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## Statutory and Ethical Barriers in the Patenting of Medical and Surgical Procedures, 29 J. Marshall L. Rev. 891 (1996)

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# STATUTORY AND ETHICAL BARRIERS IN THE PATENTING OF MEDICAL AND SURGICAL PROCEDURES

WILLIAM B. LAFFERTY\*

*The Patent System . . . added the fuel of interest to the fire of genius.*

Abraham Lincoln<sup>1</sup>

## INTRODUCTION

Members of the medical community are in a quandary over the patenting of surgical and medical techniques.<sup>2</sup> Since the 1950s, U.S. patent law has acknowledged the patentability of medical procedures.<sup>3</sup> However, medical practitioners only now realize that a patent covering their innovative techniques can bestow many benefits.<sup>4</sup> As a result, patents filed for medical processes have steadily increased.<sup>5</sup> Despite this, the American Medi-

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1. ABRAHAM LINCOLN, *Second Lecture on Discoveries and Inventions*, in 3 THE COLLECTED WORKS OF ABRAHAM LINCOLN 363 (Roy P. Basler ed., 1953).

2. Recently, an ophthalmologist who patented a medical procedure to improve cataract surgery by eliminating the use of stitches filed an infringement suit against a medical group for using his procedure during cataract surgery. Joan Szabo, *Should Medical Procedures Be Patented? Doctor Groups Say No by Supporting Bill*, PHYSICIANS FIN. NEWS, June 30, 1995, at 3. Dr. Samuel Pallin wants to collect a five dollar royalty from physicians for every procedure on cataract patients. *Id.* It has been estimated that over 2000 surgeons are infringing the patented procedure. *Id.* See also Ron Stodghill, *First, Do No Harm. Then, Get a Patent*, BUS. WK., July 24, 1995, at 86 (stating that the AMA considers that allowing doctors to patent their surgical techniques is unethical and opportunistic although doctors argue that such patents are incentives for research, allows financial benefits for medical discovery and offers professional recognition for such discoveries); Robert L. Lowes, *Are You Stealing From Other Doctors?*, MED. ECON., Mar. 11, 1996, at 206.

3. Lowes, *supra* note 2, at 196.

4. Szabo, *supra* note 2, at 3; Stodghill, *supra* note 2, at 86.

5. Lowes, *supra* note 2, at 196. Lowes reports that the Patent Office is awarding about 100 pure procedure patents each month which is more than double the number of this type of patents from a decade earlier. *Id.* Also, the Patent Office estimated that 1000 patents for surgical or medical techniques would be issued in 1995. Stodghill, *supra* note 2, at 87.

cal Association (AMA) established a policy prohibiting the patenting of medical and surgical techniques.<sup>6</sup> The AMA believes patenting medical procedures causes potential and often real professional and ethical problems.

For example, an ophthalmologist named Dr. Samuel L. Pallin sought publication of his research article on performing stitchless cataract surgery.<sup>7</sup> The Journal of Cataract and Refractive Surgery rejected the article, leaving Dr. Pallin limited means of publishing his research for the benefit of the public.<sup>8</sup> As a result, Dr. Pallin filed for a U.S. patent for his surgical innovation which was issued in 1992.<sup>9</sup> Currently, this patent is at the center of legal disputes between Dr. Pallin and other physicians because they want to utilize Dr. Pallin's procedure on their own patients without paying Dr. Pallin's requested licensing fee. In 1993, Dr. Pallin sued Dr. Singer, a Vermont physician, for infringement of his patent which Dr. Singer contested as being invalid.<sup>10</sup> Dr. Singer claimed that surgeons other than Dr. Pallin were in fact the first inventors of the new cataract surgery technique, and he asked the court to declare the patent invalid and unenforceable.<sup>11</sup> This lawsuit has come to typify the AMA's concerns. In reaction to such situations, the AMA demands from Congress a law that prohibits physicians from patenting their medical procedures; thus, eliminating the patent's benefits to the medical community.<sup>12</sup>

This Article argues that the AMA's policy of discouraging physicians from patenting their innovative medical procedures is archaic. The Article asserts that the current patent system, which does not bar patenting medical procedures, provides a framework that actually furthers the AMA's interests. Part I begins by explaining the constitutional origin of the United States' Patent System. Part I then reviews the federal case law which established that medical processes are proper patent subject matter. Finally, Part I discusses the Patent Act which provides the framework for patenting physician medical process inventions. While discussing the Patent Act, the Article identifies specific statutory barriers associated with the patenting of these process inventions. Part II examines the AMA's anti-patent policy and the AMA's

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6. Alex Gramling, *AMA Calls Process Patents Unethical*, MED. TRIB. FOR THE FAM. PHYSICIAN, July 13, 1995, at 1; Lowes, *supra* note 2, at 196; Stodghill, *supra* note 2, at 86.

7. Lowes, *supra* note 2, at 206; Stodghill, *supra* note 2, at 86.

8. Lowes, *supra* note 2, at 206; Stodghill, *supra* note 2, at 86.

9. Lowes, *supra* note 2, at 206; Stodghill, *supra* note 2, at 86.

10. Lowes, *supra* note 2, at 209.

11. *Id.*

12. H.R. 1127, Medical Procedures and Innovation Affordability Act, 104th Cong., 1st Sess. (1995); S. No. 1334, Medical Procedures and Innovation Affordability Act, 104th Cong., 1st Sess. (1995).

ethical arguments supporting that policy. Part II then criticizes the AMA's policy against the patenting of medical and surgical procedures by arguing that the AMA's policies should parallel the policies of the Patent and Trademark Office ("PTO"), the legislature and the judiciary. Finally, Part III of this Article concludes that the U.S. patent system should continue to allow the patenting of medical procedures. Supporting the patentability of these procedures fulfills the AMA's interests, the physician's interests, and, most importantly, the public's interests.

### I. THE CURRENT PATENT SYSTEM

A patent is the exclusive right granted by the federal government to an inventor for a limited period of time allowing the inventor to exclude others from making, using, offering to sell or selling his invention.<sup>13</sup> However, these rights do not confer upon inventors the right to make, use, offer to sell or sell the invention. Rather, a patent only confers on the inventor the right to exclude others<sup>14</sup> from practicing the invention if such people have not paid him a certain fees.<sup>15</sup>

For example, suppose the PTO grants to an inventor a patent comprised of elements A, B and C and then a second inventor invents A, B, C and D. The PTO may grant a patent to the second inventor for his invention of A, B, C and D. However, the second inventor's making, using, offering to sell or selling of his own invention would infringe on the first inventor's patent which is comprised of only A, B and C. Moreover, only if no other patented invention contains elements A and B could the first inventor be able to legally practice his own invention without violating the rights of an earlier inventor.

Thus, although an inventor holds a patent on his invention, a patent grant is not a legal monopoly. This is because, as in the instant example, an inventor has no right to infringe on another's patent simply because the inventor holds a patent on an improvement of the other inventor's patent. Instead, for the second inventor to legally practice his invention, A, B, C, and D, he must ob-

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13. 35 U.S.C. § 271(a) (1994). Section 271(a) was recently amended as a result of the General Agreement on Tariffs and Trade (GATT). This amendment allows a patent holder to sue for direct infringement arising from "offers to sale" in addition to making, using and selling. *Id.* This amendment became effective on January 1, 1996. *Id.*

14. 35 U.S.C. § 261 (1994). "Patents shall have the attributes of personal property." *Id.*

15. 35 U.S.C. § 41 (1994). The most common fees associated with obtaining a patent are filing, application processing (prosecution), patent issue and maintenance fees. *Id.* Since December 12, 1980, maintenance fees are due at 3.5, 7.5 and 11.5 years after issuance to keep the patent in force for its full term. *Id.*

tain a license from the first inventor allowing him to utilize the combination of A, B, and C. It is important to note that this scheme does not prevent the dissemination of the second inventor's creation to the public because when an inventor obtains a patent, the patent, describing the invention, is published to the world. Moreover, the personal property right to exclude others only extends within the borders of the United States and its territories.<sup>16</sup>

To enforce the right the patent confers, the law permits the patentee to file a patent infringement suit in federal court. The patent owner can file this claim when the patent owner's exclusive rights are encroached.<sup>17</sup> Additionally, because an owner can often obtain copyright, trademark and/or trade secret protection in addition to a patent, the owner can utilize his distinguishable protective concepts to create a protective umbrella. In some instances the rights that a certain protection conveys to the owner may overlap with another form of protection. For example, an author may be able to obtain a copyright on a book and acquire trademark protection for the book's title when used in association with related goods or services.

Prior to June, 1995, the term of protection was seventeen years from the issue date of a patent.<sup>18</sup> However, after June, 1995, patent protection extended to a twenty year term for most patents.<sup>19</sup> The twenty year term starts from the filing date of a U.S. patent application in the PTO.<sup>20</sup> Congress implemented this change to satisfy the terms of the GATT agreement.<sup>21</sup>

Unlike most countries which follow a "first-to-file" system,<sup>22</sup> the United States follows a "first-to-invent" system.<sup>23</sup> Under the first-to-invent system, the PTO grants a patent to the inventor who is first to invent, not the inventor who first files an application. Thus, although a subsequent inventor could beat the original inventor to the patent Office, the original inventor would ultimately be granted the patent if he could prove he was first to invent.

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16. 35 U.S.C. §§ 100(c), 154, 271(a) (1994). Also, an invention made, used or sold in outer space on a space craft under the control of the United States, or if by agreement otherwise with the state of registry of the space craft, is considered to be made, used or sold in the United States. 35 U.S.C. § 105 (1994).

17. 35 U.S.C. § 281 (1994).

18. 35 U.S.C. § 154.

19. 35 U.S.C. § 154(a)(2) (1994).

20. *Id.*

21. General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125, 1202.

22. JEFFREY G. SHELDON, HOW TO WRITE A PATENT APPLICATION § 1.5.1 (1995).

23. *Id.*

In the United States, there are three types of patents.<sup>24</sup> The most common is the utility patent, which protects the functional aspects of a process or product.<sup>25</sup> In addition, there are design patents for protecting the ornamental design of an article<sup>26</sup> and plant patents for protecting new plants.<sup>27</sup> The term of protection for utility patents and plant patents is twenty years,<sup>28</sup> whereas the term of protection for design patents is fourteen years.<sup>29</sup>

Congress has created five statutory classes for utility patents.<sup>30</sup> If an invention does not fit into one of these five classes, the PTO cannot grant a utility patent. One of these five classes of utility patents is the process patent.<sup>31</sup> Process patents, otherwise known as method patents, protect an invention of a series of steps to be performed in a process.<sup>32</sup> However, a process patent significantly differs when compared to a machine or apparatus patent. A machine or apparatus patent protects the structure of the invention from infringement. Nonetheless, this article focuses only on the process or method patent which covers medical and surgical procedures.

#### A. Constitutional Source

Early British law is the genesis of American patent law. The British patent laws originated from the Letters of Protection to John Kempe in 1331 and the Statute of Monopolies enacted in 1624.<sup>33</sup> John Kempe obtained the first royal grant to develop a cloth industry.<sup>34</sup> However, this grant was not the form of protection we are familiar with today, rather the grant only allowed John Kempe to avoid strict regulations on competition.<sup>35</sup> As a result of abuses with similar monopolies, Parliament passed the Statute of Monopolies.<sup>36</sup> This statute limited the grant of protection to fourteen years which in England developed into what is

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24. 35 U.S.C. §§ 101, 161, 171 (1994).

25. 35 U.S.C. § 101.

26. 35 U.S.C. § 171.

27. 35 U.S.C. § 161.

28. 35 U.S.C. §§ 154, 161.

29. 35 U.S.C. § 173.

30. 35 U.S.C. § 101. An inventor may obtain a patent for a process, machine, manufacture, composition of matter or any improvements of either. *Id.*

31. *Id.*

32. 35 U.S.C. § 101(b) (1994).

33. THE ENCYCLOPEDIA OF PATENT PRACTICE AND INVENTION MANAGEMENT 387, 393-94 (Robert Calvert ed. 1974) [hereinafter ENCYCLOPEDIA OF PATENT PRACTICE].

34. *Id.* at 387. However, the world's first patent was granted in Venice in 1443 for a flour mill. *Id.* at 385.

35. *Id.*

36. *Id.* at 393.

now known as a patent.<sup>37</sup>

After the United States gained independence from Britain, the states retained the authority to issue patents.<sup>38</sup> However, since 1824, the states have not issued any patents.<sup>39</sup> The reason for this is the subsequent enactment of the U.S. Constitution empowered the federal government with the authority to grant patents. The Constitution enables Congress "[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."<sup>40</sup> To achieve this goal, Congress enacted the Patent Act which it has repeatedly revised and amended.<sup>41</sup>

One of the Patent Act's most important functions is that it creates a quid pro quo. Pursuant to the Patent Act, when the PTO grants a patent to an inventor for an invention, the inventor then has an exclusive property right over the invention.<sup>42</sup> Moreover, inventor can transfer the exclusive property right to his heirs and assigns.<sup>43</sup> In exchange, the inventor must disclose the invention to the public.<sup>44</sup> The inventor discloses the complete invention to the public to promote the progress of science. However, the government specifies what may be patented, and prior to the 1950s, the courts held that medical and surgical procedures were unpatentable subject matter.

### B. Early Case Law

One of the first medical procedure patents issued was for a process of anesthetizing patients.<sup>45</sup> This process involved the patient inhaling ether which would make the patient insensitive to

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37. *Id.*

38. *Id.* at 395-96.

39. *Id.* at 396-97. However, the first patent issued in America was issued in 1641 for a method of manufacturing salt. *ENCYCLOPEDIA OF PATENT PRACTICE*, *supra* note 33, at 395. The term of protection was for ten years and was granted by the colony of Massachusetts. *Id.*

40. U.S. CONST. art. 1, § 8, cl. 8.

41. 35 U.S.C. §§ 1-376 (1994). Congress enacted the first patent statute in 1790. Act of Apr. 10, 1790, ch. 7, 1 Stat. 109. This act has been replaced or revised four times. *Id.* The Act presently in effect is the Patent Act of 1952. *Id.* The Patent Act also authorizes the PTO to issue their Rules of Practice in the Code of Federal Regulations (CFR) and in the Manual of Patent Examining Procedure (MPEP). *Id.* These patent regulations may be found in Title 37 of the CFR.

42. 35 U.S.C. §§ 1-376.

43. 35 U.S.C. § 100(d); 35 U.S.C. § 261.

44. 35 U.S.C. § 112.

45. *Morton v. New York Eye Infirmary*, 17 F. Cas. 879, 882 (S.D.N.Y. 1862) (No. 9865).

pain.<sup>46</sup> The courts later held that this patent was invalid.<sup>47</sup> Subsequently, the Patent Office broadly interpreted this case to mean that patents on medical procedures were prohibited.<sup>48</sup> The PTO believed that medical and surgical procedures for treating humans were not patentable because the procedures could not accomplish the same results for all patients.<sup>49</sup> Thus, the Patent Office established that "the method or modes of treatment of physicians of certain diseases are not patentable."<sup>50</sup>

However, in 1954, the Board of Patent Appeals<sup>51</sup> decided that medical or surgical procedures to be used on humans are patentable.<sup>52</sup> The Board of Appeals departed from the general reluctance to patent medical procedures because predicting uniform results from medical processes became more accurate.<sup>53</sup> Thus, the judiciary and the PTO no longer fear that medical process patents interfere with public interest. In fact, the judiciary recognizes the important role that these patents play in medical research; therefore, the judiciary has changed the law to keep up with this contemporary technology.

### C. A Discussion of the Patent Act

In order to be granted a patent by the PTO, an inventor must prove that the invention is new, useful and non-obvious.<sup>54</sup> In addition, the inventor must show that his invention is either a "process, machine, manufacture, composition of matter or any new and useful improvement thereof."<sup>55</sup> When the inventor is demonstrating that the invention has novelty, utility and non-obviousness, the inventor must prove those qualities against the "prior art." The phrase "prior art" refers to the existing body of technological information before the date of invention of the subject matter sought to be patented.<sup>56</sup>

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46. *Id.*

47. *Id.* at 883.

48. William D. Noonan, *Patenting Medical and Surgical Procedures*, J. PAT. OFF. SOC'Y, Aug. 1995, at 653 (citing *Ex Parte* Brinkerhoff, 24 Comm'r Dec 349 (1883)).

49. DONALD S. CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, § 1.03[3] (1995).

50. 24 Comm'r Manuscript Dec. 349 (Case No. 182, July 5, 1883), reprinted in 27 J. PAT. OFF. SOC'Y 797 (1945).

51. The Board of Patent Appeals is an administrative board at the PTO that hears appeals from the decisions of examiners rejecting claims of patentability of applicants.

52. *Ex parte* Scherer, 103 U.S.P.Q. 107, 110 (Pat. Off. Bd. App. 1954).

53. At this time, the AMA Judicial Council stated that it no longer considered medical process patents unethical because of the expenses required for modern research. Noonan, *supra* note 48, at 655.

54. 35 U.S.C. §§ 100-103 (1994).

55. 35 U.S.C. § 101.

56. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149-50 (1989)



Only after the inventor successfully proves that the invention has the above qualities, will the PTO grant the inventor the right to exclude others from making, using, offering to sell or selling the invention in the United States.<sup>57</sup> Furthermore, a patent application must describe the invention's characteristics and parameters in sufficient detail to allow one to practice the invention.<sup>58</sup> This includes the best mode known to the inventor of practicing the invention.<sup>59</sup> If the PTO grants the patent, it is then published to the world, along with all of the invention's details. As a result of this disclosure, the inventor's exclusive rights last for twenty years from the date the patent application is filed in the PTO.<sup>60</sup>

This Section of the Article focusses on the hurdles that an invention must cross before the PTO will grant a patent. First, this Section discusses what the PTO considers patentable and the scope of protection over a patented invention. Second, this Section explains the Patent Act's provisions requiring the invention be novel. The Section explains the statutory bars that the invention must avoid before the invention meets the novelty requirement. Lastly, this Section explores the non-obviousness requirement by again revealing the statutory bars that the invention must pass in order to meet this requirement.

### 1. Patentability and Scope of Protection

Section 101 of the Patent Act prescribes what is patentable subject matter for a process patent.<sup>61</sup> The Supreme Court broad-

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(discussing that the novelty requirement is not met when the prior art anticipates the invention being considered for patenting).

57. 35 U.S.C. § 154 (1994).

58. 35 U.S.C. § 112 (1994).

59. *Id.*

60. 35 U.S.C. § 154(a)(2).

61. See *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (allowing the patenting of a process by applying a formula in a step for curing rubber and satisfying § 101 rather than claiming the formula itself as patentable); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (excluding laws of nature, natural phenomena and abstract ideas as patentable subject matter); *Parker v. Flook*, 437 U.S. 584, 590 (1978) (holding post-solution activity with an algorithm is improper patent subject matter); *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972) (holding algorithms or formulas are not patentable subject matter because they are merely ideas and the patenting of algorithms or formulas would wholly preempt the ideas); *Tilghman v. Proctor*, 102 U.S. 707, 708 (1880) (holding a patent for a process is patentable although process patents are not yet statutorily provided for); *In re Freeman*, 573 F.2d 1237, 1247 (C.C.P.A. 1978) (prohibiting the rejection of patent applications relying upon a point of novelty within a computer program); *In re Richman*, 563 F.2d 1026, 1030 (C.C.P.A. 1977) (excluding data gathering in a process patent for correcting radar calculations with a formula as proper patent subject matter); *Cincinnati Traction Co. v. Pope*, 210 F. 443, 446 (6th Cir. 1913) (stating that the patenting of business transactions is prohibited; however, a method of doing business with a train ticket comprising a physical structure defined by written

ened the scope of the patent grant by holding that patentable subject matter "include[s] anything under the sun that is made by man."<sup>62</sup> Section 101 also contains a utility requirement, by requiring the invention be new and useful.<sup>63</sup> Section 101 provides that whoever "discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent."<sup>64</sup> "Process"<sup>65</sup> is defined as "a new use of a known process, machine, manufacture, composition of matter, or material."<sup>66</sup> The Supreme Court of the United States defines a process as "an act or series of acts, performed upon the subject matter to be transformed and reduced to a different state."<sup>67</sup> Currently, the PTO includes medical processes in the above definitions.

In 1988, Congress broadened the scope of protection for process patents by enacting the Process Patent Amendment.<sup>68</sup> Pursuant to the Amendment, patentees may exclude others from using or selling, within the United States, products illegally made by their patented process.<sup>69</sup> Further, the patentees may exclude others from importing such products into the United States<sup>70</sup> irrespective of whether those merchants themselves are patented in the United States.<sup>71</sup> Without this protection, an imported product made outside the United States could be assumed to have

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indicia is patentable subject matter).

62. *Chakrabarty*, 447 U.S. at 309 (holding that living micro-organisms genetically altered by man are patentable) (citing S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952)).

63. "Useful" is defined as something which is not mischievous or immoral and "new" is defined as "substantially new in its structure and mode of operation, and not merely a change in form." *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (Mass. Cir. Ct. 1817) (No. 8568). Moreover, an invention does not have to be an advance over the prior art under the utility requirement. *Bedford v. Hunt*, 3 F. Cas. 37, 37-8 (Mass. Cir. Ct. 1817) (No. 1217). See *In re Buting*, 418 F.2d 540, 544 (C.C.P.A. 1969) (rejecting method claims where efficacy evidence is insufficient to support utility in humans); *In re Jolles*, 628 F.2d 1322, 1327 (C.C.P.A. 1980) (holding that evidence of utility towards use on humans is relevant and animal models are acceptable if they have predictability towards humans); *Ex Parte Maas*, 9 U.S.P.Q.2d 1746, 1748 (Bd. of Pat. App. & Int. 1987) (affirming examiner's rejection for lack of patentable utility where the burden is on the applicant to show significance of the utility experiments).

64. 35 U.S.C. § 101.

65. In 1952, Congress adopted the term "process" in place of the "art". 35 U.S.C. § 100(b).

66. *Id.*

67. *Diamond*, 450 U.S. at 183.

68. Process Patent Amendment Act of 1988, Pub. L. No. 100-418, §§ 9001-9007 (codified as amended at 35 U.S.C. §§ 271(g), 287(b), and 295 (1994)).

69. 35 U.S.C. § 295.

70. *Id.*

71. *Id.*

been made according to the patentee's process.<sup>72</sup> Therefore, Congress enhanced all patentees' ability to protect their process patents.

## 2. *The Invention Must Be Novel*

Section 102 imposes one of the most common barriers to obtaining a utility patent — novelty.<sup>73</sup> Generally, § 102 defines novelty as the requirement that the invention have components that are different not only from all previous inventions, but also from what is otherwise known.<sup>74</sup> Under § 102, the PTO will not patent an invention where all the elements in the invention are present in a single issued U.S. or foreign patent or where the complete invention was described in a publication anywhere in the world.<sup>75</sup> Furthermore, the PTO will reject a patent application if the PTO determines that the invention is already known to the United States public.<sup>76</sup> The reasoning is that the invention was anticipated or was already in the public's possession.<sup>77</sup>

More specifically, §§ 102(a) through (g) are known as statutory bars which often prevent inventors from obtaining patents. Among those, §§ 102(a), (b), (e) and (g) define prior art for purposes of the novelty requirement.<sup>78</sup> Sections 102(a), (b), (e) and (g) assert when and how prior art can disqualify an invention from being patented.<sup>79</sup> If prior art contains elements similar to those in the applicant's invention, the PTO may cite that prior art against the applicant's invention.<sup>80</sup> As a result, the PTO may find that the applicant's invention has been contemplated and thus, does not meeting the novelty requirement.<sup>81</sup>

### a. Knowledge/Use

Section 102(a) prevents an inventor from obtaining a patent where the invention is already known or someone in the United

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72. *Id.*

73. 35 U.S.C. §§ 102, 103.

74. *Id.*

75. *Id.*

76. *Id.*

77. *In re Borst*, 345 F.2d 851, 854-55 (C.C.P.A. 1965).

78. *In re Bass*, 474 F.2d 1276, 1285 (C.C.P.A. 1973). The *Bass* court stated that not everything in § 102 is prior art. *Id.* Only, subsections (a), (b), (e) and (g) deal with prior art. *Id.* Also, the same court in 1964 stated that references cited under subsections (a), (b) and (e) are prior art. *In re Harry*, 333 F.2d 920, 923 (C.C.P.A. 1964). Moreover, the United States Supreme Court has held that a pending U.S. patent application is prior art. *Hazeltine Research, Inc., v. Brenner*, 382 U.S. 252, 254-55 (1965).

79. 35 U.S.C. §§ 102 (a), (b), (e), (g).

80. *Id.*

81. *Id.*

States used the invention before the inventor's date of invention.<sup>82</sup> In the context of § 102(a), the invention is "already

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82. 35 U.S.C. § 102(a). The date of invention is the date the invention is deemed to have been invented. *See* CHISUM, *supra* note 49, at § 3.08. There are three possible ways to obtain an invention date. RONALD B. HILDRETH, *PATENT LAW: A PRACTITIONER'S GUIDE* 104 (1993). The first is when the inventor conceives the complete and operable invention in his mind. *Id.* Also, the inventor may be required to demonstrate diligence after his conception. *Id.* at 105. Diligence is a continuing effort to file a patent application or to make the invention. CHISUM, *supra* note 49, at § 10.07. The second possible date of invention is the date of actual reduction to practice. HILDRETH, *supra* at 104. Simply, an actual reduction to practice is the physical construction of the complete and operable invention. *Id.* Lastly, an invention date may be the date of constructive reduction to practice by filing a patent application in the U.S. PTO. *Id.* The effective filing date is the date the U.S. application is actually filed in the PTO or the date that may be obtained from the benefit of an earlier filed application. *Id.* at 39. Thus, prior art under § 102(a), (e) and (g) can be overcome by showing an invention date prior to the date of the cited reference; an effective filing date. *Id.* With the effective filing date, an inventor's application receives an earlier date of invention which may avoid some prior art. *Id.* Thus, a constructive reduction to practice may be the invention date as well as the effective filing date.

However, a statutory bar based upon § 102(b) cannot be eliminated by showing a date of invention prior to the cited prior art. 35 U.S.C. § 119 (1994); *Patents Trademarks and Copyrights*, 37 C.F.R. § 1.131 (1995). This is because § 102(b) focuses upon the effective filing date of the inventor's U.S. patent application in the PTO. 35 U.S.C. § 102 (1994). Four types of patent applications can provide for an effective filing date before the actual U.S. filing date in order to avoid certain § 102 statutory bars: a § 120 continuation application, a § 120 continuation-in-part application, a § 121 divisional application, or an application under § 119. HILDRETH, *supra* at 39. However, the effective filing date cannot include the benefit of a foreign convention date for determining § 102(b) statutory bars because of an exception specified at the end of the first paragraph of section 119. 35 U.S.C. § 119; *see also* HILDRETH, *supra* at 43, 58. A continuation application is a second application for the same invention filed by the same inventor containing the same disclosure which is filed while the first application is still pending. CHISUM, *supra* note 49, at § 13.03[2].

In a continuation application, the inventor retains the benefit of the earlier filing date of the first application. *Id.* A continuation-in-part is a second application for the same invention by the same inventor adding new matter which was not contained in the disclosure of the first application. *Id.* § 13.03[3]. Also, the first application is still pending when the continuation-in-part is filed. *Id.* As a result of the new disclosure, new and different claims are required which are only entitled to a later filing date than the pending first application. *Id.* A divisional application is an application carried out of a pending application and disclosing and claiming only subject matter disclosed in the earlier application. CHISUM, *supra* note 49, § 13.03[4]. The divisional application is usually filed as a result of a restriction requirement and is entitled to the original application's filing date. *Id.* Under § 119, a U.S. patent applicant who has filed an earlier patent application in a convention foreign country may receive the benefit of the earlier filing date of the corresponding foreign application in the foreign convention country. 35 U.S.C. § 119. The countries which are members of the International Convention are provided in § 201.13 of the Manual of Patent Examining Procedure. *PATENT AND TRADEMARK OFFICE, UNITED STATES DEPT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE* § 201.13 (6th ed. rev. Sept. 1995). However, only if the U.S. patent

known" if the public could have accessed knowledge of the invention's existence in the United States.<sup>83</sup> Therefore, if an invention has been previously discovered before the applicant discovered it and the public could have "known" of the invention's existence, the PTO will deem the applicant's invention anticipated and, thus, barred for lack of novelty. The purpose behind this provision is to prevent a subsequent inventor from securing a patent where the invention has already been put in the public domain.

#### b. Prior Patents on the Invention

Sections 102(a) and 102(b) expressly prohibit a patent for an invention where that invention has already been patented. Sections 102(a) and 102(b) can be distinguished in two ways: first, by whose patent may be cited against an applicant as prior art; and, second, whether the cited reference either antedates the inventor's invention date or the inventor's effective filing date. Section 102(a) bars an applicant from claiming an invention that is patented by someone other than the inventor, anywhere in the world, before the inventor's date of invention.<sup>84</sup> However, § 102(b) bars the inventor from claiming an invention that is patented by the inventor or anyone else, more than one year before the inventor's effective filing date of the inventor's U.S. patent application.<sup>85</sup>

#### c. Publications

Sections 102(a) and 102(b) both prohibit the issuance of a patent where the invention is described in a printed publica-

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application was filed within twelve months of the same invention's earlier filing date in the foreign convention will the applicant be entitled to the earlier filing date for the U.S. patent application. 35 U.S.C. § 119. The earlier foreign filing date for the same invention becomes the effective filing date for the U.S. patent application. *Id.* Moreover, according to § 119, the U.S. filing date can not include the benefit of an earlier foreign convention filing date for determining § 102(b) statutory bars. *Id.*; see also HILDRETH, *supra* at 43, 58.

Alternatively, an applicant may antedate the prior art cited by the examiner by declaring that the invention was completed in this country before the filing date of his U.S. patent application. 37 C.F.R. § 1.131. The inventor merely swears to the date he first conceived the invention in the United States and obtains a date than that on which he actually filed his application. However, the inventor can not obtain the benefit of this rule where the prior art is cited under § 102(b). 37 C.F.R. 1.131.

83. See *In re Borst*, 345 F.2d 851, 855-56 (C.C.P.A. 1965) (creating an exception to the general rule requiring access for the public where the documents were classified by the Atomic Energy Commission); *Illinois Tool Works, Inc. v. Solo Cup, Inc.*, 461 F.2d 265, 270-71 (7th Cir. 1972) (requiring knowledge of the invention's existence by others rather than by the inventor).

84. 35 U.S.C. § 102(a).

85. 35 U.S.C. § 102(b).

tion.<sup>86</sup> In the context of a published description of the invention, §§ 102(a) and 102(b) are distinguished by who authored the description and, again, the date from which the publication of such description must antedate.<sup>87</sup> Under § 102(a), if the PTO finds that a description of the applicant's invention, which was not authored by the inventor, appeared in a printed publication in the United States or a foreign country prior to the time the applicant discovered the invention, the PTO may cite that description as prior art against the applicant.<sup>88</sup> Whereas under § 102(b), if the PTO finds that a published description of the applicant's invention, authored by anyone including the applicant, appeared anywhere in the world more than one year prior to the applicant's effective filing date, the PTO may cite that reference as prior art against the applicant.<sup>89</sup> It is important to note that these provisions allow the inventor to begin disseminating a description of the invention before filing for a patent, so long as such dissemination is no earlier than a year before the invention's filing date, and the patent itself becomes public after the PTO issues it. However, to determine whether a published description constitutes prior art, the PTO must find two additional requirements.

First, the published description must contain enough detail to enable one ordinarily skilled in the relevant art to recreate and practice the invention with one's own knowledge and without undue experimentation.<sup>90</sup> This type of description is commonly known as an "enabling disclosure." However, a published description still qualifies as an enabling disclosure even though no one made the invention. Rather, a single publication which contains all of the invention's elements anticipates the invention and will qualify as prior art even though additional information is required to enable one to make the invention.<sup>91</sup> The description's

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86. 35 U.S.C. § 102 (a). *See generally In re Wyer*, 655 F.2d 221 (C.C.P.A. 1981) (holding that microfilm is a printed publication and that there are no physical requirements in the form of the publication so long as the publication was intended for others to see).

87. Section 102(b) allows the inventor's own prior work to be cited against his subsequent invention and focuses upon the effective filing date. 35 U.S.C. § 102(b). On the other hand, § 102(a) prohibits the citing of the applicant's own work against him because the statute requires knowledge *by others* and focuses upon the invention date. 35 U.S.C. § 102(a).

88. 35 U.S.C. § 102(a).

89. 35 U.S.C. § 102(b); *In re Legrice*, 301 F.2d 929, 933-34 (C.C.P.A. 1962) (stating that the description must be detailed enough so that one can practice the invention without undue experimentation).

90. *Legrice*, 301 F.2d at 939 (providing that a picture of a plant does not qualify as an enabling disclosure); *see also Paperless Accounting Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659 (Fed. Cir. 1986) (holding that foreign patent contained an insufficient disclosure to anticipate against U.S. application for the same invention).

91. *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) (indicating how much dis-

detail merely needs to convince one skilled in the art that the invention will work.<sup>92</sup> Yet, failure in recreating the invention by those skilled in the art is evidence that the publication's disclosure does not satisfy this enablement requirement.<sup>93</sup>

Second, the public must be able to access the published description before such description of the invention qualifies as prior art under § 102(b).<sup>94</sup> For example, a magazine publication is accessible on the day it is received by the public rather than the date on the face of the publication.<sup>95</sup> Additionally, an undergraduate thesis located in a university library is accessible if it is cataloged and indexed in a meaningful way.<sup>96</sup> If the date the thesis became available is uncertain, the court will rely upon established business practices to determine when the publication was accessible to the public.<sup>97</sup> Nevertheless, a college thesis is not considered accessible if a researcher in the relevant field could not discover the thesis using reasonable diligence.<sup>98</sup>

To determine whether a bar exists once the date of a publication is established, one examines the publication for an enabling disclosure and then verifies the reference's dissemination to someone ordinarily skilled in the relevant subject.<sup>99</sup> Therefore, to obtain a patent, the applicant-inventor must avoid the above statutory bars. However, these bars can be used in other ways. For example, an accused infringer may successfully defend himself by proving that the patentee failed to overcome one of the above mentioned statutory bars created by disclosure in a publication

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closure is required for enablement).

92. *Id.* Thus, it is not necessary for the invention to actually be made in order to satisfy the enablement requirement. *Id.*

93. *Id.*

94. *Northern Telecom, Inc., v. Datapoint Corp.*, 908 F.2d 936-37 (Fed. Cir. 1990) (keeping documents on military installation requiring security clearance for access and not for public release were not accessible to the public); *De Graffenried v. United States*, 16 U.S.P.Q.2d 1321, 1331 (Cl. Ct. 1990) (restricting access to registered users is insufficient access to the public because of confidentiality requirements).

95. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 139 (Fed. Cir. 1986) (requiring the applicant to show the date one ordinarily skilled in the art would have received the publication in the mail); *Ex Parte Hudson*, 18 U.S.P.Q.2d 1322, 1323 (Bd. of Pat. App. and Int. 1990) (reversing examiner's application rejection where publication was not received by public before the critical date).

96. *Cf. In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989) (holding that the storage of undergraduate thesis in a shoe box and cataloged by the author's name is not considered an example of information accessible to the public).

97. *Id.*

98. *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986).

99. *See E.I. Du Pont de Nemours & Co. v. Cetus Corp.*, 19 U.S.P.Q.2d 1174, 1186 (N.D. Cal. 1990) (holding that a doctor's funding proposal was an accessible printed publication where the doctor was recognized as an expert on the relevant subject).

constituting prior art.

d. Public Use

Pursuant to § 102(b), the PTO will not grant a patent if the claimed invention was in public use or on sale in the United States for more than one year before the filing date of the inventor's U.S. patent application. Section 102(b) bars inventors from obtaining a patent if they wait longer than the one year grace period to file a patent application for their invention.<sup>100</sup> The one year grace period is designed to allow inventors the time to evaluate commercial acceptance of their invention in the public domain.

However, "public use" is a term of art, defined differently than its common usage. For public use to bar a patent, the use need not be public.<sup>101</sup> A public use statutory bar exists, according to § 102(b), even though the public never saw the invention.<sup>102</sup> Generally, public use is defined as use of the invention by anyone who is not under a restriction or an obligation of secrecy to the inventor.<sup>103</sup> To establish a statutory bar, such use may be as limited to a single individual using the invention or the use of a prototype.<sup>104</sup>

However, public use for experimental purposes will not prevent the PTO from granting a patent because of a statutory bar. An experimental use exists if the primary purpose of the public use is to complete the invention, rather than to pursue commercial goals.<sup>105</sup> This exception to the public use bar allows the inventor to publicly test an invention if the nature of the invention requires such testing.<sup>106</sup> This exception permits the inventor to test the invention in its intended environment; thus, giving the inventor the surroundings necessary to perfect the discovery.<sup>107</sup>

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100. 35 U.S.C. § 102(b).

101. *Kinzenbaw v. Deer & Co.*, 741 F.2d 383, 390 (Fed. Cir. 1984) (stating that "[a] commercial use is a public use even if it is kept secret.>").

102. *Egbert v. Lippmann*, 104 U.S. 333, 337-38 (1881) (holding that sleeping on rights for 11 years bars the granting of patent rights where the inventor created a prototype corset for his girlfriend which was never in public view).

103. *Id.*; *In re Smith*, 714 F.2d 1127, 1134 (Fed. Cir. 1983).

104. *Egbert*, 104 U.S. at 336.

105. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 134-35 (1878) (concluding that six years of testing road surface constituted experimental use); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990) (finding no public use bar to patent which claimed light fixture requiring outdoor testing to determine whether the invention would serve its purpose); *Pennwalt Corp. v. Akzoa Inc.*, 740 F.2d 1573, 1581 (Fed. Cir. 1983) (stating that experimenting for FDA purposes in order to commercially exploit the invention is not necessarily experimental use for statutory bar purposes).

106. *See, e.g., Manville*, 917 F.2d at 549.

107. *Id.*



The existence of a public use bar without experimental use must be determined by considering the totality of the circumstances.<sup>108</sup> The relevant factors in this analysis include the lack of record keeping, the lack of control by the inventor, the lack of secrecy obligations on the part of the user and the existence of promotional activities.<sup>109</sup> Establishing these factors indicates that the primary purpose of the use at issue was other than experimental; thus, invoking § 102(b)'s public use bar which blocks the issuance of a patent. However, as seen above, if the patentee establishes experimental use, that use negates § 102(b)'s statutory bar for public uses,<sup>110</sup> even if for an extended time.

#### e. On Sale

Section 102(b) also provides a statutory bar where the invention has been on sale more than one year before the filing of a patent application.<sup>111</sup> Public policy prohibits the inventor from exploiting the invention commercially for longer than one year. This statutory bar forces the inventor to choose between obtaining patent protection promptly after the sale or taking a chance against competitors without the patent protection.<sup>112</sup> The invention does not have to be sold, rather, the invention merely has to be offered for sale. Moreover, an on-sale-bar can arise without the invention being physically on hand.<sup>113</sup> No requirement exists that the invention be reduced to practice requiring all the limitations to be present. Instead, a model of the invention may be sufficient.<sup>114</sup> Furthermore, a price quotation could constitute an offer for sale even though the quote failed to specifically identify the invention.<sup>115</sup> Consequently, an invention can be on sale and invoke the statutory bar despite the lack of inventory on hand.

#### f. Patented in a Foreign Country

Section 102(d) asserts a bar for lack of novelty where the

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108. *United States Envtl. Prod., Inc., v. Westall*, 911 F.2d 713, 716-17 (Fed. Cir. 1990).

109. *Id.*

110. *TP Lab., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971-72 (Fed. Cir. 1984). The Court of Appeals for the Federal Circuit has characterized experimental use as negating public use, rather than as an exception to public use. *Id.*

111. 35 U.S.C. § 102(b).

112. *General Elec. Co. v. United States*, 654 F.2d 55, 61 (Ct. Cl. 1981).

113. *BarMag Barmer Maschinenfabrik Ag v. Murata Mach., Ltd.*, 731 F.2d 831, 836-37 (Fed. Cir. 1984); *see UMC Elecs., Co. v. United States*, 816 F.2d 647, 657 (Fed. Cir. 1987) (holding that a bid proposal to the Navy constituted statutory on-sale-bar where the invention was represented in the proposal).

114. *UMC Elecs. Co.*, 816 F.2d at 657.

115. *Sonoscan Inc. v. Sonotek, Inc.*, 936 F.2d 1261, 1263-64 (Fed. Cir. 1991).

inventor both filed and patented the same invention in a foreign country.<sup>116</sup> Section 102(d) bars the issuance of a patent if the U.S. patent-applicant, the agent, or assign successfully patented the invention, or the invention was subject to an inventor's certificate in a foreign country more than one year before the inventor filed for the U.S. patent.<sup>117</sup> Accordingly, if an inventor's corresponding foreign application was filed more than one year before the filing date for a U.S. patent and if the foreign patent application was granted before the U.S. application's effective filing date, there is a § 102(d) statutory bar.<sup>118</sup>

#### g. Disclosure in a United States Patent

Section 102(e) denies a patent to an applicant where a prior inventor described the same invention in a U.S. patent application, and the PTO eventually grants a patent to the prior inventor for the invention.<sup>119</sup> This part of the statute requires that the cited reference have an earlier filing date than the current applicant and that the PTO issue the patent after the current applicant's invention date.<sup>120</sup> The purpose behind this provision, as well as other provisions, is to prevent a second applicant from securing a patent over the first inventor, in instances where the second applicant discovered an invention and may not have known of the prior inventor.<sup>121</sup> Moreover, § 102(e) prevents the first inventor from being penalized because of examination delays at the PTO. Such delays in issuing the patent to the first inventor prevent the patent from providing notice of the first inventor's discovery to the subsequent applicant.

#### h. Made by Another/Interferences

Section 102(g) bars a person from securing a patent if another person in the United States had made and had not abandoned, suppressed or concealed the invention.<sup>122</sup> Subsection (g) does not

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116. 35 U.S.C. § 102(d).

117. *Id.*

118. *In re Talbott*, 443 F.2d 1397, 1399 (C.C.P.A. 1971).

119. 35 U.S.C. § 102(e). A reference cited under § 102(e) is prior art once the patent eventually issues. *In re Harry*, 333 F.2d 920, 923-24 (C.C.P.A. 1964). The Supreme Court has held that a pending U.S. patent application is prior art. *Hazeltine Research, Inc., v. Brenner*, 382 U.S. 252, 256 (1965).

120. 35 U.S.C. § 102(e).

121. *See generally* *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926) (illustrating the first inventor rule).

122. 35 U.S.C. § 102(g); *see also* *Gayler v. Wilder*, 51 U.S. 477, 497 (1850) (abandoning invention used for private purposes does not constitute prior art); *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982) (holding that describing the invention in a publication is insufficient for 102(g) purposes because subsection (g) requires that the invention actually be made); *Palmer v. Dudzik*, 481 F.2d 1377, 1385-86

require that an inventor have actual personal knowledge that another inventor previously made the invention.<sup>123</sup> Rather, this section is the basis for an interference proceeding, which is an administrative proceeding in the PTO before the Board of Patent Appeals and Interferences. During this proceeding, the PTO determines priority between two inventors claiming the same invention, invented at different times.<sup>124</sup> As a result of § 102(g), the inventor who loses the interference proceeding is prohibited from obtaining a patent. Generally, the PTO awards priority to the senior inventor, who is the first inventor to file, over the junior inventor. After the PTO determines that the senior inventor was also the first to invent, the senior inventor may apply for the patent.

It is important to understand that the term "invention" or "to invent" actually refers to a two-step process. An invention consists of its conception plus its reduction to practice.<sup>125</sup> Accordingly, for an inventor to have discovered an invention, he must have formed the complete invention in his mind, followed by either an actual or constructive reduction to practice.<sup>126</sup> A constructive reduction to practice is filing an enabling patent application in the PTO.<sup>127</sup> Alternatively, an actual reduction to practice is making the complete and operable invention with all of its limitations.<sup>128</sup>

A common problem with interferences between two competing inventors who have invented at different times is where one of the inventors was the first to conceive the invention but the last to reduce the invention to practice.<sup>129</sup> For instance, before the first inventor could reduce his ideas to practice, thus making his invention, the second inventor both conceived and reduced to practice the same invention.<sup>130</sup> In situations such as these where the se-

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(C.C.P.A. 1973) (awarding priority to the junior inventor where the court determined that although the senior commercially used the invention, such use conveyed no information to the public, thus failing to negate a conclusion that the invention was concealed pursuant to § 102 (g)); *Sutter Prod. Co. v. Pettibone Mulliken Corp.*, 428 F.2d 639, 645 (7th Cir. 1970) (pending confidential application is 102(g) prior art once the patent issues);

123. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1460 (Fed. Cir. 1984).

124. 35 U.S.C. § 135.

125. EARNEST B. LIPSCOMB, *LIPSCOMB'S WALKER ON PATENTS*, § 3:11 (3d ed. 1984).

126. *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985); *Gunter v. Stream*, 573 F.2d 77, 81 (C.C.P.A. 1978).

127. *Travis v. Baker*, 137 F.2d 109, 111 (C.C.P.A. 1943).

128. *Newkirk v. Lulejian*, 825 F.2d 1581, 1582-83 (Fed. Cir. 1987); *Great N. Corp. v. Davis Core & Pad Inc.*, 782 F.2d 159, 165 (Fed. Cir. 1986).

129. *Automatic Weighing Mach. Co. v. Pneumatic Scale Corp.*, 166 F. 288, 290-91 (1st Cir. 1909).

130. *Id.*

nior is the first to conceive, but second to reduce to practice, the senior inventor's priority over the junior depends upon three key inquiries: (1) whether the senior conceived the ideas for the complete invention before the junior conceived his ideas; (2) whether the senior reduced the invention to practice before the junior reduced the invention to practice; and, (3) whether the senior exhibited uninterrupted diligence to reduce to practice, beginning just prior to the junior's conception date up to the senior's reduction to practice.<sup>131</sup> Diligence is the "continuous inventive activity by the inventor who was first to conceive" the invention.<sup>132</sup>

Even though the second inventor is the first to reduce the invention to practice after conception, thus completing the invention, the first inventor may still be awarded priority. A first inventor will be awarded priority if he demonstrates uninterrupted diligence towards reducing the invention to practice and if his conception date was earlier than the second inventor's. However, if the senior fails to show uninterrupted diligence to reduce to practice the proposed invention although he conceived the ideas before the junior inventor, the PTO could award priority to the junior inventor who then could secure the patent on the invention.<sup>133</sup> Thus, in an interference proceeding, the statutory bar under § 102(g) prohibits an inventor from securing a patent where the complete invention was first made by another in this country.<sup>134</sup>

### 3. The Invention Cannot Be Obvious

Even if the applicant's invention is not exactly described in a prior art reference, the PTO will still deny a patent if the differences between the invention proposed to be patented and the prior art references are obvious.<sup>135</sup> Section 103 requires that the invention be non-obvious from the standpoint of someone with ordinary skill in the invention's technology.<sup>136</sup> For example, to es-

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131. *Id.*

132. MCCARTHY, THOMAS J., MCCARTHY'S DESK ENCYCLOPEDIA OF INTELLECTUAL PROPERTY, 97-98 (1991). Moreover, an attorney's own diligence in completing a patent application is relevant in the priority determination. *Bey v. Kollonitsch*, 806 F.2d 1024, 1029 (Fed. Cir. 1986). Generally, a patent attorney is required to work on patent applications in the chronological order based upon when the inventor makes his disclosure. *Id.* However, where the applications consist of related technology, work that is other than chronological may show reasonable diligence. *Id.* A delay in filing a patent application will not be excused where the applicant is awaiting funding to prosecute the application. *Griffith v. Kanamaru*, 816 F.2d 624, 625-26 (Fed. Cir. 1987).

133. *Automatic Weighing Mach.*, 166 F. at 305.

134. 35 U.S.C. § 102(g).

135. *Graham v. John Deere Co.*, 383 U.S. 1, 3-4 (1966).

136. 35 U.S.C. § 103.

tablish that the subject invention is obvious, the PTO may combine elements from many different issued patents determined to be relevant to the specific technology. To combine references containing the elements of the pending invention, there must be a motivation to combine those reference in order to sustain a rejection based on obviousness.<sup>137</sup> In other words, there must be a suggestion of the combination of elements from the prior art references and an expectation of success when those elements are combined.<sup>138</sup> However, the courts have only required a reasonable expectation of success in light of the prior art rather than an absolute predictability of success.<sup>139</sup> Furthermore, the full range of technology in the invention's field must be considered when combining prior art to constitute a valid rejection for obviousness.<sup>140</sup>

The U.S. Supreme Court has held that § 103 requires a four-part factual inquiry.<sup>141</sup> Under this analysis, "the scope and content of the prior art are to be determined; the differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."<sup>142</sup> To avoid using hindsight in determining obviousness, the fourth inquiry involves secondary considerations of objective evidence such as commercial success, long felt needs and the failure of others.<sup>143</sup> Once the PTO has completed this inquiry, the PTO can determine whether an applicant's invention is or is not obvious. The PTO employs the obviousness inquiry, discussed above, no matter what type of invention, method or process is involved.

Therefore, although various provisions of the Patent Act prohibit the issuance of a patent, such as an inventor's failure to establish a patentable invention or the existence of a statutory bar

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137. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

138. *Id.*

139. See, e.g., *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988) (denying a patent where publication explicitly suggested the likelihood of success).

140. *Dow Chem. Co.*, 837 F.2d at 473.

141. *John Deere Co.*, 383 U.S. at 17.

142. *Id.* Whether references are within the scope of relevant prior art or are nonanalogous is determined by whether the cited "reference is within the field of the inventor's endeavor" and "whether the reference is reasonably pertinent to the particular problem with which the inventor was involved." *In re Deminski*, 796 F.2d 436, 441 (Fed. Cir. 1986). The determination of what is ordinary skill in the art is a factual inquiry by the fact finder where expert testimony may be given as to the level of ordinary skill at the time the invention was made. *Marlsbary Mfg. Co. v. Ald, Inc.*, 447 F.2d 809, 811 (7th Cir. 1971).

143. *John Deere Co.*, 383 U.S. at 17. Where there is evidence of another's failure, it demonstrates a lack of likelihood of success. *Amgen, Inc., v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1208 (Fed. Cir. 1991) (holding patent valid over obviousness claim where no reasonable expectation of success can be derived from the prior art).

based upon the inventor's or others' activities, nothing in the Patent Act prevents a member of the medical community from securing a patent for a medical process. Moreover, the Patent Act is the basis for the PTO to implement its own rules for the examination of such patents. Thus, inventors from all fields currently have the right to apply for patent protection for inventive surgical methods and procedures, and the policies behind the statutory bars do not prohibit physicians from enforcing such processes. However, the AMA continues to lobby Congress to enact laws that prevent or limit the medical community as well as everyone else from pursuing their right to patent their innovative medical procedures.

## II. THE FRAMEWORK OF THE CURRENT PATENT SYSTEM FURTHERS THE AMA'S INTERESTS

The AMA advocates an archaic policy of discouraging physicians from patenting medical procedures. Nonetheless, the current U.S. patent system provides a sufficient framework for patenting medical procedures which furthers the AMA's interests. Section A details the AMA's policy of discouraging physicians from patenting their procedures and the AMA's argument supporting that policy. Section A further illustrates how the AMA's policy is at odds with public policy. Section B argues that the AMA's policy of discouraging medical procedure patents is archaic and does not further the AMA's interests as well as does the current patent system. It argues that the patent system better promotes research and development while the AMA's policy actually impedes such development. Lastly, Section B argues that the current system provides sufficient statutory barriers and safeguards which protect the AMA's ethical concerns.

### A. *The American Medical Association's Patent Policy versus Public Policy*

In response to the increased number of physicians seeking patent protection, the AMA and other physician groups contend that patent protection for medical procedures will increase the cost of health care and prevent patient access to needed medical treatment.<sup>144</sup> These groups support legislation to end patent protection for medical and surgical process patents.<sup>145</sup> The AMA believes that medical practitioners are ethically obligated to share their inventions with other practitioners without expecting finan-

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144. Szabo, *supra* note 2; Gramling, *supra* note 6. For a list of the medical groups that support banning medical process patents, see Lowes, *supra* note 2, at 204.

145. Szabo, *supra* note 2; see *infra* notes 154-56 and accompanying text for a discussion of the bills in Congress.

cial reward. Accordingly, the AMA insists that it is unethical to obtain and enforce medical procedure patents.<sup>146</sup> However, current U.S. public policy, in conjunction with the Patent Act, promotes the patenting of medical procedures. Because the AMA's policy and public policy conflict, physicians and others desiring to patent their medical procedure inventions are in a tug of war with other physicians who desire to utilize the inventors' innovative procedures without paying a royalty. This contentious situation engulfs many physicians like Dr. Pallin and the physicians he is suing for patent infringement.

The AMA subscribes to ethical principles originating from the Hippocratic Oath that are designed to benefit the patient. The Hippocratic Oath, which does not have the force of law, creates an ethical responsibility on the part of physicians to provide medical service to humanity without regard to their own reward or financial gain.<sup>147</sup> It follows, the AMA argues, that medical practitioners are ethically obligated to share their inventions with their peers and should not attempt to financially benefit by patenting their discoveries and asking future users of the discovered procedure to pay a royalty.<sup>148</sup> The AMA attempts to add substance to this argument by insisting that patenting medical and surgical procedures would overly restrict the use of these procedures and increase health care's financial burdens. The Association argues that a medical procedure necessary in a patient's care may be patented and, therefore, unavailable unless a licensing fee is paid.<sup>149</sup> Consequently, the AMA claims that applying and obtaining a patent would violate medical ethics.

However, the AMA's position on the patenting of medical and surgical procedures seems inconsistent with its position on the patenting medical apparatuses or drugs.<sup>150</sup> Presently, the AMA is not concerned about the cost of licensing fees for these products, although the basis for these fees is no different than those for patented procedures. The AMA's justification for this distinction is that the licensing fee is incorporated into the cost of the device or drug. Hence, the physician does not have to worry about infringing a patent when using the device or drug because the license to

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146. Surprisingly, the AMA does not object to the patenting of medical drugs or devices for financial gain. Gramling, *supra* note 6.

147. STEDMAN MEDICAL DICTIONARY 716-17 (25th ed. 1990). More particularly, in Opinion 9.08 of the Code of Medical Ethics, physicians are to be condemned for withholding "new medical knowledge, skills and techniques from colleagues" for personal gain. COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, THE CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS Opinion 9.08 (1996-97).

148. Gramling, *supra* note 6.

149. Yank D. Coble, Jr., et al., *Patenting of Pure Surgical and Other Procedures*, *Journal of the Florida Medical Association*, FLA. MED., May 1996, at 330.

150. Gramling, *supra* note 6.

use the product was automatically obtained when the product was purchased.<sup>151</sup> On the other hand, where a medical process can be performed without first paying for it, the AMA argues that there is a possibility of a physician infringing a patent for that process.

Even though our modern patent law has had trouble keeping up with other types of contemporary technology such as biotechnology and computer software,<sup>152</sup> the law currently provides for the patenting of inventive medical and surgical procedures by all inventors whether they are medical professionals or others who are not bound by current medical ethics. Although the AMA insists that medical ethics should discourage the patenting of medical processes by both medical and non-medical persons, public policy is the catalyst that shapes our law. In fact, the current public policy yields protection of rights in contemporary technology which has surpassed the bounds of medical ethics.

The AMA, however, continues to attempt to turn back the clock. It is the public policy of promoting medical procedure patents that the AMA would like to end. As early as turn of the century, legislation sought, and failed, to abolish medical process patents.<sup>153</sup> Presently, there are two bills in Congress attempting to resolve the AMA's problem.<sup>154</sup> The Senate version provides that it is not an infringement of another's patent for a health care provider or physician to use the patented medical procedure and that the patent remains valid and enforceable.<sup>155</sup> On the other hand, the House's version prohibits the outright granting of a patent on procedures for performing medical and surgical procedures except when the procedure is a necessary component of an independently patentable device or apparatus.<sup>156</sup> This pending legislation arose as a result of the publicized patent infringement suits initiated by Dr. Samuel Pallin mentioned earlier. However, contrary to the AMA's beliefs and fears, the Patent Act actually advances the AMA's interest in servicing humanity by employing the best possi-

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151. *Id.*

152. M. A. Stapleton, *Clinton's Computer Guru Says Law Must Keep Up with New Technologies*, CHI. DAILY L. BULL., Nov. 6, 1995, at 1; Seth Shulman, *Patent Medicine*, TECH. REV., Nov./Dec. 1995, at 30-31; see *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (expanding the scope of patentable subject matter to include man-made bio-organisms).

153. Noonan, *supra* note 48, at 654.

154. See H.R. 1127, Medical Procedures and Innovation Affordability Act, 104th Cong., 1st Sess. (1995); S. 1334, Medical Procedures and Innovation Affordability Act, 104th Cong., 1st Sess. (1995).

155. S. Rep. No. 1334, Medical Procedures and Innovation Affordability Act, 104th Cong., 1st Sess. (1995).

156. H.R. 1127, Medical Procedures and Innovation Affordability Act, 104th Cong., 1st Sess. (1995).



ble medical care to the patient.

### *B. The Patent Act Furthers the AMA's Interests*

The primary purpose of having a Patent Act is to promote the sciences as the U.S. Constitution mandates.<sup>157</sup> Simply, patent protection insures that the public, not just the inventor will benefit from the inventor's labor. For example, by giving medical practitioners the incentive to create, the public benefits in two ways: the incentive hastens the discovery of the invention, and the invention is released into the public domain for all to use without a fee after the term of protection expires.<sup>158</sup> These benefits actually promote the goals of the AMA; they just are not as narrowly defined as the AMA's goal of insuring access to health care.

As seen above, the AMA believes that medical professionals should share their inventions without expecting financial reward. The AMA argues that obtaining licenses and paying royalties will prevent dissemination of the processes and will raise health care costs. The AMA continues to assert this argument despite the fact that many medical procedures have been patented during the past one hundred and fifty years with no significant or widely perceived adverse affect on health care delivery.<sup>159</sup> However, the AMA supports its view by citing the Hippocratic Oath which places the responsibility on the physician to provide medical service to humanity without financial reward.

This Section refutes the AMA's arguments and the assumptions on which those arguments are based. The Section illustrates how the overall concept of the patent system, with its statutory bars, promotes research and development and increases the availability of new, innovative medical processes while only minutely affecting the cost of health care. This Section first illustrates how the patent system framework furthers the medical profession's goals of serving humanity by improving medical technology. Second, it explains how the statutory bars, discussed earlier, yield more beneficial inventions than would the AMA's proposed rules while the bars simultaneously limit the number of inventions that qualify for patent protection.

#### *1. The Patent System Furthers the AMA's Interest of Serving Humanity*

Over time, the current patent system will expedite the development of improved medical procedures and will avoid the duplication of research efforts. As with all new patented inventions,

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157. 35 U.S.C. § 101 (1994).

158. *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995).

159. Noonan, *supra* note 48, at 663.

once the PTO grants a patent for a medical procedure, that process is published in a patent which is available for the world to see. This increases the likelihood that the procedures will be disseminated to more people. Conversely, the AMA's proposed alternative may condemn an innovative procedure to merely being published in a periodical available only to a select few in the medical community, thus causing an innovative and useful medical procedure to languish without the attention it deserves.<sup>160</sup> Or worse yet, the physician may simply use it himself or share it with only those in his community.

On the other hand, when the PTO issues the patent, there exists an incentive for others in the field to design around the patent and break new scientific ground, thus improving medical technology in that area. This incentive occurs whether or not the patentee licenses the invention to others or practices it himself.<sup>161</sup> Furthermore, the patentee need not exercise the right to require others to obtain a license to use the invention.

The AMA and others who advocate abolishing the granting of patent rights available to medical and surgical inventors should evaluate longstanding principles that support the United States' patent system. Arguably, the AMA has missed the relevant point; the patenting of medical procedures may not only be the catalyst for discovering patentable and unpatentable inventions, but may provide a potential source of additional income to offset the ever increasing cost of medical research. Research and development of many medical procedures would not occur but for the reward that the patent system yields.<sup>162</sup> Where private financing is necessary for the research and development of medical procedures, an inventor most likely would have difficulty finding those funds if the new procedure could not be patented.<sup>163</sup> Without the assurance that private financiers will recoup their investments by the enforcement of a medical process patent, financiers would pursue

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160. Allan Bloomberg, et al., *Patenting Medical Technology: "To Promote the Progress of Science and Useful Arts"*, 317 NEW. ENG. J. MED., 565, 566 (1987). Cedars-Sinai Hospital gives part of the royalties it receives to further other medical research and education. *Id.* at 567. "Accordingly, to publish a medical discovery rather than patent it may delay rather than hasten its availability to the medical community." *Id.*

161. 35 U.S.C. § 271(d)(4) (1994) (stating that refusal to license is not patent misuse or an illegal extension of patent rights); *SCM v. Xerox*, 463 F. Supp. 983, 1012-13 (D. Conn. 1978), *aff'd*, 645 F.2d 1195 (2d Cir. 1981), *cert. denied*, 455 U.S. 1016 (1982) (refusing to license a valid patent is lawful).

162. Noonan, *supra* note 48, at 656-57.

163. *Id.* The research and development of the Surrogate Embryo Transfer (SET) technology of the 1980s was funded by venture capital instead of the National Institutes of Health (NIH). *Id.* Noonan asserts that the inventor most likely would not have been able to obtain this funding but for the fact that the procedure was patentable. *Id.*

financing other non-medical research.<sup>164</sup> For this reason, many inventors assign the rights to their inventions over to corporations which then are responsible for prosecuting the patent in the PTO, and, once the patent is granted, the corporation manages the licensing aspects of the patent. For example, the income from patents currently creates investment capital for Cedars-Sinai Hospital to reinvest in the development of more medical innovations.<sup>165</sup> Moreover, by advocating patent policies similar to those of Cedars-Sinai's which promotes the patenting of procedures discovered by physicians, more medical procedures will be published as patents available for the world to see and improve upon.<sup>166</sup> Thus, the AMA could further the goals of the current patent system, as well as its own, if it realized the demand for the current patent system's utility.

The current system has served us well for centuries with relatively few changes. This is because the current system is flexible enough to deal with contemporary problems associated with determining patentable subject matter. In fact, The Court of Appeals for the Federal Circuit was created in 1982 specifically to obtain consistency and coherence in patent law.<sup>167</sup>

Nevertheless, many medical process patents obtained by smaller organizations or individual physicians are often left unenforced for three primary reasons: finding patent infringement is an arduous process; enforcing the patent is costly; and, proving infringement at trial is difficult.<sup>168</sup> For large corporations who have more resources and only a few competitors, investigation and enforcement are less burdensome.<sup>169</sup> Additionally, the infringement of patented drugs or apparatuses is also easier to detect because they are sold on the open market.<sup>170</sup> However, detecting the infringement of a medical procedure patented by a single doctor is more difficult because of the real possibility that hundreds of thousands of individual physicians might be infringing the patent in the privacy of their own offices.<sup>171</sup> In addition, damage awards that are insufficient to recover the cost of litigation against scattered defendants strongly deter physicians from

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164. Noonan, *supra* note 48, at 656-57.

165. Bloomberg et al., *supra* note 160, at 566. Cedars-Sinai gives part of the royalties it receives to further other medical research and education. *Id.* at 567.

166. "Accordingly, to publish a medical discovery rather than patent it may delay rather than hasten its availability to the medical community." *Id.*

167. CHISUM, *supra* note 49, at *overview* 14. The establishment of this court strengthens the patent grant by eliminating the earlier reluctance of courts to hold patents valid.

168. Noonan, *supra* note 48, at 661-62.

169. *Id.*

170. *Id.*

171. *Id.*

pursuing patent infringement cases.<sup>172</sup> Even though a patentee may perceive that others are infringing upon the patent, proving actual infringement at trial can be difficult. The reason for this is that proving the infringing physician was using the patented process often requires determining what the physician was thinking when engaging in the procedure.<sup>173</sup> Hence, many physicians who do patent their procedures are deterred from enforcing their patents and they thus serve the AMA's interest by allowing the world to utilize their inventions without charge.

As the preceding example illustrates, situations like Dr. Pallin's are uncommon.<sup>174</sup> However, the current system will resolve the Pallin infringement suit by determining whether the first inventor of the stitchless eye surgery was in fact Dr. Pallin. The court will decide whether Dr. Pallin's patent is valid based upon the statutory bars previously discussed, including the novelty or obviousness in light of prior art. Such determinations may force a court to declare a physician's medical procedure patent invalid, hence relinquishing the procedure into the public domain.

## 2. *The Statutory Bars Further the AMA's Interests*

Patentable subject matter "include[s] anything under the sun that is made by man."<sup>175</sup> Currently, the law is not prejudiced against medical professionals and allows them to patent innovative medical and surgical procedures.<sup>176</sup> Nevertheless, the Patent Act mandates that all inventions, medical processes or non-medical processes, satisfy certain statutory bars. Those statutory bars, explained above, require an alleged invention which fits within a statutory subject matter category to be new, useful and non-obvious for it to be patentable.<sup>177</sup> When the inventor successfully establishes these criteria, the PTO grants a patent which allows the inventor to exclude others from practicing his invention for a limited period of time.<sup>178</sup> Hence, the Patent Act motivates many to invent. However, because these bars limit the scope of patentability for inventions which in turn prevents numerous

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172. *Id.* Logistically, suing scattered defendants would be difficult and expensive. *Id.*

173. *Id.* at 661-62 (discussing the difficulty of proving infringement of a patented procedure to determine the sex of a fetus because the patentee would have to prove what the allegedly infringing doctor was thinking when viewing an ultrasound).

174. *Id.* at 663 (asserting that suits such as Pallin's is a new phenomenon).

175. See *supra* note 62 and accompanying text for a discussion of the scope of the patent grant.

176. See *supra* notes 52-53 and accompanying text for a discussion of the patentability of medical procedures.

177. 35 U.S.C. §§ 101-103 (1994).

178. See *supra* note 57 and accompanying text for a discussion of the rights of a patent owner.

patent applications from being granted, the Patent Act fuels the creation of many inventions that others can use without a license. In fact, the probability that the PTO will grant a biological process patent is only half the probability of the PTO granting a patent for conventional mechanical and electrical inventions.<sup>179</sup> The following discussion highlights the Patent Act's statutory bars that serve the AMA's interests.

An inventor of a medical process or method must satisfy § 101's utility requirement, namely, that the invention is useful.<sup>180</sup> Section 101's utility requirement acts as a barrier against physicians who do not truly discover a useful invention. A physician must satisfy the utility requirement before the PTO will grant a patent which confers to the patentee the right to collect royalties for other's use of the invention. Where a patent applicant's discovery fails for lack of utility under the current Patent Act, the discovery is not afforded patent protection, and the AMA, as well as the rest of the public, would have unencumbered access to the discovery without incurring a licensing fee. Similarly, § 102 may also bar a patent on an invention.

Section 102 contains a number of subsections providing conditions that the invention must meet before the PTO will consider it novel. To be novel the invention must not be anticipated by prior art. Essentially, "[n]ovelty rewards the first to invent."<sup>181</sup> An inventor who is first to invent a novel surgical or medical procedure, which overcomes the other bars, is entitled to a patent under current patent law.

Section 102's subsections sufficiently safeguard the AMA's interest of limiting the number of patents on medical procedures by prohibiting the patenting of medical and surgical procedures for different reasons that address the novelty issue. Ironically, it is the existence of these provisions in conjunction with the rest of the Patent Act which encourages inventors to race to discover new innovations. Consequently, along with the patentable inventions, the race inures the discovery of unpatentable, but still useful inventions that are available without cost to the public.

Under § 102(a), a medical procedure that is merely accessible to others is deemed to be already known; thus, the PTO would consider the medical procedure anticipated.<sup>182</sup> Even medical procedures that no one has used would be unpatentable if the proce-

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179. Noonan, *supra* note 48, at 661.

180. See *supra* note 63 and accompanying text for a discussion of the utility requirement.

181. ARTHUR R. MILLER & MICHAEL H. DAVIS, *INTELLECTUAL PROPERTY IN A NUTSHELL* 54 (1990).

182. See *supra* notes 82-83 and accompanying text for a discussion of 35 U.S.C. § 102(a).

dures are already in the public domain. Hence, because the PTO would not grant a patent in this situation, the public could utilize the procedure without obtaining a license.

Sections 102 (a) and (b) limit patentability of a proposed invention where the medical or surgical process has already been patented in or outside the United States.<sup>183</sup> These sections provide such bars in two different instances. First, if the process has already been patented in the United States, the inventor cannot obtain a patent. When the reference's term of protection runs, the process enters the public domain. Accordingly, where a cited U.S. patent discloses the process sought to be patented and the reference is older than its term of protection, the process is available to the public without a licensing fee.

Second, if an inventor waits more than a year after he has obtained a foreign patent to file for a U.S. patent, or someone else patented the process outside the United States before the U.S. applicant's invention date, the process is deemed unpatentable.<sup>184</sup> Unlike the previous bar, members of the AMA and other physicians would have unrestricted access to the medical process in the United States even though the foreign patent has not expired.

Often medical practitioners share their discoveries by publishing them in journals. Section 102(b) also bars an inventor from obtaining a patent for lack of novelty where a description of the invention was published more than a year before the effective filing date of the patent application.<sup>185</sup> This bar has two roles. First, it allows the inventor to introduce his invention, via publication, to the public up to one year prior to filing for a patent. Physicians may use the procedure without a license until the PTO eventually issues a patent for that procedure. Hence, the AMA's concern that patenting these procedures will prevent physicians from accessing recent discoveries is unfounded. Second, this provision has an estoppel characteristic that protects the potential user. It, in essence, estops the inventor from beginning to require licenses to use the invention after the public had access to the invention for more than a year.

Section 102(b) has another feature that also has similar dual roles that further the AMA's interests. In the medical care setting, § 102(b) allows a physician to place his process in the public realm to evaluate commercial acceptance of the process.<sup>186</sup> This

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183. 35 U.S.C. § 102(a), (b).

184. *Id.*

185. See *supra* notes 86-99 and accompanying text discussing the prohibition on issuing a patent where the invention is described in a printed publication.

186. See *supra* notes 101-05 and accompanying text for a discussion of the public use bar.

includes a physician offering to sell his services which involves his invention.<sup>187</sup> Similar to the above scheme, if the physician fails to file for a patent within one year from the date the process entered the public domain, the process becomes unpatentable. However, one caveat does exist. If the use of the invention was experimental and was necessary to perfect the invention, the inventor may be able to obtain an exception to the bar.<sup>188</sup> This novelty requirement, similar to the ones above, is flexible enough to allow the inventor to place the invention into the public before filing for a patent, but after one year in the public realm, the statute prohibits the patenting of the invention, thus estopping the inventor from being able to patent his invention and obtain royalties from others using his invention.

Section 102(d) asserts a bar when the patentee, or someone on behalf of the patentee, patents the subject invention in a foreign country. If the process invention in question has been the subject of a foreign patent application by the same inventor who is now applying for the U.S. patent and the corresponding foreign patent was filed more than one year before the U.S. patent's effective filing date, and if the corresponding foreign application is issued before the effective filing date, the inventor would be barred from obtaining a U.S. patent.<sup>189</sup> Similarly, other medical professionals may freely use the unpatentable procedures. In addition to the novelty requirement, the invention must also be non-obvious, pursuant to § 103, before the PTO will grant a patent.<sup>190</sup> This requirement acts as a bar which prevents a medical practitioner from obtaining a patent on process when the steps in the process are obvious from prior art. One way an inventor may overcome a rejection based on obviousness is by arguing that the invention is not obvious because nobody else attempted to patent the invention until now. However, similar to the utility and novelty bars, when the PTO rejects the inventor's patent application because the invention is obvious, the public can use the process without a license. Therefore, the Patent Act's statutory bars further the AMA's interests by limiting the patentability of medical procedures that results in numerous inventions, the creation of which was spurred by the Act itself, that will never be patented and will remain in the public domain for all to utilize.

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187. See *supra* notes 111-15 and accompanying text for a discussion of when the inventor is barred from selling the invention.

188. See *supra* notes 105-10 and accompanying text for a discussion of when experimental use is an exception to the public use bar.

189. See *supra* notes 116-18 and accompanying text for a discussion of 35 U.S.C. § 102(d).

190. See *supra* notes 135-43 and accompanying text for a discussion of the statutory bar for obviousness.

### III. CONCLUSION

The AMA's narrow policy actually hinders medical research and is contrary to the constitutional mandate providing for medical process patents, currently followed by the judiciary, the PTO and the legislature. Moreover, the constitutional authority to issue patents, the Patent Act, as well as the case law, recognize the benefits and incentives created by medical process patents. The legislature and the judiciary have changed the laws to allow the PTO to keep up with contemporary technology and broaden the scope of patentable subject matter and afford new technologies patent protection. The AMA should also recognize, as the judiciary, the PTO and the legislature have, that these process patents play an important role in initiating medical research. Now is not the time for the legislature to start narrowing the scope of patentable subject matter by prohibiting enforcement of medical process patents where the current system of incentives is required for investment in medical research. Narrowing the scope of protection available to physicians and research facilities would discriminate, in terms of a limited patent grant, against the very people the AMA represents. Furthermore, disallowing medical professionals from patenting their procedures would prevent the development of inventions that would be released to the public because the inventions failed to overcome the rigid statutory bars. Thus, the current patent grant is necessary to encourage investment in medical research and fulfill the AMA's goal of improved health care. The continued support of patenting medical procedures will foster improved medical procedures that will benefit humanity, and over time, the intellectual property portfolios within the medical community will differentiate the premiere health care providers.



