disclose to

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relation between its various clauses.

<sup>181</sup> U.S. Patent No. 4,455,333 (filed Mar. 3, 1981).

<sup>182</sup> EDNA STAEBLER, FOOD THAT REALLY SCHMECKS 193-94 (McGraw-Hill Ryerson Ltd. 1968). The complete recipe is reproduced in footnote 1 of the opinion. *Procter & Gamble*, 711 F. Supp. at 763 n.1.

<sup>183</sup> *Procter & Gamble*, 711 F. Supp. at 763 n.1.

<sup>184</sup> *Id.* at 766.

the PTO any information material to the patentability of the pending claims.<sup>185</sup> P&G, however, did not disclose Hong's opinion to the examiner and instead argued that the variation among molasses products meant that the molasses chosen for use in the recipe might contain less than 15% crystallization resistant sugar.<sup>186</sup> P&G's argument was based on its having searched for and found a single, industrial-grade molasses product that contained less than 15% crystallization resistant sugar.<sup>187</sup> This apparently was enough to convince the examiner that that the Railroad Cookie recipe did not inherently anticipate claim 35. P&G also waited until four days prior to the issuance of the '333 Patent to inform the examiner that one of its employees had used a molasses containing 26.8% crystallization resistant sugar to prepare the recipe because it was "the kind that a homemaker would likely use in baking the Railroad [C]ookies."<sup>188</sup> Because of its late submission, this statement was never considered by the examiner.<sup>189</sup> P&G also failed to disclose to the PTO its own analyses confirming that four different conventional molasses each contained at least 30% crystallization resistant sugar.

¶55 Based on these multiple incidents of lack of candor to the PTO, the court found the statutory presumption of validity to be "less compelling."<sup>190</sup> Strictly speaking, this statement was contrary to Federal Circuit case law, which holds that the presumption of validity can neither be weakened nor strengthened because it is merely a procedural device allocating the burden of proof.<sup>191</sup> However, as noted previously, there is a slim and arguably semantic difference between a weakened presumption, which the Federal Circuit prohibits, and the clear and convincing evidentiary burden being more easily carried by a challenger relying on PTO-unconsidered art, which the Federal Circuit supports.<sup>192</sup> The point is that the examiner could not fully consider the relevance of the recipe as prior art because P&G withheld extrinsic evidence highly relevant to the issue of inherent anticipation. The examiner's decision to allow claim 35 was accordingly entitled to less deference from the court.

¶56 Nevertheless, there still seemed to be a close question of whether a person following the recipe would *necessarily* use a molasses containing at least 15% crystallization resistant sugar. That is the standard for inherent anticipation as applied to this case.<sup>193</sup> Although P&G had established that at least one molasses product contained less than 15% crystallization resistant sugar, the court disposed of the issue by characterizing as an admission the statement of a P&G employee to the PTO that "a homemaker would probably be most likely to use (i.e., Crosby's Fancy Molasses) in baking the Railroad Cookies."<sup>194</sup> On the issue of the crystallization resistant sugar, the court concluded:

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<sup>185</sup> 37 C.F.R. § 1.56 (2004).

<sup>186</sup> *Procter & Gamble*, 711 F. Supp. at 766.

<sup>187</sup> *Id.* at 770 n.10 ("the CrystaFlo Molasses Granules contained only 1.5±0.5% [crystallization resistant sugar]"). The "15% crystallization resistant sugar" is derived from the application's written description, which states, "[p]articularly good crystallization resistant sugars are fructose, dextrose, and mixtures of sugars of which fructose and dextrose together comprise at least about 15% by weight, and solutions thereof." U.S. Patent No. 4,455,333 col.5 l.31-35 (filed Mar. 3, 1981).

<sup>188</sup> *Procter & Gamble*, 711 F. Supp. at 767.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

<sup>191</sup> *See, e.g., Avia Group Int'l, Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988).

<sup>192</sup> *See, e.g., SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1355-56 (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."); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050 (Fed. Cir. 1988) ("reliance on [PTO-unconsidered art] when that art is more pertinent than the art considered by the PTO may facilitate meeting the burden of proving invalidity"); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1573 (Fed. Cir. 1984) ("prior art not before the PTO may facilitate meeting the challenger's ability to meet the burden of proof on invalidity"); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 821 (1984) ("What the production of new prior art or other invalidating evidence not before the PTO does is to eliminate, or at least reduce, the element of deference due the PTO, thereby partially, if not wholly, *discharging* the attacker's burden, but neither shifting nor lightening it or changing the standard of proof.").

<sup>193</sup> *See, e.g., MEHL/Biophile Int'l Corp. v. Milgram*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates."); *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("under principles of inherency, prior art that does not expressly disclose claim limitations anticipates if it necessarily functions in accordance with, or includes, those limitations"); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) ("Under the principles of inherency, if a structure in the prior art necessarily functions in accordance with the limitations of a process or method claim of an application, the claim is anticipated.").

<sup>194</sup> *Procter & Gamble*, 711 F. Supp. at 767.

Because an overwhelming majority of the other molasses brands most likely to be used to follow the Railroad Cookie recipe contain enough invert sugar to fulfill the recitations of claim 35, P & G's argument that the possible availability of industrial grade molasses with an invert sugar content less than 17.5% does not vitiate Nabisco's claim of anticipation. The discovery of the Crysta-Flo Molasses Granules for the purposes of this litigation, therefore, does not produce a genuine dispute about a material fact.<sup>195</sup>

The court thus found that the crystallization resistant sugar limitation of claim 35 was inherently taught by the Railroad Cookie recipe, and that the recipe therefore taught all elements of the claim. The court went on to conclude that claim 35 was anticipated by the recipe.<sup>196</sup>

¶57 *Procter & Gamble* illustrates that even when an examiner considers a prior art reference, her assessment of the relevance of the reference may be insufficient for failure to consider extrinsic evidence that was not presented to the PTO in a timely manner or not revealed until the discovery phase of litigation. The difference in thoroughness between an examiner's consideration of a reference and a court's consideration of the same reference may be particularly large in the context of inherent anticipation.

*D. Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp.—The Anticancer Drug Case*

¶58 *Bristol-Myers Squibb*<sup>197</sup> involved a dispute over a particular method of administering the anticancer drug Taxol. Bristol-Myers Squibb (BMS) sued several other pharmaceutical companies for infringement of two patents on Taxol administration methods. The district court granted defendants' motion for summary judgment, holding claims 1, 2, 5, 6, 8, and 9 of U.S. Patent No. 5,670,537 ("the '537 Patent") invalid as anticipated by a PTO-considered technical article by Kris et al. ("the Kris article") describing a Taxol clinical trial.<sup>198</sup> The Federal Circuit affirmed the judgment as to claims 1, 2, 5, and 8, but vacated and remanded judgment as to claims 6 and 9.<sup>199</sup>

¶59 The district court's discussion of deference-related issues was limited to mentioning the statutory presumption of validity and the clear and convincing evidence standard borne by defendants.<sup>200</sup> Although the Kris article is among fifty-two references listed on the face of the '537 Patent and is therefore presumed to have been considered by the examiner during prosecution, the opinion is conspicuously silent on any errors or deficiencies associated with the examiner's consideration of the reference.

¶60 Claims 1, 2, 5, 6, 8, and 9 of the '537 Patent are reproduced below.<sup>201</sup>

1. A method for treating a patient suffering from a Taxol-sensitive tumor comprising
  - (i) premedicating said patient with a medicament that reduces or eliminates hypersensitivity reactions, and
  - (ii) parenterally administering to said patient about 135-175 mg/m<sup>2</sup> Taxol over about three hours.
  
2. A method for treating a patient suffering from a Taxol-sensitive tumor comprising
  - (i) premedicating said patient with a medicament that reduces or eliminates hypersensitivity reactions; and
  - (ii) parenterally administering to said patient about 135 mg/m<sup>2</sup> Taxol over about three hours.

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<sup>195</sup> *Id.* at 771.

<sup>196</sup> *Id.* at 773.

<sup>197</sup> *Bristol-Myers Squibb Co. v. Boehringer Ingelheim Corp. (Bristol-Myers Squibb I)*, 86 F. Supp. 2d 433 (D.N.J. 2000), *aff'd sub nom. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc. (Bristol-Myers Squibb II)*, 246 F.3d 1368 (Fed. Cir. 2001).

<sup>198</sup> *Bristol-Myers Squibb I*, 86 F. Supp. 2d at 442.

<sup>199</sup> *Bristol-Myers Squibb II*, 246 F.3d at 1381.

<sup>200</sup> *Bristol-Myers Squibb I*, 86 F. Supp. 2d at 436.

<sup>201</sup> U.S. Patent No. 5,670,537, col.15 l.46 to col.16 l.47 (filed Sep. 19, 1996).

5. A method for treating a cancer patient to effect regression of a Taxol-sensitive tumor, said method being associated with reduced hematologic toxicity, said method comprising:

(i) premedicating said patient with a medicament that reduces or eliminates hypersensitivity reactions; and

(ii) parenterally administering to said patient about 135-175 mg/m<sup>2</sup> Taxol over about 3 hours.

6. The method of claim 5 wherein the step of premedicating said patient comprises the administration of a medicament selected from the group consisting of steroids, antihistamines, H<sub>2</sub> receptor antagonists, and combinations thereof.

8. A method for treating a cancer patient to effect regression of a Taxol-sensitive tumor, said method being associated with reduced hematologic toxicity, said method comprising:

(i) premedicating said patient with a medicament that reduces or eliminates hypersensitivity reactions; and

(ii) parenterally administering to said patient about 135 mg/m<sup>2</sup> Taxol over about 3 hours.

9. The method of claim 8 wherein the step of premedicating said patient comprises the administration of a medicament selected from the group consisting of steroids, antihistamines, H<sub>2</sub> receptor antagonists, and combinations thereof.

The claims relate to administration of Taxol to a patient using a particular method and dose, after administering a drug to reduce the adverse side effects known as “hypersensitivity reactions” that sometimes accompany Taxol treatment. In the clinical trial reported in the Kris article, seventeen patients were treated with Taxol, and three of them suffered hypersensitivity effects.<sup>202</sup> The Taxol treatment regimen studied did not include pretreatment to reduce hypersensitivity effects.<sup>203</sup> In view of the hypersensitivity effects and a failure to observe anticancer effects, the Kris article concluded that “further usage of Taxol is not indicated with this drug formulation on this administration schedule.”<sup>204</sup> However, the last paragraph of the article stated that “[f]urther studies are needed to see if pretreatment regimens, alternative schedules, or a reformulated preparation will permit the safe administration of this compound.”<sup>205</sup> The primary questions in the anticipation analysis were whether the Kris article had taught and enabled the pretreatment feature of the disputed claims.

¶61

Before reaching the enablement question, the court construed the claims and determined whether all of their limitations were taught by the Kris article. It found that the Kris article taught administration of Taxol to patients with Taxol-sensitive tumors (two patients in the Kris study suffered from renal cell carcinoma, which was one of the types of Taxol-sensitive tumors taught in the '537 Patent) at the claim 1 prescribed dose and method of administration (in the Kris study, Taxol was administered parenterally for three hours at doses including 135 and 160 mg/m<sup>2</sup>).<sup>206</sup> The court further found that the Kris article’s statement that “[f]urther studies are needed to see if pretreatment regimens . . . will permit the safe administration of this compound” was sufficient to teach the claim 1 limitation of “premedicating patient with a medicament that reduces or eliminates hypersensitivity reactions.”<sup>207</sup> In doing so, the court rejected BMS’s argument that the mere

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<sup>202</sup> *Bristol-Myers Squibb I*, 86 F. Supp. 2d at 438.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 440.

<sup>207</sup> *Id.* at 441.

suggestion to premedicate was not enough,<sup>208</sup> stating that “the ‘tenor’ of the explicit reference is immaterial to an anticipation analysis.”<sup>209</sup>

¶62 The final question for the court was whether the Kris article had enabled the inventions of the disputed claim—that is, “whether one skilled in the art to which the ‘invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought.”<sup>210</sup> In finding that the Kris article had enabled the invention, the court relied primarily on one of BMS’s statements to the PTO during prosecution:

[T]he claimed invention is not drawn to a synergistic combination, but rather to a novel method for administering Taxol to patients that have been pre-treated with *conventional* medication for minimizing hypersensitivity reactions in combination with Taxol infusion over a duration not exceeding 6 hours. . . . It would be understood by one skilled in the art that the administering physician will often administer several such anti-hypersensitivity medications prophylactically prior to the administration of Taxol. *There is a variety of such medications, and their selection and use would be conventional.*<sup>211</sup>

The court treated this statement as an admission by BMS that the Kris article’s suggestion to premedicate, combined with conventional knowledge about the selection and use of pretreatment medication, was enough to enable one skilled in the art to practice BMS’s claimed inventions.

¶63 The district court thus concluded that claims 1, 2, 5, 6, 8, and 9 of the ’537 Patent were anticipated by the Kris article. In doing so, the court found that independent claims 1, 2, 5, and 8 did not materially differ in their limitations.<sup>212</sup> In an analysis that would be criticized by the Federal Circuit, the district court also found that the specific classes of premedication agents recited in claims 6 and 9 did not contribute to the patentability of those claims because the agents fell into the category of “conventional medication for minimizing hypersensitivity reactions” mentioned by BMS during prosecution.<sup>213</sup>

¶64 BMS appealed, arguing, *inter alia*, that the Kris article could not anticipate because (1) as a failed experiment, it did not teach the premedication limitation, (2) it did not enable premedication, notwithstanding BMS’s statements during prosecution, and (3) it did not teach the specific premedication agents of claims 6 and 9.<sup>214</sup> The Federal Circuit rejected the first two arguments but agreed with the third.

¶65 In arguing that the Kris article did not teach the premedication limitation, BMS noted that Kris did not actually administer premedication to reduce the hypersensitivity reaction.<sup>215</sup> The Federal Circuit responded that “anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabling to one of skill in the art.”<sup>216</sup> The Federal Circuit thus upheld the district court’s finding that the Kris article taught the premedication limitation of the disputed claims.

¶66 On the issue of enablement, the Federal Circuit upheld the district court’s ruling, but it relied on different evidence. Whereas the district court had focused on BMS’s admission that selection and use of premedication agents was conventional knowledge of those skilled in the art, the Federal Circuit noted that BMS’s admission “does not necessarily characterize the state of the art more than one year prior to filing,”<sup>217</sup> as required for anticipation under 35 U.S.C. § 102(b). Nevertheless, the Federal

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<sup>208</sup> *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.* (quoting *In re Sasse*, 629 F.2d 675, 681 (C.C.P.A. 1980)).

<sup>211</sup> *Id.* (emphasis added).

<sup>212</sup> *Id.* at 442 (“The patents in suit have been constructed without the stated goals of reducing toxicity levels and tumor regression deemed claim limitations (*see Markman* Opinion).”).

<sup>213</sup> *Id.*

<sup>214</sup> *Bristol-Myers Squibb II*, 246 F.3d at 1377.

<sup>215</sup> *Id.* at 1378.

<sup>216</sup> *Id.* at 1379.

<sup>217</sup> *Id.*

Circuit found that multiple references of record were sufficient to enable the selection and use of premedication agents as of the critical date.<sup>218</sup> Having agreed with the district court's conclusions—if not always its reasoning—on claim construction, identity of invention, and enablement, the Federal Circuit held that the district court did not err in holding claims 1, 2, 5, and 8 anticipated by the Kris article.<sup>219</sup>

¶67 Noting that the Kris article did not teach the specific premedicating agents of claims 6 and 9, the Federal Circuit vacated and remanded the district court's holding that those claims were invalid as anticipated by Kris.<sup>220</sup> It vacated, rather than reversed, because of the possibility that the class of drugs used for premedication was so limited that a reference to the class would effectively disclose the specific agents within the class.<sup>221</sup>

¶68 Although the district court's treatment of claims 6 and 9 was sloppy, *Bristol-Myers Squibb* nevertheless illustrates that an examiner considering over fifty references during examination of a patent application may overlook a critical disclosure in one of those references. It does no disservice to examiners to acknowledge that, compared to the limited inquiry of examination, the much more extensive and adversarial evaluation of validity during litigation is likely to reveal critical and previously unconsidered aspects of references that were nominally considered by the PTO.

*E. Tyler Refrigeration Corp. v. Kysor Industrial Corp.—The Grocery Store Freezer Case*

¶69 *Tyler Refrigeration Corp. v. Kysor Industrial Corp.*<sup>222</sup> involved a dispute between two manufacturers of a type of grocery store freezer case that allows consumer access to frozen products via a freezer's open front face. Tyler Refrigeration Corporation ("Tyler") sued Kysor Industrial Corporation ("Kysor") for infringement of three patents, and Kysor asserted the defense of claim invalidity and also counterclaimed Tyler's infringement of Kysor's own patent. After a bench trial, the district court held, *inter alia*, that the disputed claims of Tyler's patents were anticipated by Kysor's patent. The Federal Circuit affirmed.

¶70 Whether Tyler's claims were anticipated by Kysor's patent hinged on whether one of Tyler's claimed limitations was inherent in Kysor's patented design. Tyler had convinced the examiner that its claimed feature was not inherent in the prior art, but the district court disagreed. The underlying factual dispute related to air flow in the freezer case. The technical challenge was to keep the food cold without allowing frost build-up in the open freezer case. In other words, it was like trying to make the freezer unit of a home refrigerator-freezer function well even when the freezer door is left open constantly. Tyler solved this problem, in part, by maintaining a flowing curtain of air across the front face of the freezer case during both refrigeration and defrost cycles. This feature was a key limitation of claims in Tyler's patent application.<sup>223</sup> During prosecution of this application, the claims were rejected as anticipated by Kysor's U.S. Patent No. 4,026,121 of Aokage et al. ("Aokage").<sup>224</sup> Tyler overcame the rejection by successfully arguing that the Aokage design did not expressly or

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<sup>218</sup> *Id.*

<sup>219</sup> *Id.* at 1380.

<sup>220</sup> *Id.*

<sup>221</sup> *Id.*

<sup>222</sup> *Tyler Refrigeration Corp. v. Kysor Indus. Corp. (Tyler Refrigeration I)*, 601 F. Supp. 590 (D. Del. 1985), *aff'd* 777 F.2d 687 (Fed. Cir. 1985). Note that *General Electric, Procter & Gamble*, and *Tyler Refrigeration* are all cases from the District of Delaware, but they were heard by different judges. So, there is not a rogue-judge effect at work here. However, there may be a rogue-district effect. A recent study of forum shopping for patent cases suggests that among the ten districts hearing the most patent cases, the District of Delaware and the District of Massachusetts are least likely to hold for patentees. Specifically, although patentees won 58% of all patent suits overall, their win rate was 46% in the District of Delaware and 30% in the District of Massachusetts. See Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 917 (2001). The District of Delaware also has, by far, the highest proportion of patent cases on its civil docket. *Id.* at 903. One might argue that it therefore has the greatest expertise in patent cases and should accordingly be considered an expert district rather than a rogue district.

<sup>223</sup> See, e.g., U.S. Patent No. 4,144,720, claim 1, last cl.

<sup>224</sup> *Tyler Refrigeration I*, 601 F. Supp. at 595 (D. Del. 1985).

inherently maintain an air curtain during the defrost cycle, as required by Tyler's claims.<sup>225</sup> The '654 application subsequently issued as U.S. Patent No. 4,144,720 to Subera et al. ("the '720 Patent").

¶71

In reanalyzing this underlying factual issue, the district court first carefully considered the disclosure of Aokage in light of the testimony of the lead inventor.<sup>226</sup> The court found that Tyler's interpretation of a specific sentence in Aokage as teaching disruption of the air curtain during the defrost cycle was inconsistent with other parts of Aokage<sup>227</sup> and "defie[d] logic" because it would have led to warming of the frozen products.<sup>228</sup> The court summarized that "Tyler's argument that the Aokage patent taught those in the art to destroy the protective air curtain during defrost ignores common sense, distorts logic, and misinterprets the express words of the patent in the light of prior well-known phenomena."<sup>229</sup> The court separately found that maintenance of the air curtain during defrost was inherent in the Aokage design.<sup>230</sup> On the basis of these findings, the court held that the asserted Tyler claims were invalid as anticipated by Aokage.<sup>231</sup> Having held the Tyler claims invalid as anticipated, the court did not reach Kysor's allegation that the Tyler patents were unenforceable for fraud on the PTO.<sup>232</sup>

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The district court did not generally discuss the presumption of validity or deference to the PTO. However, this issue of deference was implicitly addressed by the court's detailed refutation of Tyler's arguments, which had been accepted by the examiner.

In its appeal to the Federal Circuit, Tyler argued that

the district court ignored the presumption of validity which was harder to overcome because the PTO had considered Aokage in its determination of the patentability of the [Tyler] patents, and therefore that the burden of proof may be more difficult to meet. *See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359, 220 U.S.P.Q. 763, 770 (Fed.Cir.), *cert. denied*, 469 U.S. 821, 105 S. Ct. 95, 83 L. Ed. 2d 41 (1984).<sup>233</sup>

The Federal Circuit disagreed, saying that

the district court properly considered all the available evidence on inherency and permissibly determined that Kysor has met its burden of proving anticipation by clear and convincing evidence. The judge took account of the presumption of validity but this is a case in which the court could, as it did, decide differently from the PTO examiner on the basis of the evidence before the court.<sup>234</sup>

At least in this case, therefore, the Federal Circuit seemed to say that a district court's use of the clear and convincing evidence standard constituted sufficient deference to the PTO when a challenger relied on PTO-considered art. Noticeably absent from the Federal Circuit's opinion was any language suggesting that the challenger should have greater difficulty meeting the clear and convincing evidence standard when relying only on PTO-considered art.<sup>235</sup>

#### *F. Upsher-Smith Labs., Inc. v. Pan Am Labs., Inc. —The Vitamin Case*

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<sup>225</sup> *Id.* at 596.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.* at 596-97.

<sup>228</sup> *Id.* at 597.

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.* at 599.

<sup>232</sup> *Id.* at 607.

<sup>233</sup> *Tyler Refrigeration Corp. v. Kysor Indus. Corp. (Tyler Refrigeration II)*, 777 F.2d 687, 690 (Fed. Cir. 1985).

<sup>234</sup> *Id.*

<sup>235</sup> Compare, e.g., *Ultra-Tex Surfaces Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000) ("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 . . ."); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990) (finding challenger's "burden is especially difficult when the prior art was before the PTO examiner during prosecution of the application"); *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1359 (Fed. Cir. 1983) (holding burden is less easily carried when challenger relies only on cited art).

¶73 *Upsher-Smith*<sup>236</sup> involved a dispute over a patented vitamin formulation. Upsher-Smith Laboratories (“Upsher-Smith”) sued Pan American Laboratories for infringing claims of two Upsher-Smith patents. Having earlier held on summary judgment that the disputed claims of the first patent were invalid as anticipated by or obvious over multiple prior art patents that had not been considered by the PTO,<sup>237</sup> the district court held, again on summary judgment, that the disputed claims of the second patent were anticipated by or obvious over the same references,<sup>238</sup> three of which had been considered by the PTO during prosecution. On appeal, the Federal Circuit reached the merits of only one of the anticipation holdings, affirming it.<sup>239</sup>

¶74 The district court acknowledged the presumption of validity and the clear and convincing evidence standard of proof.<sup>240</sup> It did not mention that three of the references relied on by defendants had been considered by the PTO. The Federal Circuit did not mention the presumption of validity, the clear and convincing evidence standard, or consideration of the reference by the PTO.

¶75 Upsher-Smith’s second patent, U.S. Patent No. 6,605,646, contained seven claims directed to vitamin supplement compositions and methods of administering them. Claim 1 is reproduced below.

1. A vitamin or supplement composition adapted for administration to a human, the active components thereof consisting essentially of folic acid, 25 to 1000 micrograms vitamin B<sub>12</sub>, and vitamin B<sub>6</sub>, the composition being essentially free of anti-oxidants.

Thus, the claim 1 composition essentially is limited to having some folic acid, a particular amount of vitamin B<sub>12</sub>, some vitamin B<sub>6</sub>, and no antioxidant. The claim would therefore be anticipated by a prior art composition consisting of folic acid, an amount of vitamin B<sub>6</sub> in the specified range, and vitamin B<sub>12</sub>. An anticipating prior art reference need *not* expressly teach that the composition is “essentially free of anti-oxidants” as long as the relevant prior art compositions do not contain antioxidants. The court found that three PTO-considered references anticipated by teaching combinations of folic acid, vitamin B<sub>12</sub> within the specified range, and vitamin B<sub>6</sub>.<sup>241</sup> Two of the references were silent on the presence of antioxidants, while a third, the “European Patent,”<sup>242</sup> taught that antioxidants were optional.<sup>243</sup> Thus, each of the references inherently taught compositions that were essentially free of antioxidants. The references also taught the limitations of dependent claims 2-6.

¶76 The court’s analysis of the anticipation of claim 1 was about as simple as one is likely to find in a litigated patent dispute. The key question, therefore, is why were these claims allowed? The PTO file history does not provide a clear answer. The file history indicates that the claims were allowed without any rejection after the applicant filed a so-called terminal disclaimer to disclaim any term of the second patent that would extend beyond that of the first patent.<sup>244</sup> Soon after the terminal disclaimer was filed, a notice of allowability followed. It included the examiner’s “reasons for allowance,” which stated, in part,

The Terminal Disclaimer filed November 1, 2002 has been entered. An obviousness-type double patenting rejection over US Patent 5,932,624 is not made.

The prior art references filed November 1, 2002 have been considered. The references alone or in combination form do not teach nor suggest the invention as instantly claimed.

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<sup>236</sup> *Upsher-Smith Labs., Inc. v. Pan Am. Labs., Inc. (Upsher-Smith II)*, 2004 U.S. Dist. LEXIS 7274 (D. Minn. 2004); *aff’d sub nom. Upsher-Smith Labs., Inc. v. PamLab, L.L.C.*, 412 F.3d 1319 (Fed. Cir. 2005).

<sup>237</sup> *Upsher-Smith Labs., Inc. v. Pan Am. Labs., Inc. (Upsher-Smith I)*, 2003 U.S. Dist. LEXIS 22980 (D. Minn. 2004).

<sup>238</sup> *Upsher-Smith II*, 2004 U.S. Dist. LEXIS 7274 at \*7-8 (D. Minn. 2004).

<sup>239</sup> *Upsher-Smith Labs., Inc. v. PamLab, L.L.C. (Upsher-Smith III)*, 412 F.3d 1319, 1323-24 (Fed. Cir. 2005).

<sup>240</sup> *Upsher-Smith II* at \*6.

<sup>241</sup> *Id.* at \*7-8.

<sup>242</sup> European Patent No. 595,005 A1 (published May 4, 1994).

<sup>243</sup> *Id.*

<sup>244</sup> U.S. Patent & Trademark Office File History for U.S. Patent No. 6,605,646 to Herbert, paper no. 4.

Accordingly the claims are deemed patentable therefrom.<sup>245</sup>

In any case, the examiner clearly stated that she had considered all the references submitted by applicants, which included the three references that were later held by the district court to anticipate claim 1.

¶77 Upsher-Smith appealed both summary judgment holdings, and the Federal Circuit reviewed them without deference. With respect to anticipation of the second Upsher-Smith patent by three references considered by the PTO, the Federal Circuit only reached the merits of anticipation by the European Patent, affirming that holding.<sup>246</sup> The unanimous Federal Circuit panel held that “the district court properly found that a prior art composition that ‘optionally includes’ an ingredient anticipates a claim for the same composition that expressly excludes that ingredient . . . .”<sup>247</sup> Citing the well-established rule that a product “which would literally infringe if later in time anticipates if earlier,” the court noted that a vitamin composition prepared according to the prior art reference and containing only vitamin B<sub>12</sub>, folate, and vitamin B<sub>6</sub> would infringe the claims at issue.<sup>248</sup> While acknowledging the scientific value of the Upsher-Smith inventor’s discovery that adding antioxidants destroys some vitamin B<sub>12</sub> and folate, the court held that the discovery did not entitle Upsher-Smith to remove a known vitamin composition from the public domain.<sup>249</sup> In its analysis, the Federal Circuit never mentioned the presumption of validity, the clear and convincing evidence standard, or the fact that the European Patent had been considered by the PTO.

¶78 *Upsher-Smith* thus appears to be a case in which the examiner either failed to adequately consider the teachings of the references of record or improperly believed that for the prior art references to anticipate, they needed to *expressly* teach the limitation that “the composition [is] essentially free of anti-oxidants.” The case offers another illustration that a district court’s analysis of inherent anticipation may be significantly more thorough and rigorous than that of the PTO.

## VI. CONCLUSIONS

¶79 Like any other party asserting invalidity of an opponent’s patent claims in litigation, a challenger asserting anticipation by PTO-considered art bears the burden of proving, by clear and convincing evidence, that the claims are invalid. In various cases, the Federal Circuit has stated or implied that the challenger’s burden may be more difficult to carry when the art relied on had been considered by the PTO. It is not clear, as a practical matter, how a district court would implement this suggestion against a challenger. The six cases discussed above indicate that when some district courts have held claims anticipated by PTO-considered art, they apply the clear and convincing evidence standard and find that it has been met, without imposing a detectable penalty against challengers based on their reliance on PTO-considered art. In four of these cases, the Federal Circuit affirmed most or all of the district courts’s holdings of anticipation.

¶80 Four key differences between patent examination and litigation justify the approach of the district courts in these cases. First, patent examination is an *ex parte* proceeding, whereas litigation is an adversarial proceeding giving the challenger a voice in the determination of validity. This difference is particularly important when a patent applicant incompletely or incorrectly characterizes the teachings of a key prior art reference during patent prosecution. Second, patent examination is a limited inquiry, requiring examiners to make judgments about many aspects of patentability for many claims in roughly twenty hours per application. In contrast, courts and litigants can devote considerably more time and resources to a focused determination of a much smaller number of key patentability issues. Third, patent examiners’ productivity is measured, in part, by a metric that gives

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<sup>245</sup> *Id.* at paper 5, 2.

<sup>246</sup> *Upsher-Smith III* at 1323-24.

<sup>247</sup> *Id.* at 1320-21.

<sup>248</sup> *Id.* at 1322.

<sup>249</sup> *Id.* at 1323.

them credit for a first rejection but not for any subsequent rejections. There is therefore an incentive for examiners to allow claims rather than repeatedly rejecting them. There is no such bias in litigation. Fourth, courts usually consider evidence that was not before the examiner. For example, courts often hear evidence about a reference's inherent teachings that was not before the examiner. A court's determination of claim validity is therefore more thorough than that of an examiner. In short, the PTO's consideration of a reference during prosecution may be a poor substitute for a court's consideration of the same reference in litigation. A challenger should therefore not be specifically penalized for relying on references that were considered by the PTO. Sufficient deference to the PTO's decision to allow claims is provided by the requirement that the challenger prove invalidity by clear and convincing evidence.

¶81

**Opportunities for further research.** The conclusions of this study would be strengthened if they were supported by a truly comprehensive survey of cases in which district courts found claims anticipated by PTO-considered art. Likewise, the contrasts drawn between examination and litigation would be sharper if supported by a critical analysis of the actual PTO prosecution file histories for all of the cases. In addressing the question of whether courts specifically penalize challengers for relying on PTO-considered art, this Article looked only at cases on one side of the ledger: cases where challengers relying on PTO-considered art prevailed. It would thus be interesting to survey the cases in which courts ultimately ruled against challengers alleging anticipation by PTO-considered art. In particular, it would be instructive to review cases in which district courts found claims anticipated by PTO-considered art and the Federal Circuit reversed.