# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



## CAN I SHOW YOU SOMETHING? THE PUBLIC USE BAR AND OVEREMPHASIS ON PUBLIC ACCESS

#### BENJAMIN LEE

#### ABSTRACT

The public use bar has long been a shield protecting the public against unscrupulous inventors hoping to create public dependency before seeking patent monopolization. Courts have repeatedly sided in favor of protecting the public interest. But how much protection do inventors themselves deserve in this battle of interests? This comment examines the history and application of the tests for public use utilized by the courts. Going further, the comment highlights the Federal Circuit's low corroborating evidence requirement in Pronova Biopharma Norge AS v. Teva Pharmaceuticals USA and questions whether this comports with the policies underlying patent law or too readily turns an allegation of public access into an invocation of public use.

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Cite as Benjamin Lee, Can I Show You Something? The Public Use Bar and Overemphasis on Public Access, 14 J. MARSHALL REV. INTELL. PROP. L. 590 (2015).

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### CAN I SHOW YOU SOMETHING? THE PUBLIC USE BAR AND OVEREMPHASIS ON PUBLIC ACCESS

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#### I. INTRODUCTION

The Founding Fathers understood that progress should be fostered, labor should be rewarded, and new discoveries must build on the old. When they drafted the Constitution, the Founders empowered Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." In this intellectual property clause, federal copyright and patent laws were born.

The patent law represents a compromise between the interests of inventors, the government, and the public. To promote the progress of science and useful arts, inventors receive temporary monopolies over their discoveries or inventions. This right of exclusion serves as an incentive to inventors "to risk the often enormous costs in terms of time, research, and development." This right comes at a price: the inventor must fully disclose the invention to the public so that others might build upon it. The public enjoys new products, increased employment and better lives.<sup>3</sup>

Yet this compromise does not, as stated, represent all the interests of the public. What of inventions presented to the public such that free access to the product by the public becomes presumed? The law recognizes that such inventions have become part of the public domain and no inventor may now claim a monopoly over them. This idea of balancing the interests of inventors against those of the public is embodied in 35 U.S.C. § 102 as the "public use" and "on-sale" bars.<sup>5</sup>

It is for the courts to determine whether an inventor has forfeited the right to a patent under the public use or on-sale bars. Many tests have been used by the courts.<sup>6</sup> Many more have been proposed. Some tests value the interests of the

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 $<sup>^{\</sup>rm 1}$  U.S. Const. art. I, § 8, cl. 8.

<sup>&</sup>lt;sup>2</sup> Kewanee v. Bicron, 416 U.S. 470, 480 (1974).

 $<sup>^{3}</sup>$  Id.

<sup>&</sup>lt;sup>4</sup> The policy behind the public use bar is the protection of the public from inventors who might seek to assert a monopoly on an invention after first creating widespread public reliance or dependence on the invention either by gifting the invention to the public or permitting its use by the public prior to patenting; *see* Pennock v. Dialogue, 27 U.S. 1, 14 (1829).

<sup>&</sup>lt;sup>5</sup> The policy behind the on-sale bar is the protection of the public from inventors who might seek to extend their monopoly on an invention beyond the statutory period; see Pennock at 14.

<sup>&</sup>lt;sup>6</sup> William C. Rooklidge W. Gerard von, Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability, 63 St. John's L. Rev. 1, 7 (1988).

inventors and use a balancing of factors.<sup>7</sup> Other tests value public interests and stress bright-line rules and strict interpretations.<sup>8</sup>

This article will examine the history of the public use bar and the on-sale bar, the tenets of the experimental use doctrine, and the Federal Circuit's muddled attempts to reconcile the on-sale and public use bars. The article will then analyze whether public access alone should be sufficient to invoke the public use bar and whether the Federal Circuit's ruling in *Pronova* advances policy interests or should be overturned as a misapplication of law. Finally, this article will propose new statutory definitions to return to respecting the inventors and better conform to public interests.

#### II. BACKGROUND

#### A. The Statutory Bars

The statutory bars to patentability appear in 35 U.S.C. § 102.9 The statute provides inventors with a one-year grace period to file for a patent from the first time the invention is publicly used or offered for sale. 10

#### B. The Early Doctrines

In order to discuss the changes to the public use bar, we must examine the onsale bar, modifications of which provide necessary context. Originally, courts utilized the on-hand doctrine when deciding whether to apply the on-sale bar.<sup>11</sup> This doctrine stressed that, prior to sale, the invention had to be reduced to practice.<sup>12</sup> Reduction to practice marked the end of the inventive process; the invention was complete and further experimentation was impossible.<sup>13</sup>

<sup>&</sup>lt;sup>7</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability*, 63 St. John's L. Rev. 1, 31 (1988) (examining the Federal Circuit's emphasis on examining the "totality of the circumstances" where the on-sale and public use bars present "an infinite variety of legal problems wholly unsuited to mechanically-applied, technical rules.")

<sup>&</sup>lt;sup>8</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability,* 63 St. John's L. Rev. 1, 13 (1988) (discussing a case in which the Supreme Court refused to apply the experimental use doctrine based on the status of the invention as "complete" and the lack of intent to test the invention.)

<sup>9 35</sup> U.S.C. § 102(a)(1) (2014).

<sup>10 35</sup> U.S.C. § 102(b)(1) (2014.

<sup>&</sup>lt;sup>11</sup> McCreery Eng'g Co. v. Mass. Fan Co., 195 F. 498, 500-501 (1st Cir. 1912) (holding that "proof of a mere contract to construct from plans and to deliver in future a machine or manufacture not proven to have been previously completed, falls short of proof that the machine or invention was 'on sale ")

<sup>&</sup>lt;sup>12</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability*, 63 St. John's L. Rev. 1, 7-8 (1988).

 $<sup>^{13}</sup>$  *Id*. at 9.

In 1975, the Second Circuit created a three-part test to replace the "on-hand" doctrine in order to account for possible inventions reduced to practice when offered for sale, but not "on-hand" for delivery. <sup>14</sup> Courts trying to apply this analysis attempted to "shoehorn the reduction to practice concept into the on-sale bar analysis" and "looked to see whether the invention was 'sufficiently' reduced to practice for purposes of the bar." <sup>15</sup>

In response to the confusion this "sufficiently reduced" standard created, <sup>16</sup> the Federal Circuit, in 1987, created the "totality of the circumstances" analysis. <sup>17</sup> This analysis required evaluation of the facts surrounding the transaction in light of the policies of 35 U.S.C. § 102. Using legislative history and case law, courts identified four primary policies underlying the on-sale bar. <sup>18</sup>

In contrast to the on-sale bar, the public use bar utilized a balancing standard from an early time. In 1877, the Supreme Court gave a rule expressing the necessity of examining the circumstances. <sup>19</sup> Cases following this rule focused on the policies involved and the factual circumstances surrounding the use. <sup>20</sup> In determining whether there had been a public use, the court's primary concern was the public interest. <sup>21</sup> In 1984, the Federal Circuit adopted the "totality of the circumstances" language in public use bar analysis. <sup>22</sup>

<sup>&</sup>lt;sup>14</sup> Timely Products Corp. v. Arron, 523 F.2d 288, 302 (2d Cir. 1975)(The Second Circuit created a three-part test requiring: (1) the complete invention claimed must have been embodied in or obvious in view of the thing offered for sale; (2) the invention must have been tested sufficiently to verify that it is operable and commercially marketable; and (3) the sale must be primarily for profit rather than for experimental purposes).

<sup>&</sup>lt;sup>15</sup> UMC Elecs. Co. v. United States, 816 F.2d 647, 655 (Fed. Cir. 1987).

 $<sup>^{16}</sup>$  Id.

<sup>&</sup>lt;sup>17</sup> *Id*. at 663.

<sup>&</sup>lt;sup>18</sup> Tone Bros. v. Sysco Corp., 28 F.3d 1192, 1198 (Fed. Cir. 1994).

<sup>&</sup>lt;sup>19</sup> Elizabeth v. Pavement Co., 97 U.S. 126, 133 (1877) (finding that an inventor's test of a new paving method did not constitute a public use. The inventor constructed a small patch of pavement on a public toll road. This patch of pavement was used for six years before the inventor's filing for patent. The Court expressed the necessity of examining "the circumstances under which [the] pavement was put down, and the object and purpose that [the inventor] had in view.")

<sup>&</sup>lt;sup>20</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale" and "Public Use" Bars to Patentability*, 63 St. John's L. Rev. 1, 35 (1988)("In its early 'on sale' and 'public use' cases, the Supreme Court often focused on the policy of avoiding detrimental public reliance on pre-application disclosure.")

<sup>&</sup>lt;sup>21</sup> Watson v. Allen, 254 F.2d 342, 345–46 (D.C. Cir. 1958).

<sup>&</sup>lt;sup>22</sup> Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1535 (Fed. Cir. 1984)(In analyzing whether there was a public use of an apparatus for separating solids from liquids such as waste water, the court stated that "the issue must be determined by considering the totality of the circumstances."); see also TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1984) (In reviewing a District Court dismissal of a charge of patent infringement, the Federal Circuit explained that the court should have looked at all of the evidence put forth by both parties and should have decided whether the entirety of the evidence led to the conclusion that there had been "public use.")

#### C. The Experimental Use Doctrine

The public use and on-sale bars can be blocked by invocation of the experimental use doctrine. This doctrine serves as a justification for activities that would otherwise bar patentability under the public use bar or the on-sale bar.<sup>23</sup>

The experimental use doctrine allows inventors to develop their inventions more fully and ensure that such inventions work as intended and for their intended purposes. Courts will allow for sales and uses of claimed inventions if such use or sale is experimental in nature.<sup>24</sup> As with the on-sale bar and the public use bar, the analysis for the experimental use doctrine considers the circumstances surrounding the use.<sup>25</sup>

#### D. Pfaff Changes the Landscape

In response to the uncertainty and confusion the "totality of the circumstances" analysis and "substantial completion" created across jurisdictions, the Supreme Court granted certiorari in *Pfaff v. Wells Electronics*, *Inc.* in 1998.<sup>26</sup>

In that case, Wayne Pfaff, inventor of a computer chip socket, sued Wells Electronics for infringement. Wells in turn claimed that Pfaff's patent was invalid under the on-sale bar. Pfaff had begun working on his invention after being approached by Texas Instruments.<sup>27</sup> Eleven days prior to the critical date for his patent, Pfaff received a written confirmation of a purchase order for 30,100 of his new sockets for \$91,155.<sup>28</sup>

<sup>&</sup>lt;sup>23</sup> Watson, 254 F.2d at 346.

<sup>&</sup>lt;sup>24</sup> Allen Eng'g Corp. v. Bartell Indus., 299 F.3d 1336, 1354 (Fed. Cir. 2002)(When deciding the applicability of the experimental use doctrine, the court should look at whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation.); see also Baxter Int'l, Inc. v. Cobe Labs., Inc., 88 F.3d 1054, 1060 (Fed. Cir. 1996) ("The experimental use doctrine operates in the inventor's favor to allow the inventor to refine his invention" and "[i]f it is not the inventor or someone under his control or 'surveillance' who does these things, there appears to us no reason why he should be entitled to rely upon them to avoid the statute.").

<sup>&</sup>lt;sup>25</sup> EZ Dock v. Schafer Sys., 276 F.3d 1347, 1352 (Fed. Cir. 2002)(In determining whether a sale of a polyethylene dock constituted an experimental use, the court considered whether the patent owner was engaged in wide sales of the docks at the time of purchase and whether the docks as stored were marked for sale with signs, brochures, or other markings. The court also found that the fact that the purchaser had initiated the purchase, the fact that the purchaser did not pay full market price for the dock, and the fact that the inventor had added free equipment and free installation were relevant to the experimental use determination.); see also Elizabeth 97 U.S. at 133 (The court, considering the facts surrounding the inventor's alleged public use, determined such use to be experimental in nature and insufficient to invalidate a patent).

 $<sup>^{26}</sup>$  Pfaff v. Wells Elecs, 525 U.S. 55, 60 (1998) ("Because other courts have held or assumed that an invention cannot be "on sale" ... unless and until it has been reduced to practice...and because the text of  $\$  102(b)makes no reference to "substantial completion" of an invention, we granted certiorari.) (internal citations omitted).

<sup>&</sup>lt;sup>27</sup> *Id.* at 58 (Pfaff began working on the socket in November of 1980, when representatives of Texas Instruments asked him to develop a new device for mounting and removing semiconductor chip carriers.)

<sup>&</sup>lt;sup>28</sup> Id. at 57-58 (April 19, 1981 constituted the critical date for the on-sale bar because Pfaff's application for patent occurred on April 19, 1982. On April 8, 1981, Texas Instruments provided

The Court ruled that, although Pfaff did not reduce his invention to practice until within the statutory grace period, the transaction with Texas Instruments constituted a sale and invalidated his patent.<sup>29</sup> Jettisoning the "totality of the circumstances" test for the on-sale bar,<sup>30</sup> the Court created a new "ready for patenting" standard.<sup>31</sup> The Court provided two routes to establish that an invention was "ready for patenting" but noted that there may be others.<sup>32</sup>

The Court did not comment on the proper standard for the public use bar or whether this "ready for patenting" standard should be applied there as well. Perhaps this silence was meant to convey that the "totality of the circumstances" analysis for the public use bar was to remain untouched.

#### E. The Federal Circuit's Indecision

In 2002, the Federal Circuit appeared to confirm the continued viability of the "totality of the circumstances" analysis for the public use bar in *Netscape Communications*. <sup>33</sup> In that case, the Federal Circuit found that patents for systems that performed remote access and searching of a computer database were barred due to public use before the critical date. <sup>34</sup>

In addition to explicitly declaring the standard to be that of the "totality of the circumstances",<sup>35</sup> the court listed "circumstances"<sup>36</sup> relevant to the consideration and final evaluation of the patents.<sup>37</sup> The court explicitly noted as well that the "totality

Pfaff with a written confirmation of a previously placed oral purchase order for 30,100 of his new sockets for a total price of \$91,155.)

- <sup>29</sup> Id. at 68–69.
- <sup>30</sup> Some argued that the elimination of the "totality of the circumstances" analysis for the onsale bar was, ultimately, a mistake. See, e.g., Lucius L. Lockwood, Note, Ready, Set, Patent! How the Supreme Court in Pfaff v. Wells Electronics Jumped the Gun, 40 JURIMETRICS J. 399, 400 ("...abandoning the totality of circumstances test is unlikely to promote the advancement of useful arts.")
- <sup>31</sup> *Pfaff* at 67–68. (The court held that the on-sale bar applies when two conditions are satisfied before the critical date: (1) the product must be the subject of a commercial offer for sale, and (2) the invention must be ready for patenting.)
- <sup>32</sup> Id. at 67–68 ("Ready for patenting" may be satisfied in "at least" two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.)
- <sup>33</sup> Netscape Communs. Corp. v. Konrad, 295 F.3d 1315, 1320 (Fed. Cir. 2002)("We look to the totality of the circumstances when evaluating whether there has been a public use...")
- $^{34}$  Id. at 1323 (declaring the claimed features of the patents at issue had been placed in the public's possession).
  - 35 *Id*. at 1320.
- <sup>36</sup> A court may also consider corroborating evidence or lack thereof when analyzing a potential public use; *see* 3M v. Chemque, Inc., 303 F.3d 1294, 1307 (Fed. Cir. 2002)(The court found that there was no use for "public use" purposes where there was evidence in the record that samples of a sealant produced by plaintiff 3M were sent to various corporations, but defendants presented no evidence showing that anyone ever used the samples.)
- <sup>37</sup> Netscape, 295 F.3d at 1320 (The circumstances to be considered in a "totality of the circumstances" analysis may include: the nature of the activity that occurred in public; the public access to and knowledge of the public use; whether there was any confidentiality obligation imposed on persons who observed the use; whether persons other than the inventor performed the testing;

of the circumstances" was to be considered alongside the policies underlying the public use bar.  $^{38}$ 

In 2004, the Federal Circuit reversed course and applied the "ready for patenting" standard from Pfaff to a public use bar analysis in SmithKline.<sup>39</sup> The Federal Circuit adapted the Pfaff on-sale test to the public use bar and held that use by someone other than the inventor of an invention ready for patenting would constitute a public use.<sup>40</sup>

Strangely, despite disposing of the "totality of the circumstances" analysis utilized in that case, the Federal Circuit cited to *Netscape* for the definition of "public use" for this new test.<sup>41</sup> This reimagining of *Pfaff* produced the "ready for patenting" test for public use.

Later in that same year, the Federal Circuit would change position again and reinstate the "totality of the circumstances" analysis in *Bernhardt*.<sup>42</sup> In that case, the Federal Circuit considered the validity of six design patents for furniture where Bernhardt had displayed its furniture designs in an exhibition to key customers and media representatives thirteen months prior to applying for the patents.<sup>43</sup>

The court returned to the "totality of the circumstances" analysis in conjunction with policy considerations underlying the statutory bars. 44 Citing once again to *Netscape*, the court listed several factors necessary for the analysis. 45 The Federal Circuit went so far as to criticize the district court's singular focus on the absence of any confidentiality agreements and explicitly noted the failure to utilize the "totality of the circumstances" analysis. 46

the number of tests; the length of the test period in relation to tests of similar devices; and whether the inventor received payment for the testing.)

<sup>39</sup> SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1316 (Fed. Cir. 2004)(The court explicitly noted the test created by the Supreme Court in *Pfaff* and declared that "[a] similar analysis applies to the public use bar under § 102(b).")

<sup>40</sup> *Id.* at 1316–17 (The court noted that "although the commercial sale prong is inapplicable," § 102(b) erected a bar where, before the critical date, the invention was "ready for patenting and was used by a person other than the inventor who is under no confidentiality obligation.")

41 Id. at 1317.

<sup>42</sup> Bernhardt, L.L.C. v. Collezione Europa USA, Inc., 386 F.3d 1371, 1379 (Fed. Cir. 2004) ("In determining whether an invention was in public use, a court "must consider how the totality of the circumstances comports with the policies underlying the on sale and public use bars...")

43 Id. at 1374-76.

<sup>44</sup> *Id.* at 1379 (The court invoked both the "totality of the circumstances" analysis and declared that courts should also consider policies underlying the statutory bars including "discouraging the removal of inventions from the public domain which the public justifiably comes to believe are freely available, prohibiting an extension of the period for exploiting the invention, and favoring prompt and widespread disclosure of inventions..."); *see also* Lucius L. Lockwood, Note, *Ready, Set, Patent! How the Supreme Court in Pfaff v. Wells Electronics Jumped the Gun*, 40 JURIMETRICS J. 399, 401 (explaining the most commonly cited policies behind the on-sale bar.)

<sup>45</sup> Bernhardt at 1379. ("Additional factors a court must consider and weigh in determining whether the use was "public" under § 102(b) include, inter alia, the nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there was any confidentiality obligation imposed on persons who observed the use . . . . ")

<sup>46</sup> *Id.* at 1381 (The Federal Circuit noted that "the district court focused on the absence of any confidentiality agreements and did not discuss or analyze how the totality of circumstances surrounding Bernhardt's 1999 Pre-Market comports with the policies underlying the public use bar.")

<sup>&</sup>lt;sup>38</sup> Id. at 1320.

The court made no mention of its earlier ruling in *SmithKline* or its new "ready for patenting" analysis. The Federal Circuit had procedurally undone its prior opinion. Effectively, the Federal Circuit swept the *SmithKline* ruling under the rug for the time being.

Although *SmithKline* was later vacated and decided on other grounds at an en banc rehearing,<sup>47</sup> these three cases illustrate how even the Federal Circuit is unsure of the proper standard for the public use bar. In trying to reconcile the on-sale bar's "ready for patenting" standard with the public use bar, have we strayed from the policies in which the "totality of the circumstances" test and patent law, in general, were grounded?

#### III. ANALYSIS

This section introduces the *Pronova* case and analyzes the facts under both the "ready for patenting" and "totality of the circumstances" standards before examining whether public access has been overemphasized.

#### A. The Pronova Case

Suppose the existence of a company. The company has spent significant resources developing a product to help with treatment of an ailment. The product is a more concentrated form of a particular blend of compounds previously known to afford various health benefits. Eager to see that the product reaches a wide market and curious about additional applications, the company contacts an expert on the compounds used in its blend.

The company finds out the expert has applied for a grant to study the effects of those compounds on a different ailment. The company proposes that the expert use its new blend in the study. He expresses concern about impurities in the company's samples. As a show of good faith, the company sends him two vials and a report on what the samples contain. There is no record that he ever uses the samples for any purpose.

Two years later the company patents the blend. Later, the company sells the patent to you. Some time passes and you find a new company utilizing your patented blend. The infringer points to the original patent owner's actions with the expert as an invalidating public use. This is precisely the situation in which Pronova Biopharma found itself after acquiring a patent and accusing Teva Pharmaceuticals of infringing that patent.<sup>48</sup>

<sup>&</sup>lt;sup>47</sup> SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1364 (Fed. Cir. 2005)(The court invalidated the patent on the grounds that the claims covered unpatentable subject matter because the patent, correctly construed, claimed "every single crystal" including those arising in nature.)

<sup>&</sup>lt;sup>48</sup> Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 517 (D. Del. 2012)(Defendant Teva Pharmaceuticals alleged that Norsk Hydro, original owners of the patent now owned by Pronova Biopharma, made a public use of its omega-3 fish oil product by disclosing its contents and providing product samples to one Dr. Victor Skrinska, a medical researcher at St. Vincent Charity Hospital and the Cleveland Research Institute with expertise in omega-3 fatty acids.)

#### B. Pronova Under "Ready for Patenting"

Applying the ready for patenting standard from *Pfaff* and as used in *Smithkline*, Pronova will lose due to the actions of Norsk Hydro, the original patent owner. Recall that the *Pfaff* court provided a non-exhaustive list of two avenues to achieve "ready for patenting" status.<sup>49</sup> Using the facts as alleged by Dr. Skrinska, Norsk Hydro's actions would satisfy both prongs.

Firstly, Norsk Hydro arguably reduced the fish oil products to practice. Under no confidentiality agreement<sup>50</sup> that would invoke experimental use,<sup>51</sup> Dr. Skrinska claims to have used the samples in a study to assess their effect on wellness.<sup>52</sup> Oversight from Norsk Hydro might have created the type of relationship allowing invocation of a saving experimental use exception.<sup>53</sup> Unfortunately, this was not the case.<sup>54</sup>

Secondly, Norsk Hydro produced descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. Norsk Hydro provided Dr. Skrinska with such a description when shipping him samples in order to alleviate his concerns with impurities.<sup>55</sup>

Under the scheme introduced by the Federal Circuit for analyzing public use through "ready for patenting," Dr. Skrinska's alleged use confirming the contents of the samples would constitute a patent-invalidating public use of an invention that was ready for patenting. In reality, Pronova conceded that Norsk Hydro shared the invention after it had met the ready for patenting requirement.<sup>56</sup> Had that been the

<sup>49</sup> Pfaff at 67-68.

<sup>&</sup>lt;sup>50</sup> Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 518 (D. Del. 2012)(The court found that there were no confidentiality concerns or other mentions of the potential uses in the cover letter accompanying the liquid samples and Pronova did not identify any such restrictions.)

<sup>&</sup>lt;sup>51</sup> Lough v. Brunswick Corp., 86 F.3d 1113, 1120 (Fed. Cir. 1996)(The court held that to determine whether a use is experimental the totality of the circumstances must be considered, including "various objective indicia of experimentation surrounding the use, such as ... the existence of a secrecy agreement between the patentee and the party performing the testing ...")

<sup>&</sup>lt;sup>52</sup> Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 519 (D. Del. 2012)(Dr. Skrinska stated that six volunteers were selected from the Cleveland Research Institute staff for a study using the Norsk Hydro capsules which involved taking "approximately six capsules a day for two weeks," and after which they looked at fatty acid composition in the membranes of platelets.)

 $<sup>^{53}\ {\</sup>rm Lough}\ v.$  Brunswick Corp., 86 F.3d 1113, 1120 (Fed. Cir. 1996.

<sup>&</sup>lt;sup>54</sup> Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 519 (D. Del. 2012)(Dr. Skrinska alleged that he recorded the results of the study in a notebook, although no one from Norsk Hydro asked to see the results of the study, and he did not send them any data.)

<sup>&</sup>lt;sup>55</sup> Pronova BioPharma Norge AS v. Teva Pharms. USA, Inc., 549 Fed. Appx. 934, 942–943 (Fed. Cir. 2013) (In an unpublished opinion, the Federal Circuit concluded that Norsk Hydro provided Dr. Skrinska with the invention claimed in Norsk Hydro's patent with no secrecy obligation or limitation for his unfettered use. The court held that this access began, at the latest, in September of 1987, when Norsk Hydro shipped to Dr. Skrinska samples that made public all aspects of the claimed inventions, because the shipment included a certificate of analysis revealing the composition of the supplied products.)

<sup>&</sup>lt;sup>56</sup> Id. at 939 (The court concluded that there was no dispute regarding the "ready for patenting" requirement because the parties agreed that Norsk Hydro sent samples to Dr. Skrinska meeting the limitation of the asserted claims of the patent and the invention was, therefore, reduced to practice.)

determining factor as it was in the Federal Circuit's ruling in *Smithkline*, then Pronova would also have conceded invalidity of its patent under the public use bar.

#### C. Pronova Under "Totality of the Circumstances"

Applying the totality of the circumstances analysis utilized in *Netscape* and *Bernhardt*, Pronova's fate is not so bleak. Recalling that the *Netscape* test is a balancing of factors, <sup>57</sup> Pronova's situation requires significantly more consideration.

First, *Netscape* calls for consideration of the nature of the activity that occurred in public.<sup>58</sup> In this case, Norsk Hydro distributed two samples to Dr. Skrinska.<sup>59</sup> Dr. Skrinska allegedly performed a subsequent test to confirm the accuracy of the certificate of analysis included with the samples.<sup>60</sup> Later, Skrinska claimed to have conducted a study using six volunteers.<sup>61</sup> This factor would seem to weigh against Pronova.

Second, the public access to and knowledge of the public use must be considered. 62 Dr. Skrinska had access to the samples and the certificate of analysis disclosing all elements of the claimed invention. 63 Allegedly, Dr. Skrinska shared the samples with five other individuals who volunteered for a study and mentioned the existence of the samples to a Dr. Wei, assistant professor of medicine at Case Western Reserve University. 64 According to Dr. Skrinska's testimony, knowledge of the samples and their composition was available to "everyone" at the Cleveland Research Institute and that "regular meetings and updates" provided information on Dr. Skrinska's study. 65 Such spread of knowledge would weigh against Pronova.

Third, whether there was any confidentiality obligation imposed on persons who observed the use may factor into the analysis. <sup>66</sup> Pronova has admitted that no restrictions were attached to the samples delivered to Dr. Skrinska by Norsk Hydro. <sup>67</sup> The lack of any imposed obligation of confidentiality on Dr. Skrinska or the volunteers in his alleged study would weigh against Pronova as well.

Next, whether persons other than the inventor performed the testing and the number of tests should be considered. <sup>68</sup> In this case, the tests at issue were performed by Dr. Skrinska, an individual admittedly independent of Norsk Hydro. <sup>69</sup>

<sup>&</sup>lt;sup>57</sup> Netscape, 295 F.3d at 1320.

<sup>&</sup>lt;sup>58</sup> *Id*.

 $<sup>^{59}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 518 (D. Del. 2012).

 $<sup>^{60}</sup>$  *Id*.

<sup>&</sup>lt;sup>61</sup> Id. at 519.

<sup>62</sup> Netscape, 295 F.3d at 1320.

 $<sup>^{63}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 518 (D. Del. 2012).

<sup>64</sup> Id. at 519.

<sup>&</sup>lt;sup>65</sup> *Id*.

<sup>66</sup> Netscape, 295 F.3d at 1320.

 $<sup>^{67}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 518 (D. Del. 2012).

<sup>&</sup>lt;sup>68</sup> Netscape, 295 F.3d at 1320.

 $<sup>^{69}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 518–19 (D. Del. 2012).

Further, after confirming the composition of the samples, Dr. Skrinska allegedly began an unrelated study. This behavior belies an assumption that he, Dr. Skrinska, was free to do with the samples as he wished. These fourth and fifth factors weigh against Pronova as well.

Sixth, *Netscape* calls for consideration of the length of the test period in relation to tests of similar devices.<sup>71</sup> In the Pronova case, Dr. Skrinska's test to confirm sample composition is not given a length of time during which the test occurred.<sup>72</sup> Because Dr. Skrinska was sought out for his expertise in the field, it is likely a fair assumption that such tests took no longer than typically required. Noteworthy, however, is the alleged study involving volunteers that took place over the course of two weeks.<sup>73</sup>

This abbreviated trial seems, at a glance, to be irregular. Unfortunately, the *Pronova* case provided no insight into whether this was truly atypical of testing for a fish oil supplement ingestion. The However, even showing deference to Dr. Skrinska's knowledge in the field, it is difficult to assume that a two-week trial using a small sampling of six volunteers is representative of the rigor shown in dietary supplement testing. With the available information, this sixth factor does not truly weigh in favor of or against Pronova.

Finally, whether the inventor received payment for the testing may be considered in the analysis.<sup>75</sup> Norsk Hydro received no payment for the tests and did not ask to see the results of the tests allegedly conducted by Dr. Skrinska.<sup>76</sup> This lack of financial relationship weighs against Pronova.

At first blush, it appears that the vast majority of the *Netscape* factors weigh against Pronova. Taking the facts as alleged, Dr. Skrinska's activities and Norsk Hydro's apparent lackadaisical attitude towards the fate of the samples leads inexorably to the conclusion that there was a public use, even under the totality of the circumstances analysis.

There is, however, one additional factor for consideration in this case. Dr. Skrinska's near complete lack of corroborating evidence for his claims. The District Court that originally heard this case found this lack of corroborating evidence to be quite damning to the defendant's argument of invalidity by prior public use. Two letters were the only documentary evidence of Skrinska's activities.

One, a letter from Dr. Wei to Norsk Hydro, stated that Dr. Wei had "learned of the existence" of Norsk Hydro's invention from Dr. Skrinska and would like to know more or possibly obtain a sample.<sup>79</sup> The other was a letter from Norsk Hydro to Drs. Wei and Sheehan describing reticence at simply distributing more samples.<sup>80</sup>

<sup>&</sup>lt;sup>70</sup> *Id*. at 519.

<sup>&</sup>lt;sup>71</sup> Netscape, 295 F.3d at 1320.

 $<sup>^{72}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 518 (D. Del. 2012).

<sup>&</sup>lt;sup>73</sup> *Id*. at 519.

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

<sup>&</sup>lt;sup>75</sup> Netscape, 295 F.3d at 1320.

 $<sup>^{76}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 519 (D. Del. 2012).

<sup>&</sup>lt;sup>77</sup> *Id*.

 $<sup>^{78}</sup>$  Id.

<sup>&</sup>lt;sup>79</sup> *Id*.

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

With no evidence to corroborate Dr. Skrinska's recollection (twenty years after the fact) of his activities, the totality of the circumstances should swing sharply in favor of Pronova. The only activity claimed by Dr. Skrinska that is corroborated by the presented evidence is that Dr. Skrinska, having acquired the samples, spoke of them to two colleagues in terms general enough to require the colleagues contact Norsk Hydro for further information.<sup>81</sup>

#### D. Public Access Overemphasized?

Despite this scant evidence to corroborate Dr. Skrinska's claims, in an unpublished opinion, the Federal Circuit ruled that Dr. Skrinska's activities were sufficiently corroborated by the letters to show public access and public knowledge. 82 The correspondence from Dr. Wei was clear evidence that Dr. Skrinska had shared knowledge of Norsk Hydro's invention. 83

By the nature of the letters, however, it is unclear how much knowledge was shared. The letter from Dr. Wei to Norsk Hydro does not demonstrate that Dr. Wei had been informed of the existence of the invention. <sup>84</sup> The letter simply shows that Dr. Skrinska had mentioned the invention. If the full invention had been disclosed, why would Dr. Wei's correspondence amount to little more than a request for information about the product and its clinical usage? <sup>85</sup>

In similar fashion, the second letter shows only that knowledge of the existence of the invention was shared also with a Dr. Sheehan. Ref Does this reasonably lead to a conclusion of public use? Is this relatively low level of access enough to show the dependence upon the invention by the public that the public use bar is meant to protect? Is this the kind of "extended commercialization" or "extended . . . public disclosure" envisioned for the public use bar?

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

<sup>82</sup> Pronova BioPharma Norge AS v. Teva Pharms. USA, Inc., 549 Fed. Appx. 934, 943 (Fed. Cir. 2013) (The Federal Circuit, referring to the letters to Drs. Wei and Sheehan, held that the district court pointed to documents in the record confirming Dr. Skrinska's testimony that he shared information regarding the samples sent to him with other members of the medical community in Cleveland and did not treat that information as confidential.)

<sup>83</sup> *Id*.

<sup>84</sup> Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 519 (D. Del. 2012).

<sup>&</sup>lt;sup>85</sup> *Id*.

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

<sup>&</sup>lt;sup>87</sup> The Supreme Court noted early on that public knowledge is not enough to invoke a statutory bar. Although the law had been written strictly to include a requirement of total secrecy in 1793 to conform to English patent law from which it originated, it had been later relaxed in 1836 and the English law that served as the model for American law had been similarly qualified. *Elizabeth* 97 U.S. at 136.

<sup>&</sup>lt;sup>88</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale' and "Public Use' Bars to Patentability*, 63 St. John's L. Rev. 1, 34 (1988) ("The Supreme Court has emphasized the importance of the assurance that ideas once interjected into the public domain remain there for public use. Closely related to this objective is the notion expressed by Congress in amending the 'on sale' and 'public use' bars in 1939, that, as a result of pre-application disclosure of an invention, 'the public may...come to believe that the invention is open to anyone."); *see also* Patrick J. Barrett, *New Guidelines for Applying the on Sale Bar to Patentability*, 24 STAN. L. REV.

It is unclear that Dr. Skrinska's corroborated mention of the invention to only two additional members of the public rise to the level that the public use bar was meant to protect. Drs. Wei, Skrinska, and Sheehan, far from making and using the invention under the belief that it was freely available to the public, did not synthesize the invention despite expertise in the field but asked for more samples and information from the inventor.

#### IV. PROPOSAL

This section presents a summary of the issues; proposes statutory definitions for "public use," "public access," and "public reliance;" and examines the *Pronova* case under the proposed definitions.

#### A. Summary of the Issues

The introduction of the "ready for patenting" standard clarified implementation of the "on-sale" bar but creates confusion for the implementation of the "public use" bar. The "public use" bar must be clarified to conform to policy interests. The lack of a statutory definition has allowed courts to craft a "totality of the circumstances" test that is capable of harshly punishing inventors based on a low bar of evidence. <sup>92</sup> This is especially true where public access is concerned. Further, because the test for "public use" was designed by courts, courts may reject the existing test and draw from newly crafted standards in other areas of patent law.

A definition of public use codifying the multi-factor test and relevant policy considerations should be drafted to give inventors and courts a firm foundation to

<sup>730, 732–33 (1972) (</sup>Explaining that avoiding detrimental public reliance, encouraging patent disclosures, discouraging undesirable commercial exploitation, and lenience toward the inventor are the driving policies behind patent law.)

<sup>&</sup>lt;sup>89</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale' and "Public Use' Bars to Patentability*, 63 St. John's L. Rev. 1, 34–35 (1988).

<sup>&</sup>lt;sup>90</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale' and "Public Use' Bars to Patentability*, 63 St. John's L. Rev. 1, 34–35 (1988) ("...[A]n inventor should be prohibited from obtaining a patent after... [disclosure] ... [has] caused other[s] to start making, using, or selling it... [under] the belief that the invention is freely available to the public....the public's reasonable belief that an invention is available without restriction is discouraged by the inventor marking the product with the mark 'Patent Pending.' An inventor who fails to file an application, and consequently fails to mark his product, theoretically leads the public to believe that his invention is available for the public's benefit.")

<sup>&</sup>lt;sup>91</sup> Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 519 (D. Del. 2012).

<sup>&</sup>lt;sup>92</sup> CRAIG ALLEN NARD, MICHAEL J. MADISON & MARK P. MCKENNA, The Law of Intellectual Property 228 (4th ed. 2014) (noting that "the public use threshold is low, but clean and easier to apply than a test requiring, for example, an unreasonable number of people or articles before the public use bar attaches...[b]ut ease of application can lead to potentially harsh results")(internal quotations omitted).

understand what actions are proscribed and what burdens must be met while returning to a balancing of public and private interests.<sup>93</sup>

#### B. Proposed Public Use Laws

The current embodiment of "public use" allows an individual to constitute "the public." Developed over time through the courts, this 'one person, one article' test makes the determination easier for courts. The fact that the Federal Circuit's decision in <u>Pronova</u> was unpublished and, therefore, non-precedential, does not prevent a later court, using the same reasoning, from replicating the harshness of the results. 95

#### 1. Proposed Definition of "public use"

Under 35 U.S.C. § 102, a definition of "public use" must be added. The definition should accord with prior judicial holdings that outline relevant policy considerations and the "totality of the circumstances" balancing considerations.

The new definition should read as follows:

A "public use" of an invention:

- (1) means use of an invention prior to the critical date for that invention which resulted in public access and public reliance; and
- (2) may be found by a consideration of the totality of the circumstances, including the nature of the activity that occurred in public; the public access to and knowledge of the public use; whether there was any confidentiality obligation imposed on persons who observed the use; whether persons other than the inventor performed the testing; the number of tests; the length of the test period in relation to tests of similar devices; and whether the inventor received payment for the testing.

<sup>&</sup>lt;sup>93</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale' and "Public Use' Bars to Patentability*, 63 St. John's L. Rev. 1, 35 (1988)("The patent law was designed for the public benefit, as well as for the benefit of inventors.")

<sup>&</sup>lt;sup>94</sup> CRAIG ALLEN NARD, MICHAEL J. MADISON & MARK P. MCKENNA, The Law of Intellectual Property 228 (4th ed. 2014) (explaining that courts have taken a minimalist approach to public use where use of a single article not visible to the public eye by an inventor's wife constituted a public use because the inventor's wife was the public)(internal quotations omitted); see Egbert v. Lippmann, 104 U.S. 333, 338 (1881) (where the Court held that use of one article, prior to the critical date, by one person, who would later become patent-owner's wife, constituted an invalidating public use).

<sup>95</sup> Pronova BioPharma Norge AS v. Teva Pharms. USA, Inc., 549 Fed. Appx. 934, 934 (Fed. Cir. 2013).

Under this definition, the "totality of the circumstances" is codified as the proper test for the "public use" bar and the courts' traditional emphasis on public access and public reliance are retained.<sup>96</sup>

#### 2. Proposed Definition of "public access"

Under 35 U.S.C. § 102, a definition of "public access" should be added. The definition should balance the interests of the public with those of inventors.

The new definition should read as follows:

The term "public access" means access by one or more individuals not bound by confidentiality to the inventor.

This definition maintains the relatively low bar set by courts in that disclosure to a single individual may evidence a public use. The low bar in this arm of the definition of "public use" represents the interests of the public.<sup>97</sup>

#### 3. Proposed Definition of "public reliance"

Under 35 U.S.C. § 102, a definition of "public reliance" should be added. 98 The definition should further clarify the "public use" bar and the policy behind the statutory bar. 99

The new definition should read as follows:

The term "public reliance" means reliance on continued public accessibility by one or more persons where such reliance is corroborated by evidence of

<sup>&</sup>lt;sup>96</sup> The proposed definition makes explicit use of the factors from *Netscape* but adds portions designed to recognize the interests of the public and inventors. *Netscape*, 295 F.3d at 1320.

<sup>&</sup>lt;sup>97</sup> The interests of the public are here served where the ease of demonstrating public access is maintained. Although public access alone has been overemphasized to the benefit of the public such that any access whatsoever not subject to confidentiality may bar a patent, the argument here is not that public access should be done away with root and branch. Rather, the overemphasized public access analysis must be tempered to include the interests of the inventors as well. That this will complicate the analysis for courts somewhat should not be a consideration.

<sup>&</sup>lt;sup>98</sup> The inclusion of a public reliance factor provides protection to inventors. Previously, early cases had involved proof of actual reliance by the public on pre-application disclosures. William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale' and "Public Use' Bars to Patentability*, 63 St. John's L. Rev. 1, 36 (1988). The policy came to apply to pre-application disclosures regardless of the existence of actual reliance. *Id.* The policy shifted into avoiding the mere possibility of a detrimental reliance. *Id.* This current incarnation of the policy, while well-adapted to protection of the interests of the public, is ill-suited for protection of the interests of inventors.

<sup>&</sup>lt;sup>99</sup> William C. Rooklidge W. Gerard von, *Reduction to Practice, Experimental Use, and the "On Sale' and "Public Use' Bars to Patentability*, 63 St. John's L. Rev. 1, 34 (1988) ("Closely related to this objective is the notion expressed by Congress in amending the 'on sale' and 'public use' bars in 1939, that, as a result of pre-application disclosure of an invention, 'the public may...come to believe that the invention is open to anyone.")

bona fide actions taken in reliance on presumed continued public accessibility.

This definition prevents harsh outcomes that have occurred in the past. The requirement of corroborating evidence prevents testimony alone from invalidating a patent. The evidence must show not simply that more than one person knew of the invention, but rather that at least one person relied on the invention's continued public accessibility. The Borrowing from trademark law, the requirement that such actions taken in reliance be bona fide prevents invalidation of a patent based on reliance in name only. This arm of the definition of "public use" protects the interests of the inventor. The same of the definition of "public use" protects the interests of the inventor.

#### C. Pronova Under the Proposed Definitions

Much of the "totality of the circumstances" analysis would remain the same. Dr. Skrinska's access to the samples would still, under this new definition, constitute public access. Where the analysis would differ dramatically, however, comes from the inclusion of the public reliance requirement. Dr. Skrinska's alleged experiments and sharing of knowledge with colleagues would constitute bona fide actions taken in reliance on presumed continued public accessibility.

Dr. Skrinska's lack of evidence to corroborate those allegations, however, would cause the failure of the claim against Pronova's patent. No evidence was presented

<sup>&</sup>lt;sup>100</sup> Finnigan Corp. v. US Intn. Tr. Com., 180 F.3d 1354, 1369 (Fed. Cir. 1999)("In any event, corroboration is required of any witness whose testimony alone is asserted to invalidate a patent, regardless of his or her level of interest.")

<sup>&</sup>lt;sup>101</sup> The requirement of evidence is, again, taken from previous case law. Previous cases have explained that the presumption of validity for a patent is not easily overcome and that prior use must be proven by "clear and convincing" evidence. 3M v. Chemque, Inc., 303 F.3d 1294, 1306 (Fed. Cir. 2002). The standard proposed is merely a codification of a conclusion courts have previously independently reached.

<sup>102</sup> In trademark law, the term "bona fide" appears throughout The Lanham Act. 15 U.S.C. § 1127. The use borrowed here is that of the definition of "use in commerce" which is held to mean "the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark." 15 U.S.C. § 1127; see Specht v. Google Inc., 758 F. Supp. 2d 570, 579 (N.D. Ill. 2010)(noting the difference between a bona fide use and a "mere token use" where the "handing out [of] two business cards at social events" was not a bona fide use in commerce, but rather a "sporadic, inconsistent, limited, and unsuccessful promotion of Specht's services" constituting "a mere token use of the mark"); see 2 J. Thomas Mccarthy, McCarthy on Trademarks and Unfair Competition § 16:8 (4th ed. 1997)(recounting the history of the Congressional revision to the definition of "use in commerce" and noting that, prior to 1989, extent of actual use of a mark was irrelevant so long as it amounted to more than "a mere sham attempt" to conform with statutory... Congress [later] changed the statutory definition... to require "a greater degree of activity"). The use in the proposed definition follows that Congressional trend of increasing protection for rights holders and raises the bar for demonstration of reliance by requiring that actions taken in reliance be substantial enough to rise above a "mere token" use.

<sup>103</sup> Instead of providing inventors with a means to completely nullify the public use bar, this "public reliance" requirement acts as a reinforcement of the presumed validity of a patent. One seeking to challenge the patent on public use bar grounds must demonstrate that, instead of the existence of a mere possibility of detrimental public reliance, actual public reliance existed.

to corroborate Dr. Skrinska's alleged experiments.<sup>104</sup> The only evidence of those experiments is Dr. Skrinska's testimony.<sup>105</sup> This uncorroborated testimony would not evidence public reliance under the new rule.

Dr. Skrinska's alleged sharing of knowledge with colleagues would similarly be called into question. The correspondence with Drs. Wei and Sheehan were requests for more information from what they regarded as the source. <sup>106</sup> These actions are inconsistent with a disclosure by Dr. Skrinska conveying a belief in or reliance on the continued public accessibility of the information.

Absent corroborated public reliance, Dr. Skrinska's access would not, in and of itself, have constituted a public use. 107

#### V. CONCLUSION

Patent law has advanced and evolved since the Founders mandated its protections in the Constitution. Courts have endeavored to utilize the statutory bars in ways that balance the interests of the public and inventors. Leaving courts to divine how to reach this balance through creation of new or application of existing tests, however, serves the interests of neither the public nor inventors.

The solution does not lie in waiting for swamped and embattled courts to experience inspiration regarding how to realize the relevant policies. Congress must take clear steps to clarify the law and embody the policies behind it.

The Founders gave Congress the power to promote science and the useful arts and the burden of that promotion sits not on the shoulders of the Court, but on Congress.

 $<sup>^{104}\,\</sup>mathrm{Pronova}$  Biopharma Norge AS v. Teva Pharms. USA, Inc., 867 F. Supp. 2d 502, 519 (D. Del. 2012).

<sup>105</sup> Id.

 $<sup>^{106}</sup>$  *Id* 

<sup>&</sup>lt;sup>107</sup> This analysis reaches a similar conclusion to that reached by the original court. *Id.*