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## An Efficient Way to Improve Patent Quality for Plant Varieties

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## N O R T H W E S T E R N JOURNAL OF TECHNOLOGY AND INTELLECTUAL PROPERTY

# An Efficient Way to Improve Patent Quality for Plant Varieties

Katherine E. White

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## An Efficient Way to Improve Patent Quality for Plant Varieties

**By Katherine E. White<sup>\*</sup>** 

I.	INTRODUCTION	.79
II.	PLANT VARIETY PROTECTION OFFICE AND PVPO DATABASES	.83
III.	HOW UTILITY PATENTS AND PLANT VARIETY PROTECTION DIFFER, AND	
	WHY ONE WOULD BE PREFERABLE	.84
IV.	RELAXATION OF THE ENABLEMENT AND PUBLIC ACCESSIBILITY	
	REQUIREMENTS PERMITTING GREATER ACCESS TO PRIOR ART	.87
V.	CONCLUSION	.91

### I. INTRODUCTION

A fundamental quality of patenting an invention is that the exclusive rights granted are given only to new and nonobvious inventions, different enough from the current state of art, called prior art, to be considered unique.<sup>1</sup> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."<sup>2</sup> The scope of protection should strike a balance between granting adequate patent rights and preserving the public's ownership in the

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The Supreme Court has articulated when it is appropriate to grant patents:

Article I, § 8, cl. 8, of the Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the "Progress of Science and useful Arts."

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 147 (1989). (Novelty and nonobviousness were not part of the original patent statutes. Originally, a Board made up of the Secretary of State, the Attorney General, and the Secretary of War, had jurisdiction to grant patents. Patent Act, April 10, 1790, c.7, 1 Stat. 109. In 1793, the Act was amended so that an applicant upon following formal application requirements and paying a fee would automatically obtain a patent. Patent Act of 1793, February 21, 1793, c.11, 1 Stat. 318. Unsatisfied with granting patents without examination, Congress created the Patent Office charged with examining applications with the power to reject unworthy applications. Patent Act of 1836, July 4, 1836, c. 357, 5 Stat. 117.)

<sup>&</sup>lt;sup>2</sup> Brenner v. Manson, 383 U.S. 519, 534 (1966).

[2004]

public domain or the prior art. Detrimental to the innovative process, however, is that the Patent and Trademark Office ("PTO") sometimes grants patents that "remove existent knowledge from the public domain, or restrict free access to materials already available."<sup>3</sup> Such acts can irreversibly stifle advances in science and research.

In recent years, the PTO has been criticized for granting overly broad or defective patents on inventions that are not new and are obvious in light of the prior art.<sup>4</sup> Granting overly broad or defective patents in naturally occurring substances, like agricultural biotechnology, may create even more exacting consequences than in other disciplines because one cannot design or invent around a plant.<sup>5</sup> Even more troubling is the increased incentive to patent agricultural biotechnology after the Supreme Court's decision in *J.E.M. AG. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*<sup>6</sup> In that case, the Court held that utility patents may be issued for plants.<sup>7</sup> The court further stated that plant patents and plant variety protection are not the exclusive means of protecting new varieties of plants.<sup>8</sup> This noteworthy decision has presumably increased the likelihood that more utility patents will be sought in the future.<sup>9</sup> If utility patents on plants are granted in greater numbers, improvements in the patenting process must be made to prevent the granting of unwarranted monopolies over property that is already in the public domain.

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Several suggestions have been made to improve patent quality. For example, more examiners in specific technical fields could be hired.<sup>10</sup> Examiners could be given more time to examine patent applications.<sup>11</sup> More money could be generated from non-diverted patent fees to improve the examination system.<sup>12</sup> A post-grant open review procedure could be instituted whereby third parties could challenge patents after issuance before the PTO.<sup>13</sup> All of these suggestions are viable, but still may not solve the problem

<sup>6</sup> 534 U.S. 124 (2001).

<sup>7</sup> *Id.* at 144.

<sup>8</sup> *Id.* at 132.

<sup>9</sup> See Mark A. Janis & Jay P. Kesan, U.S. Plant Variety Protection: Sound and Fury. . .?, 39 Hous. L. REV. 727 (2002).

<sup>10</sup> 2002 U.S. PAT. & TRADEMARK OFF. PAT. PUB. ADVISORY COMMITTEE ANN. REP. 7 (2002); A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY, *supra* note 4, at 41 (stating the number of patent examiners has not kept pace with the increased workload before the Patent and Trademark Office). *See Patent Processing Improvements: Before the House Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 108<sup>th</sup> Cong. (2003) (statement of Charles E. Van Horn, American Intellectual Property Law Association), 2003 WL 21718622 (F.D.C.H.) [hereinafter *Patent Processing Improvements*].

<sup>11</sup> A PATENT SYSTEM FOR THE 21<sup>st</sup> CENTURY, *supra* note 4, at 3.

<sup>12</sup> See Patent Processing Improvements, supra note 10; U.S. PAT. & TRADEMARK OFF. PAT. PUB. ADVISORY COMMITTEE ANN. REP. 7-8 (2000).

<sup>&</sup>lt;sup>3</sup> Bonito Boats, 489 U.S. at 147 (quoting <u>Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 6</u> (1966)).

<sup>&</sup>lt;sup>4</sup> A PATENT SYSTEM FOR THE 21<sup>st</sup> CENTURY 2-3, Committee on Intellectual Property Rights in the Knowledge-Based Economy, Board on Science, Technology, and Economic Policy, National Research Council of the National Academies (Stephen A. Merrill et al. eds., 2004). *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 (2001); Jay P. Kesan & Marc Banik, *Patents as Incomplete Contracts: Aligning Incentives for R & D Investment with Incentives to Disclose Prior Art*, 2 WASH. U. J.L. & POL'Y 23, 40 (2000).

<sup>&</sup>lt;sup>5</sup> See A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY 21, *supra* note 4; Jonathan Friedland, *As Two Men Vie* to Sell Yellow Beans, Litigation Sprouts, WALL ST. J., March 20, 2000, at A1; Timothy Pratt, *Patent on* Small Yellow Bean Provokes Cry of Biopiracy, N.Y. TIMES, March 20, 2001, at F5 (reporting patentee received a patent on a bean that peasant farmers in Mexico developed several centuries ago).

<sup>&</sup>lt;sup>13</sup> A PATENT SYSTEM FOR THE 21<sup>st</sup> CENTURY, *supra* note 4, at 5, 78-82; THE FEDERAL TRADE

with respect to examining agriculture-related patent applications. What is also needed to better and more thoroughly examine these applications is improved access to and understanding of prior art and/or prior knowledge.<sup>14</sup>

During patent examination, the most prominent form of prior art the PTO relies upon is United States and foreign patents.<sup>15</sup> Technologies that are newly being patented,

COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY: A REPORT BY THE FEDERAL TRADE COMMISSION OCTOBER 2003 7-8 (2003) (recommending an alternative to challenging patent validity in federal courts to allow an administrative procedure for post-grant review in the PTO).

<sup>14</sup> For a detailed discussion on prior art *see infra* text accompanying note 15.

<sup>15</sup> In order for inventions to be patentable, they must be both novel and nonobvious from the prior art. Section 102 of the Patent Act sets forth the basis for determining novelty. 35 U.S.C. § 102 states:

A person shall be entitled to a patent unless-

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

#### 35 U.S.C. § 102 (2004)

Section 102 encompasses the criteria upon which inventions are compared to the current state of the art to determine whether an application for patent can be properly granted. Subsections 102(a), (b), (e), and (g) are considered "prior art" provisions because they relate to knowledge manifested by essentially public activities. OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1402 (Fed. Cir. 1997). *See* Application of Borst, 345 F.2d 851, 854 (C.C.P.A. 1965) (requiring that what was *known* or *used* must be accessible to the public) (citing Minneapolis-Honeywell Regulator Co. v. Midwestern Instruments, 298 F.2d 36 (7th Cir. 1961), Rem-Cru Titanium, Inc. v. Watson, 152 F. Supp. 282 (D.C.D.C. 1957)). For example, subsections 102(a) and (b) relate to public knowledge or use, or prior patents and printed publications. *Id. In re* Hall, 781 F.2d 897, 899 (Fed. Cir. 1986) (stating that "public accessibility" is the *sine qua non* in determining whether a reference constitutes a "printed publication" bar under section 102(b)) (citing *In re* Bayer, 568 F.2d 1357, 1359 (C.C.P.A. 1978); *In re* Wyer, 655 F.2d 221, 224 (C.C.P.A. 1981)). Subsection 102(e) speaks to prior filed patent applications by others that have become public by published or issued.

like business methods or agriculture biotechnology, do not have prior patents as their prior art foundation. Thus, the most relevant prior art or general knowledge is often found in non-patent literature and electronic formats.<sup>16</sup> One of the most economically efficient ways to improve patent quality in examining agricultural biotechnology patent applications is to utilize the several hundred Plant Variety Protection Office ("PVPO") databases at the United States Department of Agriculture ("USDA"). Even though the PTO has stated its desire to outsource patent searching to relieve the burdens on patent examiners,<sup>17</sup> the PTO is not using one of the federal government's most valuable resources for patent searching in agricultural technology, the PVPO.

¶5

Moreover, in August 2004, the Federal Circuit decided two cases that clarify the scope of prior art available in examining patents: *In re Elsner*,<sup>18</sup> and *In re Klopfenstein*.<sup>19</sup> In *Elsner*, the court held that evidence of a foreign sale, which would not normally be available as prior art, may enable an otherwise non-enabled printed publication disclosing a plant to create a statutory bar to patentability.<sup>20</sup> In *Klopfenstein*, the court stated that a printed publication need not be indexed nor cataloged to qualify as prior art; it need only be briefly publicly accessible to those of ordinary skill in the art.<sup>21</sup> Further, such decisions as to whether a disclosure is a printed publication are to be decided on a case-by-case basis.<sup>22</sup>

¶6

With these advances in expanding the scope of prior art, there is now an opportunity for the PTO to utilize prior art available in the PVPO databases at the Department of Agriculture. The PTO should find a way to use administrative rulemaking procedures or utilize the Presidential Executive Order powers under 35 U.S.C. § 164 to request that the USDA provide technical assistance.<sup>23</sup> Because of cases decided in

The same is true for printed publications and patents under Section 102(b), which must be in some way publicly accessible. In re Hall, 781 F.2d at 900. A single cataloged entry in a library may suffice to satisfy the publicly accessible requirement. Id.

<sup>16</sup> Wynn W. Coggins, Prior Art in the Field of Business Method Patents—When is an Electronic Document a Printed Publication for Prior Art Purposes, Address Before the American Intellectual Property Law Association (Fall 2002), *available at* <u>http://www.uspto.gov/web/menu/pbmethod/aiplafall02paper.htm</u> (last visited November 19, 2004).

<sup>17</sup> See United States Patent and Trademark Office, The 21<sup>st</sup> Century Strategic Plan 13 (2003).

<sup>21</sup> 380 F.3d at 1350.

<sup>23</sup> See 35 U.S.C. § 164 (1994):

The President may by Executive order direct the Secretary of Agriculture, in accordance with the requests of the Director [of the Patent and Trademark Office], for the purpose of carrying into

Subsection (g) addresses prior inventions by others that are either public or will likely become public because they have not been abandoned, suppressed, or concealed. *Id*.

Some 102 subsections, like 102(c) and (d) are considered "loss of right" provisions, rather than what we commonly call "prior art" provisions. *OddzOn Prods.*, 122 F.3d at 1402. Subsection 102(c) precludes those inventors who have abandoned their inventions from obtaining a patent. *Id.* Subsection 102(d) causes an inventor to lose the right to a patent by delaying the filing of a patent application too long after having filed a corresponding patent application in a foreign country. Thus subsections 102(c) and 102(d) are not considered "prior art" provisions. *Id.* 

Subsection 102(f) is the derivation provision that prohibits those who did not invent the subject matter sought to be patented from obtaining a patent. Subsection 102(f) is unique because it applies both to public knowledge and to private communications between the inventor and another that may never become public. *Id.* at 1401-02.

<sup>&</sup>lt;sup>18</sup> 381 F.3d 1125 (Fed. Cir. 2004).

<sup>&</sup>lt;sup>19</sup> 380 F.3d 1345 (Fed. Cir. 2004).

<sup>&</sup>lt;sup>20</sup> 381 F.3d at 1128.

<sup>&</sup>lt;sup>22</sup> Id.

August 2004, which relaxed the enablement and public accessibility requirements for prior art, the climate may be ripe for extensive use of information available in the PVPO databases.<sup>24</sup> It is better to have more information than less when deciding the new boundaries within which to grant a monopoly.

Part I of this article discusses the PVPO and its available databases. Part II articulates the differences between patent and plant variety protection and why both types of intellectual property are sought. Finally, Part III suggests that the enablement and public accessibility requirements for prior art have been relaxed in recent cases allowing greater access to prior art.

### II. PLANT VARIETY PROTECTION OFFICE AND PVPO DATABASES

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The 1930 Plant Patent Act allowed for the first patenting of asexually reproduced cultivars (except tubers).<sup>25</sup> But it was not until 1970 that sexually reproduced plants had *sui generis* intellectual property protection under the Plant Variety Protection Act ("PVPA").<sup>26</sup> Plant Variety Protection ("PVP") is a form of intellectual property created to "encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest."<sup>27</sup>

¶9

The PTO, an arm of the Department of Commerce, manages plant and utility patents.<sup>28</sup> In contrast, the PVPO, an agency within the Agricultural Marketing Service of the USDA, manages the PVPA.<sup>29</sup> The PVPO maintains over two hundred databases constructed from many resources (e.g. national registries, seed catalogs, review boards, etc.) in order to assemble as complete a description for a crop species as is possible so that variety specific comparisons are possible.<sup>30</sup> PVP examiners create, modify, and edit these databases. Because the information in the databases is not guaranteed to be one hundred percent accurate, the databases are not available to the public. In addition, the contents of pending applications, by statute, must be held in confidence, though the databases do reference the source of the information's original location.<sup>31</sup>

¶10

PVP examiners perform comparative searches of an applicant's allegedly new variety using the PVP crop databases in order to determine if an applicant's variety is new and distinct from all the known varieties of that species.<sup>32</sup> These searches are similar

effect the provisions of this title with respect to plants (1) to furnish available information of the Department of Agriculture, (2) to conduct through the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Director officers and employees of the Department.

<sup>&</sup>lt;sup>24</sup> See Appendix, infra, for a list of PVPO Databases .

<sup>&</sup>lt;sup>25</sup> J.E.M. AG Supply, Inc., 534 U.S. at 132.

<sup>&</sup>lt;sup>26</sup> Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970).

<sup>&</sup>lt;sup>27</sup> *Id*.

<sup>&</sup>lt;sup>28</sup> 35 U.S.C. §§ 1, 2, 101 and 161 (1994).

<sup>&</sup>lt;sup>29</sup> 7 U.S.C. § 2321 (1994); 7 C.F.R. § 97.1 (2004).

<sup>&</sup>lt;sup>30</sup> See Appendix.

<sup>&</sup>lt;sup>31</sup> 7 U.S.C. § 2426 (1994). Some information related to pending applications is published in the Plant Variety Protection Office's Official Journal.

<sup>&</sup>lt;sup>32</sup> 7 U.S.C. § 2441 (1994) (setting forth that plant variety protection applications must be examined to determine whether applicant is entitled to plant variety protection under the law). *See also* 7 U.S.C. §

[2004]

to those performed by patent examiners, except they are done using the PVPO's proprietary databases.<sup>33</sup> When discrepancies between an applicant's claims and the information in the database are found, the examiner investigates further using the originating data (e.g. seed catalogs, national registries, etc.) to verify the discrepancy. If the discrepancy is confirmed, the examiner will contact the applicant for a response to explain, clarify, or submit data supporting the applicant's claims.

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Although not currently the practice, the PVPO, if the PTO requested, could provide such comparative searches to the PTO through the PVP examiners.<sup>34</sup> If the PTO provided the PVPO with the description of the variety in which a utility application is sought, the PVPO could search the crop specific database to determine if the variety is distinct from all known varieties in the database. If the PVPO finds that the variety is not new and distinct, the discrepancy can be flagged and the originating data cited. The PVPO would then relay this information to the PTO examiner, who would determine if the information could be used as a prior art rejection. If so, the PTO examiner should reject the relevant claims and request that the patent applicant respond in order to obtain a patent.

Although the PVPO databases alone may not qualify as prior art under 35 U.S.C. § 102,<sup>35</sup> elements within those databases do qualify as prior art. It should be possible for the PTO and the PVPO to coordinate with each other to ensure that fewer overly broad patents are issued by the PTO.<sup>36</sup>

Having the PVPO take another look at the PTO's examination is comparable to the PTO's Quality Assurance Review called a "Second Pair of Eyes."<sup>37</sup> The PTO has defined a "Second Pair of Eyes" as a secondary review of applications for proper claim interpretation to ensure that the closest prior art has been discovered and correctly applied."<sup>38</sup> However, under PVPO review, the "second look" would occur outside the PTO. In fact, the PTO has suggested in its strategic plan that it would like to make improvements in its quality assurance techniques and "expand 'second-pair-of-eyes' review in advanced fields of technology as semiconductors, telecommunications, and biotechnology."<sup>39</sup> Such an improvement could occur if the PTO coordinated prior art searches with the PVPO.

# III. HOW UTILITY PATENTS AND PLANT VARIETY PROTECTION DIFFER, AND WHY ONE WOULD BE PREFERABLE

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As an arm of the Department of Commerce, the PTO issues both utility patents and plant patents. In order to obtain either of these types of patents, the plant must be novel,<sup>40</sup> useful,<sup>41</sup> and nonobvious<sup>42</sup> from the prior art.<sup>43</sup> Inventions eligible for obtaining utility

<sup>2402(</sup>a) (1994) (requiring that a plant variety be new, distinct, uniform, and stable).

<sup>&</sup>lt;sup>33</sup> See Appendix.

<sup>&</sup>lt;sup>34</sup> See 35 U.S.C. § 164 (1994).

<sup>&</sup>lt;sup>35</sup> The PVPO databases are confidential and are not open to the public and might not qualify as prior art under 35 U.S.C. § 102 (1994).

<sup>&</sup>lt;sup>36</sup> See 35 U.S.C. § 164.

<sup>&</sup>lt;sup>37</sup> U.S. Patent and Trademark Office, *supra* note 17, at 11 n.3 (2003).

<sup>&</sup>lt;sup>38</sup> Id.

<sup>&</sup>lt;sup>39</sup> *Id.* at 9.

<sup>&</sup>lt;sup>40</sup> 35 U.S.C. § 102 (1994).

<sup>&</sup>lt;sup>41</sup> 35 U.S.C. § 101 (1994).

patents are machines, processes, articles of manufacture, and compositions of matter.<sup>44</sup> Any utility patents on plants would be eligible as compositions of matter. Utility patents provide the broadest scope of protection to plants, broader than the specific variety developed. When a patent is obtained, there is no exemption for research, breeding, or farmer-saved seeds.<sup>45</sup> A utility patent owner has the right to exclude others from making, using, selling, offering for sale, or importing the invention in the United States.<sup>46</sup> Plant patents confer ownership over a specific asexually propagated plant.<sup>47</sup> There are also no exemptions for research or breeding, but seed propagation and sexual crosses are outside the scope of plant patent rights.<sup>48</sup>

¶15

A Plant Variety Protection Certificate is issued by the Plant Variety Protection Office of the USDA Agricultural Marketing Service.<sup>49</sup> Such certificates are granted on new, distinct, uniform, and stable sexually propagated plants and tubers.<sup>50</sup> Such protection allows the owner to exclude others from "selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom."<sup>51</sup> It is not considered an infringement of the PVP Certificate rights for a farmer to save seed<sup>52</sup> or to use and reproduce the protected variety for plant breeding or other bona fide research.<sup>53</sup>

¶16

Although PVP is more limited in scope than is patent protection, PVP offers certain advantages. First, unlike patent protection, applying for a PVP provides provisional protection. As soon as a PVP application is filed and the fee paid, the seed may be marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited."<sup>54</sup> Under 7 U.S.C. § 2567, upon distributing a protected plant variety with notice, rights attach.<sup>55</sup>

<sup>46</sup> 35 U.S.C. § 154(a)(1) (1994).

<sup>47</sup> 35 U.S.C. § 163 (1994). *See* Imazio Nursery, Inc. v. Dania Greenhouses, 69 F.3d 1560, 1566-67 (Fed. Cir. 1995).

<sup>48</sup> See Imazio Nursery, Inc., 69 F.3d at 1570 (holding that the infringing plant must be an asexual reproduction of the plant claimed).

<sup>49</sup> 7 U.S.C. §§ 2321-2322 (2000).

<sup>50</sup> 7 U.S.C. § 2402 (1994).

<sup>51</sup> 7 U.S.C. § 2483(a)(1) (1994).

<sup>52</sup> 7 U.S.C. § 2543 (2000).

<sup>53</sup> 7 U.S.C. § 2544 (2000).

<sup>54</sup> 7 C.F.R. § 97.140 (2004) (regulations covering labeling are as follows:

Upon filing an application for protection of a variety and payment of the prescribed fee, the owner, or his or her designee, may label the variety or containers of the seed of the variety or plants produced from such seed, substantially as follows: 'Unauthorized Propagation Prohibited –(Unauthorized Seed Multiplication Prohibited) – U.S. Variety Protection Applied For. Where applicable, 'PVPA 1994' or 'PVPA 1994-Unauthorized Sales for Reproductive Purposes Prohibited' may be added to the notice.)

<sup>55</sup> 7 U.S.C. § 2541(a) (2000). Note that if infringement occurs "prior to, or resulting from a planting prior to, issuance of a certificate for the infringed variety, a court finding the infringer to have established innocent intentions, shall have discretion as to awarding damages." 7 U.S.C. § 2564(d) (2000).

<sup>&</sup>lt;sup>42</sup> 35 U.S.C. § 103 (1994).

<sup>&</sup>lt;sup>43</sup> 35 U.S.C. § 161 (1994) (stating that any provisions in Title 35 relating to patents for inventions shall apply to plant patents, except as otherwise provided).

<sup>&</sup>lt;sup>44</sup> 35 U.S.C. § 101 (1994).

<sup>&</sup>lt;sup>45</sup> See 35 U.S.C. § 154 (1994) (defining a patent owner's right to exclude others from "making, using, offering for sale, or selling the invention into the United States" and failing to provide any exemptions from these rights).

[2004

Because both patents and PVP have value, some applicants choose to obtain both types of protection. For example, inbred lines to develop hybrids often get protected in PVPO. Such protection provides provisional protection when the PVP application is filed. Many inventors, however, may want to prevent exemptions for research and, thus, will also seek patent protection.

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In concert with determining novelty, whether an invention is nonobvious from the prior art must also be evaluated when a patent is sought.<sup>56</sup> Historically, there has been a distinction between considering prior art under §§ 102(f) and (g) for § 103 purposes.<sup>57</sup> A further requirement for prior art is that it be enabling under 35 U.S.C. § 112.<sup>58</sup> The

<sup>57</sup> *OddzOn Prods., Inc.,* 122 F.3d at 1403-04 (holding that 102(f) is a prior art provision for purposes of §103). *But see* 150 CONG REC. S7520, S7522 (2004) (enacted) (passing an amendment to 35 U.S.C. § 103(c), stating:

#### SEC. 2. COLLABORATIVE EFFORTS ON CLAIMED INVENTIONS.

Section 103(c) of title 35, United States Code, is amended to read as follows: (c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if-

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

"C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term 'joint research agreement' means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.)

The House and the Senate passed this amendment out of concern that the decision in *Oddzon* would negatively affect joint researchers who work for different entities and do not fall under the current section 103(c) exception. H.R. REP. NO. 108-425, at 2 (2004). This report states:

Enactment of the CREATE Act will provide collaborative researchers affiliated with multiple organizations a statutory 'safe harbor' similar to the one available under the patent law to researchers employed by a single organization or who have established certain types of legal relationships. In so doing, the CREATE Act will foster improved communication among researchers, provide additional certainty and structure for those who engage in collaborative research, reduce patent litigation incentives, and spur innovation and investment.

Id.

The amendment as of the date of this publication has not been signed by the President.

<sup>58</sup> 35 U.S.C. § 112 (1994) reads in part:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

<sup>&</sup>lt;sup>56</sup> 35 U.S.C. § 103 (1999), in pertinent part reads:

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

enablement and public accessibility requirements have recently been relaxed by two Federal Circuit decisions, *Elsner* and *Klopfenstein*, which open the door to delve into the information available in PVPO databases.

IV. RELAXATION OF THE ENABLEMENT AND PUBLIC ACCESSIBILITY REQUIREMENTS PERMITTING GREATER ACCESS TO PRIOR ART

In *Elsner*, the Federal Circuit held that the publication of Plant Breeder's Rights ("PBRs") applications coupled with foreign sales of plants covered by such applications may constitute a statutory bar to patentability under § 102.<sup>59</sup> This was a case of first impression for the Federal Circuit. Previously, the Board of Patent Appeals and Interferences (Board) had held, in essence, that a foreign sale could enable otherwise non-enabling references,<sup>60</sup> but the Federal Circuit had not said as much in so many words.

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In *Ex parte Thomson*,<sup>61</sup> the patent applicant claimed that the subject matter (Siokra, a cotton cultivar) was not enabled in three § 102(b) references cited against the applicant as prior art. Because the references failed to disclose at least twelve breeding steps necessary to reproduce the seeds, the references were not enabling.<sup>62</sup> Thus, the public was not in "possession" of the invention.<sup>63</sup>

The Board held that because the references disclosed the claimed Siokra and it was commercially available in at least Australia prior to the critical date,<sup>64</sup> a skilled artisan

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

<sup>62</sup> *Id.* at 1619.

 $^{63}$  See In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985) (stating that "[i]t is well-settled that prior art under 35 U.S.C. § 102(v) [sic] must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention. . . .Accordingly, even if the claimed invention is disclosed in the printed publication, that disclosure will not suffice as prior art if it was not enabling.").

<sup>64</sup> The critical date is defined as one year before the date of filing an application for patent. Any statutory barring activity occurring before the critical date renders the patent invalid or will prevent an

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<sup>&</sup>lt;sup>59</sup> 381 F.3d at 1128-29.

<sup>&</sup>lt;sup>60</sup> Ex parte Thomson, 24 U.S.P.Q.2d (BNA) 1618 (BPAI 1992).

<sup>&</sup>lt;sup>61</sup> *Id.* 

[2004]

would have had the wherewithal, upon reading the references, to purchase the commercially available seeds.<sup>65</sup> Thus, the public was already in possession of the invention such that a person of skill in the art could obtain and reproduce the invention by seed germination, without experimentation.<sup>66</sup>

In *Elsner*, the Federal Circuit, without citing *Thomson*, agreed with *In re LeGrice* that in order for a disclosure to be prior art under § 102(b) it must be enabled.<sup>67</sup> In *LeGrice*, the Court of Customs and Patent Appeals ("C.C.P.A.") held:

[I]t is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings *in combination with his* [or her] own knowledge of the particular art and be in possession of the invention.<sup>68</sup>

¶23 The Federal Circuit, however, noted that *LeGrice* did not address the manner in which a publication may be enabled, and it did not decide whether other evidence such as the availability of an invention through foreign sales may be considered in determining whether a printed publication enables a skilled artisan to reproduce the claimed plant.<sup>69</sup> The court distinguished its holding in *Elsner* from that of *LeGrice* by asserting that the key to determining whether patentability is barred is whether one of ordinary skill was enabled from the sales to reproduce the claimed plants without undue experimentation. Foreign sales, the court wrote, "may enable otherwise non-enabling printed publication" provided these sales enable one of ordinary skill in the art to reproduce the claimed plants without undue experimentation.<sup>70</sup> "The foreign sale must not be an obscure, solitary occurrence that would go unnoticed by those of skill in the art. Its availability must have been known in the art, just as a printed publication must be publicly available."<sup>71</sup>

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If a sale were recorded in the PVPO database, for example, it would probably indicate that the sale is known to those of ordinary skill in the art. In other words, it would be prudent to place the burden on the applicant to rebut the presumption that those of skill in the art would know of the material listed in the PVPO database. As the court noted in August 2004: "The determination of whether a reference is a 'printed publication' under 35 U.S.C. § 102(b) involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public."<sup>72</sup> The C.C.P.A. foreshadowed such a notion in *In re Bayer*.<sup>73</sup>

application for patent from being granted under 35 U.S.C. § 102(b).

<sup>70</sup> Elsner, 381 F.3d at 1131.

<sup>71</sup> *Id.* (citing *In re* Bayer, 568 F.2d 1357, 1361 (C.C.P.A. 1978)) ("[A] printed document may qualify as a 'publication' under 35 U.S.C. § 102(b). . .so long as accessibility is sufficient to raise a presumption that the public concerned with the art would know of the invention.")). *Accord* Klopfenstein, 380 F.3d at 1350 (stating "[t]he more transient the display the less likely it is to be considered a 'printed publication'").

<sup>72</sup> Klopfenstein, 380 F.3d at 1350 (citing In re Cronyn, 890 F.2d 1158, 1161 (Fed. Cir. 1989); In re Hall,

<sup>&</sup>lt;sup>65</sup> *Thomson*, 24 U.S.P.Q.2d (BNA) at 1620.

<sup>&</sup>lt;sup>66</sup> *Id.* at 1619.

<sup>&</sup>lt;sup>67</sup> Elsner, 381 F.3d at 1127 (citing In re LeGrice, 301 F.2d 929 (C.C.P.A. 1962)).

<sup>&</sup>lt;sup>68</sup> *LeGrice*, 301 F.2d at 936.

<sup>&</sup>lt;sup>69</sup> *Elsner*, 381 F.3d at 1130. *See generally LeGrice*, 301 F.2d at 944 (holding only that a printed publication on a new plant variety must meet the same standards of enablement that non-plant patents must meet before being used as a statutory bar under 35 U.S.C. § 102 (b)).

¶25 In *Bayer*, the patent applicant's master's thesis had been filed in the university library prior to the critical date. Although in the library, the thesis remained uncataloged and unshelved, but was accessible to members of the graduate committee before whom the applicant had defended his thesis. In this case, the court discussed "what degree of public accessibility is required for a printed document to qualify as a publication."<sup>74</sup> In analyzing such requirements, the court said:

[W]e think it apparent that a printed document may qualify as a 'publication' under 35 U.S.C. § 102(b), notwithstanding that accessibility thereto is restricted to a 'part of the public,' so long as accessibility is sufficient to raise a presumption that the public concerned with the art would know of [the invention].<sup>75</sup>

¶26 Although the court in *Bayer* did not find applicant's graduate committee to raise such a presumption,<sup>76</sup> perhaps this type of presumption should exist for information listed in the PVPO databases. It would be reasonable to at least place the burden on the applicant to rebut the presumption that those of skill in the art would know of the material listed in the PVPO database. Although skilled artisans do not have access to the PVPO databases unless they are examiners, there is information in the databases that does qualify as prior art. When a PVPO examiner, through searching the PVPO databases, finds a variety is not new and distinct, the discrepancy can be flagged and the originating data cited. The PVPO could coordinate with the PTO examiner, who would determine if the originating data could be used as a prior art rejection. If so, the relevant patent claims should be initially rejected and the patent applicant should be required to traverse the rejection and make a *prima facie* case for patentability.<sup>77</sup>

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Another case supporting the expansion of the scope of prior art is *In re Argoudelis*.<sup>78</sup> In *Argoudelis*, the C.C.P.A. held that a utility patent claiming antibiotic compounds produced by a microorganism was enabled by depositing the microorganism in a public depository.<sup>79</sup> In particular, the court stated that depositing the invention was appropriate "because of the particular area of technology involved."<sup>80</sup> The applicant otherwise could not adequately disclose the invention through written words as to how to obtain the invention from nature.<sup>81</sup> "[A]ny person with access to the pending application . . .can reproduce the invention from the disclosure as it was originally

<sup>76</sup> Id.

<sup>781</sup> F.2d 897, 899 (Fed. Cir. 1986)).

<sup>&</sup>lt;sup>73</sup> 568 F.2d 1357.

 $<sup>^{74}</sup>$  *Id.* at 1360.

<sup>&</sup>lt;sup>75</sup> *Id.* at 1361 (citing Camp Bros. & Co. v. Portable Wagon Dump & Elevator Co., 251 F. 603, 607 (7th Cir. 1917)).

<sup>&</sup>lt;sup>77</sup> In re Oetiker, 977 F.2d 1443 (Fed. Cir. 1992) (citing CHISUM, PATENTS, § 11.03 et seq. (1992)). See In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1983) (stating that the concept of making a *prima facie* case in *ex parte* examination is a procedural mechanism that allocates the burdens of production and the burdens of persuasion between the examiner and the applicant).

<sup>&</sup>lt;sup>78</sup> 434 F.2d 1390 (C.C.P.A. 1970).

<sup>&</sup>lt;sup>79</sup> *Id.* at 1392-93.

<sup>&</sup>lt;sup>80</sup> *Id.* at 1392.

<sup>&</sup>lt;sup>81</sup> *Id*.

filed."<sup>82</sup> In other words, the deposit permits public access to the invention, thereby satisfying the enablement requirement under §112 ¶1.<sup>83</sup> Even though "deposits are not part of the patent application, and the Patent Office exercises no control over them,"<sup>84</sup> the court found that the deposits satisfied the written description and enablement requirements.<sup>85</sup> The court noted that it is too speculative to suggest that the deposits would become unavailable, thus making the written description non-enabling and rendering the disclosure insufficient under §112 ¶1.<sup>86</sup> This case foreshadows the proposition held in *Elsner* that public accessibility to one of ordinary skill in the art is the sine qua non to enablement.<sup>87</sup>

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When examining patent applications, the PTO should look expansively and broadly at the available prior art rather than construing prior art narrowly. The examination process already puts the burden on the patent applicant to make a *prima facie* case of patentability.<sup>88</sup> The PTO should cite references found in the prior art, including those in the PVPO databases, and then allow the applicant an opportunity to traverse any rejections to overcome any references cited as prior art.

In further support of expanding the scope of prior art, the Federal Circuit, in *Klopfenstein*, listed the four relevant factors to determine whether a temporarily displayed reference is a publicly accessible "printed publication" under § 102(b): 1) "the length of time the display was exhibited;" 2) "the expertise of the target audience;" 3) "the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied;" and 4) "the simplicity or ease with which the material displayed could have been copied."<sup>89</sup>

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In *Klopfenstein*, the Board upheld the denial of the appellants' application for patent on the ground that it was not novel under 35 U.S.C. § 102(b) because it had been described in a printed publication before the critical date.<sup>90</sup> Two years before the appellants filed for patent, a printed publication, consisting of a fourteen-slide presentation, which disclosed every limitation of the invention, was printed and displayed continuously for two and a half days at an American Association of Cereal Chemists

<sup>85</sup> *Id. See also* Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 976- 83 (Fed. Cir. 2002) (Rader, J., dissenting) (extensively discussing the origins of the written description and enablement requirements in 112 ¶ 1 and criticizing the current characterizations of those requirements).

<sup>87</sup> *Elsner*, 381 F.3d at 1128 (stating:

The PTO asserts that when a publication is combined with a foreign sale which results in possession of the plant by one of skill in the art, it is that *possession alone* which is capable of enabling the publication. That is not correct. Only when possession derived in this manner enables a person of skill in the art to practice asexual reproduction of the plant in a manner consistent with the statute can a non-enabling publication and foreign sale act as a § 102(b) bar.) (emphasis added).

<sup>88</sup> Oetiker, 977 F.2d at 1443 (citing CHISUM, PATENTS, § 11.03 et seq. (1992)). See In re Piasecki, 745 F.2d 1468 (Fed. Cir. 1983) (stating that the concept of making a *prima facie* case in *ex parte* examination is a procedural mechanism that allocates the burdens of production and the burdens of persuasion between the examiner and the applicant).

<sup>89</sup> 380 F.3d at 1350.

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

<sup>&</sup>lt;sup>82</sup> *Id.* at 1393.

<sup>&</sup>lt;sup>83</sup> See 35 U.S.C. § 101 (1994).

<sup>&</sup>lt;sup>84</sup> Argoudelis, 434 F.2d at 1394.

<sup>&</sup>lt;sup>36</sup> Argoudelis, 434 F.2d at 1394.

meeting.<sup>91</sup> A month later, the same slide presentation was put on display for less than a day at an Agriculture Experiment Station at Kansas State University.<sup>92</sup> Because of these displays, the PTO rejected appellants' application.

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Before the Board, the appellants argued that the lack of distribution and the lack of evidence of copying the presentation precluded it from being considered a "printed publication" under § 102(b).<sup>93</sup> Because those of ordinary skill in the art had access to the presentation, this introduced the appellants' invention into the public domain and thus represented a "printed publication" under § 102(b).<sup>94</sup> The court agreed with the Board finding that public accessibility is the *sine qua non* for which a prior art reference will be judged under § 102(b).<sup>95</sup> Although distribution and indexing are factors to be considered, they are not required.<sup>96</sup> The court articulated the aforementioned factors that must be evaluated to determine whether a reference is sufficiently publicly accessible.<sup>97</sup>

The holding in *Klopfenstein* further reveals the Federal Circuit's willingness to look at prior art more expansively than in the past. This provides an opportunity for the PTO to begin utilizing the PVPO databases to obtain a broader spectrum of prior art.

While the PVPO does not evaluate obviousness, the PTO does. The PTO should review the PVPO databases, not only for novelty, but also for determinations of nonobviousness. For example, if the invention that is the subject of a patent application would have been obvious to one of ordinary skill familiar with traditional breeding techniques, then no patent should be granted.

#### V. CONCLUSION

The Patent and Trademark Office has recently been criticized for granting patents with overly broad claims that grant a monopoly over property that is in the public domain.<sup>98</sup> Although these mistakes are inevitable, such errors are more detrimental in areas where the patented subject matter is in naturally occurring substances, like agricultural biotechnology, because one cannot design or invent around a plant.

Because of the Supreme Court's holding in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* that utility applications for plants may be granted, it is likely that patents for plants will be sought with greater frequency in the future.<sup>99</sup> Thus, improvements in the patenting process should be made to increase the prior art available in the patenting process. An important resource that is not currently utilized is the hundreds of Plant Variety Protection Office databases in the U.S. Department of Agriculture.

Even at a time when the PTO has suggested outsourcing its patent search capabilities, the PTO has not utilized the PVPO databases.<sup>100</sup> The PTO should make accessing this information a key priority. Although not all information in the PVPO

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<sup>&</sup>lt;sup>91</sup> *Id.* at 1347.

 <sup>&</sup>lt;sup>92</sup> Id.
<sup>93</sup> Id.

 $<sup>^{94}</sup>$  Id.

<sup>&</sup>lt;sup>95</sup> *Id.* at 1350.

<sup>&</sup>lt;sup>96</sup> Id.

<sup>&</sup>lt;sup>97</sup> Id.

<sup>&</sup>lt;sup>98</sup> National Research Council of the National Academies, *supra* note 4.

<sup>&</sup>lt;sup>99</sup> 534 U.S. 124.

<sup>&</sup>lt;sup>100</sup> See United States Patent and Trademark Office, supra note 17.

databases would be considered prior art under § 102, some of it would be so designated. The PTO should use administrative rulemaking procedures or utilize the Presidential Executive Order powers under 35 U.S.C. § 164 to request that the USDA provide technical assistance. Because of *Elsner* and *Klopfenstein*, which relax the enablement and public accessibility requirements for prior art, the climate may be ripe for utilizing information available in the PVPO databases. It is better to have more information than less when deciding the new boundaries in which to grant exclusive patent rights.