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**Note**

**Patent Policy and Medical Procedure Patents: The  
Case for Statutory Exclusion From Patentability**

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## I. INTRODUCTION

1. Until recently, medical procedures<sup>1</sup> were rarely patented.<sup>2</sup> Today, however, one attorney estimates that as many as fifteen medical procedures are patented every week.<sup>3</sup> Some attribute the trend to economic problems.<sup>4</sup> This trend has led at least four major medical specialty groups to take stands against the practice, and one has gone so far as to declare it unethical.<sup>5</sup> The American Medical Association (“AMA”) House of Delegates voted in June 1994 to condemn the patenting of medical and surgical procedures.<sup>6</sup> The AMA House of Delegates also directed the AMA to urge the federal government to outlaw the practice.<sup>7</sup>
2. Recently, Dr. Samuel Pallin, who holds a patent on a procedure for performing cataract surgery without sutures,<sup>8</sup> initiated what legal experts think is the first American patent infringement suit involving a medical procedure patent and a physician defendant.<sup>9</sup> If he prevails in court, Dr. Pallin plans to charge ophthalmologists nationwide a royalty for using his procedure.<sup>10</sup> If the estimates are correct that up to half of all cataract procedures performed in the United States involve Dr. Pallin’s technique, a decision in Dr. Pallin’s favor could result in a significant cost increase to patents and the health care system in general.<sup>11</sup>
3. Section II of this Note describes the law on the patentability of medical procedures in the United States and abroad. Section III discusses the costs and benefits of granting medical procedure patents. The Note argues that the costs of granting such patents outweigh the benefits, and that patent policy does not justify granting monopolies on medical procedures. Section IV argues that Congress should amend the patent statute to exclude medical procedures from the definition of patentable material.

## II. LAW IN THE UNITED STATES AND ABROAD

### A. *United States*

4. Historically, the medical profession has distrusted “patent medicines” and has considered patents on medical inventions to be contrary to the philanthropic nature of the physician’s profession.<sup>12</sup> Early patent decisions reveal a similar hostility to medical patents among the courts.<sup>13</sup> In 1862, the New York Circuit Court held in *Morton v. New York Eye Infirmary*<sup>14</sup> that the patentee’s claimed invention of a procedure for performing surgical operations with the use of ether was unpatentable because both ether and the process of inhaling vapors were old.<sup>15</sup>

Although the court's rationale seems to have rested on the traditional rule that no patent may issue for the discovery of a new but analogous use of an old product, the case referred to the "natural functions of an animal."<sup>16</sup> This language has given rise to the notion that medical and surgical procedures used to treat the human body are not patentable processes.<sup>17</sup>

5. The United States Patent and Trademark Office ("Patent Office") adopted this position in *Ex Parte Brinkerhoff*.<sup>18</sup> *Brinkerhoff* claimed a procedure for treating piles that involved the use of certain instruments upon which the applicant had already obtained a patent.<sup>19</sup> The Commissioner of Patents stated categorically that "the methods or modes of treatment of physicians of certain diseases are not patentable." The Commissioner relied on the *Morton* case but stated more clearly another rationale for excluding medical procedures — the uncertainty that any medical procedure would achieve the desired result.<sup>20</sup>

6. Although in *Dick v. Lederle Antitoxin Laboratories*<sup>21</sup> the District Court for the Southern District of New York upheld a patent on a skin test for detecting the susceptibility of humans to scarlet fever, in *Martin v. Wyeth, Inc.*,<sup>22</sup> the District Court for the District of Maryland noted that medical procedure patents might be inconsistent with public policy.<sup>23</sup> The case involved a patent on a procedure for treating mastitis in milk cows.<sup>24</sup> Although the parties did not argue the issue of whether a medical or surgical procedure was within the statutory class of patentable subject matter, the court stated that

[t]he professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage. In this respect it would seem also that public interest is here involved.<sup>25</sup>

7. Recent Patent Office decisions have retreated from the *per se* rule of *Brinkerhoff*. A number of Patent Office decisions have distinguished *Brinkerhoff* and have upheld claims for procedures that act upon the human body.<sup>26</sup> In 1954, in *Ex Parte Scherer*,<sup>27</sup> the Patent Office Board of Appeals overruled *Brinkerhoff's* exclusion of all medical treatment procedures.<sup>28</sup> *Scherer* involved a claim for a new procedure for injecting medication with a pressure jet.<sup>29</sup> The Board stated that the desired result — the injection of fluid to an accurate depth — was achieved by a specific series of acts that were not dependent in any way upon the psychological and

physiological reactions of the human body, but involved only the purely physical characteristics of the human flesh.<sup>30</sup> The Board distinguished the claim in *Morton* as one involving old procedures and materials in which the novelty consisted solely of the discovery of the effects produced.<sup>31</sup> The court stated further that uncertainty of results — the reason for the decision in *Brinkerhoff* — was not a basis for denying the patentability of all medical procedures, and that the issue was more properly considered under the question of utility.<sup>32</sup>

8. *Scherer*, however, is a Patent Office decision that serves as precedent only within the agency. Moreover, the opinion deals with an injection technique that does not depend on the physiological reactions of the human body. As a result, *Scherer* is limited to its context and cannot be considered persuasive authority for the patentability of medical and surgical procedures generally.<sup>33</sup>

#### B. GATT and NAFTA

9. Under the General Agreement on Tariffs and Trade (“GATT”) and the North American Free Trade Agreement (“NAFTA”), member states are allowed to exclude medical procedures from patentability.<sup>34</sup> GATT provides that “[m]embers may ... exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”<sup>35</sup> NAFTA explicitly provides that “[a] Party may ... exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.”<sup>36</sup>

#### C. Abroad

10. Many foreign countries, including Britain and Canada, ban medical procedure patents. Section 1(1)(c) of the United Kingdom Patents Act of 1977 provides that patents may be granted only for an invention that is capable of “industrial application.”<sup>37</sup> Sections 2(6) and 4(2) provide that an invention comprising a procedure for treating the human body is not capable of industrial application and therefore is not patentable.
11. Section 2 of Canada’s Patent Act states that “invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter.”<sup>38</sup> In *Tennessee Eastman Co. et al. v. Commissioner of Patents*<sup>39</sup> the Supreme Court of Canada held a medical procedure unpatentable because it was not an invention as defined in section 2 of the Patent Act.<sup>40</sup>

### III. ECONOMIC RATIONALE AND PATENT POLICY

12. In determining whether medical procedures should be patentable, the proper question is whether a grant of patents is justifiable in light of patent policy, which in turn depends upon the economic benefits a patent monopoly would confer upon society. The patent system's sole constitutionally mandated goal is "to promote the Progress of ... useful Arts."<sup>41</sup> Congress chose to achieve this goal by granting a seventeen-year monopoly to inventors who disclose their discoveries.<sup>42</sup> A patent grant is a legal monopoly exempt from the prohibition against monopolization under antitrust law.<sup>43</sup> Although patent law is an exception to the general rule in favor of competition, it shares with antitrust law the central purposes of maximizing allocative efficiency (producing what consumers want) and maximizing productive efficiency (producing these goods using the fewest scarce resources).<sup>44</sup>

#### *A. Invention and Innovation*

13. The patent process involves both invention and innovation. An invention is the practical implementation of an inventor's idea.<sup>45</sup> Invention is more than a concept but less than the fully developed product or process first offered for sale to customers.<sup>46</sup> Innovation is the functional version of an invention, the version first offered for sale.<sup>47</sup> A patent grant is constitutionally justified only to the extent that it increases invention and innovation consistent with overall allocative and productive efficiency.
14. Courts and commentators generally agree that the patent system is designed primarily to serve the public interest by creating economic incentives for the development and disclosure of new technology, and for investment in innovation.<sup>48</sup> This "public interest" theory of patent law views the public benefit of inventions as the primary goal of the patent system, and the reward of inventors as merely a secondary means to that end.<sup>49</sup> Because patents are privileges conditioned upon public purpose,<sup>50</sup> the utility of a patent is properly analyzed *ex post*, after it exists, and the public interest assessed by examining the product's use.<sup>51</sup>

#### *B. The Incentive-to-Invent Theory*

15. The economic model, also known as the "incentive-to-invent" theory, which some commentators believe has supplanted the public interest model, examines the inventor's incentive to expend resources upon innovative activity.<sup>52</sup> The economic model asserts that an investment will be made only when there is the expectation

of receiving a patent.<sup>53</sup> This evaluation is conducted *ex ante*.<sup>54</sup> Under the incentive-to-invent theory, if competitors are free to copy an invention, competition will drive prices down to the level of the inventor's marginal cost, at which point the inventor recovers the manufacturing cost of each unit but receives no return on his original investment in research and development.<sup>55</sup> As a result, if competition prevents the inventor from recouping his investment, his incentive to invent and innovate vanish.<sup>56</sup> Lack of protection from such competition may significantly delay the implementation of socially beneficial inventions, or may prevent them entirely from being invented and developed.

16. Economists have challenged the incentive-to-invent theory on several grounds. First, the theory rests on the dubious assumption that the invention would not exist but for the efforts of the inventor who receives the patent. If another inventor might have produced the invention, a grant of monopoly power to the first inventor may be inappropriate.<sup>57</sup> Second, subjecting new inventions to monopoly control restricts their use and reduces the social benefits they provide. Granting patent monopolies restricts output, raises prices, and may prove unnecessary for stimulating invention. Alternative incentives to invest in research, such as the first-mover advantage and competition with technological rivals may be sufficient.<sup>58</sup> What these criticisms of the incentive to invent theory have in common is the view that the public benefit is maximized when incentives to invent are provided at the lowest possible cost — at the point below which innovations will be achieved without a monopoly.<sup>59</sup>

### C. *The Incentive-to-Innovate Theory*

17. Incentives to invent should be distinguished from incentives for companies to invest in innovation. Rewards other than a patent monopoly may provide significant independent incentives to invest without the costs associated with patent monopolies.<sup>60</sup> These incentives are inherent in the professional norms and self-image of the scientific community.<sup>61</sup> The reward for successful research is the acknowledgment and acclaim of one's peers, such as first publication of a new discovery in a peer-reviewed journal or nomination for an international award.<sup>62</sup> Other rewards exist, such as research grants, academic tenure, or laboratory directorships.<sup>63</sup> Assuming the amount of funding available to medical researchers remains the same, the current volume of medical research should not diminish by any significant degree in the absence of the economic incentive provided by patent monopolies.

18. The “incentive-to-innovate” theory recognizes that inventions may require considerable further investment beyond mere discovery before commercial exploitation becomes possible. The term “innovation” refers to the necessary steps between inventing a product or process and bringing it to market.<sup>64</sup> In contrast to incentives to invent, incentives for firms to invest in innovation are likely to diminish greatly in the absence of patent monopolies. In the case of basic products, investments in product development might be recouped by sales. Where the initial investment in development is great, however, as with pharmaceuticals, firms are unlikely to invest in research absent a potential patent award. In the case of processes, the only financial incentive — other than a patent grant on the process itself — is a patent grant on a product necessary for the performance of the process.

*D. The Necessity of Balancing Social Costs and Benefits*

19. For new techniques that would not exist but for patent protection, the social and economic benefits of conferring a patent monopoly outweigh the costs.<sup>65</sup> On the other hand, for procedures that would have been developed even if a patent were not available, society pays a price for a benefit it would have received without the grant of the patent monopoly and the resulting monopoly price.<sup>66</sup> In such cases, patent policy does not justify the cost of the monopoly.<sup>67</sup>
20. On a micro level, the actual impact of medical process patents is a function of the cost and the demand for the medical procedure.<sup>68</sup> When the cost of inventing and developing a procedure is low, and the demand for the procedure high, the case against patenting the medical procedure is strong.<sup>69</sup> Demand represents the price that society must pay for the patent grant. The greater the demand, the higher the cumulative royalty fees society as a whole must pay to the patent-holder. When the price to society of the patent grant exceeds the cost of bringing the procedure to consumers, the patent grant can no longer be justified. On the other hand, when the costs of inventing and developing a procedure are high but the demand for the procedure is low, the objection to patentability is weaker.<sup>70</sup>
21. In addition to considerations of economic efficiency and patent policy, humanitarian concerns should also be considered. Public health considerations should be ranked higher than the internal consistency of patent law.<sup>71</sup> As between property rights and human health and well-being, clearly the choice should be in favor of increasing the availability of medical innovations, safeguarding patient privacy, and openly sharing research methodology.<sup>72</sup>

22. Whether medical procedures should be patentable depends on whether granting a patent monopoly will bring more inventions to consumers more efficiently. Patent monopolies for medical procedures are only justifiable when the benefits of increased invention and innovation attributable to the promise of patent monopolies outweigh the total monopoly costs of all patented medical procedures. In calculating total monopoly costs, it is important to include those inventions and innovations that would not have been developed absent the promise of a patent monopoly.

#### IV. COSTS AND BENEFITS OF MEDICAL PATENTS

##### A. *Costs of granting medical procedure patents*

##### 1. Opposition From Within the Medical Profession

23. Opponents of patents of medical procedure claim that patenting corrupts the art and science of medicine.<sup>73</sup> They argue that doctors have an ethical obligation to disseminate innovations and inventions without charge.<sup>74</sup> They further claim that when patents take several years to issue, it is in the inventor's interest to keep the innovation secret during that period.<sup>75</sup> They argue that some physicians may prefer to use their patents in order to be the exclusive providers of a particular treatment,<sup>76</sup> thereby denying access to that treatment to many patients. Efforts to collect royalties and the high cost of patent litigation could also add to the nation's already enormous health care costs.<sup>77</sup>
24. Medical procedure patents have given rise to a rigorous debate in the medical profession.<sup>78</sup> A notorious example is the patenting of the surrogate embryo transfer ("SET") procedure, which enables a woman who is infertile or has a genetic disorder to bear a child fathered by her husband.<sup>79</sup> A research team led by John E. Buster, M.D., a professor at the University of California at Los Angeles ("UCLA") Medical Center, developed the procedure.<sup>80</sup> Research on the technique was funded by Fertility & Genetics Institute ("FGR"), a privately held Chicago-based company.<sup>81</sup> Ervin E. Nichols, M.D., Director of Practice Activities at the American College of Obstetrics and Gynecology, said he was astounded by the patenting of SET.<sup>82</sup> He called it "an almost unheard of precedent in medicine," which means "that any time anybody develops a new and different technique, ... it would be patented, and then nobody else could do it unless they had a license."



25. The AMA argues that the use of medical procedure patents could impede the free flow of information on new treatments that is the hallmark of the medical profession.<sup>83</sup> Dr. John Glasson, Chair of the AMA Council on Ethical and Judicial Affairs, states that physicians who develop new and better treatments have shared those treatments with colleagues by presenting them at scientific sessions and publishing them in medical journals.<sup>84</sup> He contends that the system continues to provide adequate incentives for innovation and the sharing of new techniques.<sup>85</sup>
26. Betty Anderson, Associate General Counsel of the AMA, takes the position that any medical process patent commercializes medical procedures to the detriment of the public interest.<sup>86</sup> She claims that the medical profession has always favored widespread dissemination of anything that would be beneficial to patients.<sup>87</sup> The AMA House of Delegates<sup>88</sup> and several other physician groups<sup>89</sup> have passed resolutions urging Congress to bar medical procedure patents.
27. The position of the American Academy of Ophthalmology (“AAO”) is similar to that of the AMA. Its position is that medical procedure patents are contrary to one of the fundamental tenets of medicine, that physicians have an obligation to share their knowledge and skills for the benefit of humanity. This tradition of sharing enhances patient care, leads to the early evaluation of new technologies, and permits the rapid dissemination of improved techniques.<sup>90</sup> Medical procedure patents will add extensive costs to the process of bringing new procedures to medical diagnosis and surgery.<sup>91</sup>
28. Applying royalties or licensing fees to medical procedures could also add significantly to health care costs.<sup>92</sup> Furthermore, the safety and effectiveness of medical procedures should be closely studied by the profession at large. Criticisms and recommendations published in scientific journals should be used to establish a procedure’s worth.<sup>93</sup> Patenting circumvents this process.

## 2. Enforcement Costs

### a. Royalties and Licensing Fees

29. One argument against patenting medical procedures is that transaction costs make these patents difficult and expensive to enforce.<sup>94</sup> But changes in the structure of doctors’ practices are making the use of procedures easier to monitor.<sup>95</sup> Insurers, group practices, and health maintenance organizations (“HMOs”) often have sophisticated systems for gathering data on procedures used by doctors,<sup>96</sup> thereby reducing the enforcement problem.

30. If royalties become easier to collect, physicians might be less resistant to medical procedure patents.<sup>97</sup> The growth of managed care will make this possible.<sup>98</sup> A physician working as a salaried employee for a large HMO will be less concerned with whether the HMO pays a royalty on both a medical procedure and a medical device.<sup>99</sup> The transaction costs will also decrease because the legally sophisticated HMOs will handle the paper work.

b. The Problem of Injunctive Relief

31. The issue of injunctions is also problematic in cases involving medical procedure patents because public health is involved in a majority of these cases. Generally, an injunction will issue when patent infringement is likely.<sup>100</sup> Injunctive relief, however, is discretionary and may be refused if the court determines that injunctive relief will harm the public.<sup>101</sup> The public interest defense, however, has been significantly weakened by the United States Court for the Federal Circuit. In *Shiley, Inc. v. Bentley Laboratories*,<sup>102</sup> the Federal Circuit found that the fact that removing an infringing blood oxygenator from the market might have an adverse effect on candidates for surgery was insufficient grounds for denying an injunction.<sup>103</sup> The court did, however, delay the effect of the injunction for six months to minimize problems for hospitals required to change their systems.<sup>104</sup> In the case of medical procedure patents for which no substitutes exist, it is unclear whether the court would issue an injunction at all. In light of the court's willingness to delay an injunction for six months because of public health concerns, it is doubtful that it would grant an injunction when a life-saving medical procedure without a readily available alternative was involved.

32. An injunction forces physicians to choose between abiding by their ethical obligation to heal and their legal obligation to respect the patent rights of others. Many physicians may choose to ignore injunctions.

c. Decreased accessibility to health care

33. Medical procedure patents may deprive patients of access to the best medical treatments because either the patent-holder refuses to license the treatment to certain physicians, the patent-holder charges an exorbitant licensing fee for the treatment, or transaction costs are high.<sup>105</sup> As discussed in Section IV.A.2.a. above, high transaction costs should not be an issue if an enforcement mechanism for royalties exists. The first two issues, however, continue to be problems.

34. A patentee may elect not to grant licenses to research competitors for three reasons.<sup>106</sup> First, the patentee may want to suppress the invention in order to bolster its position in a related market.<sup>107</sup> Second, the patentee may fear that licensed use of the patented invention in further research will facilitate inventing around the patent, thus undermining the future value of the patent.<sup>108</sup> Third, the patentee may wish to preserve exclusivity in subsequent research in order to maximize future claims of priority of discovery for purposes of both intellectual property law and scientific credit.<sup>109</sup>
35. Proponents of patenting medical procedures argue that the profit motive will give the inventor an incentive to make the medical procedure available to all qualified physicians.<sup>110</sup> This proposition is questionable, especially in light of the case of the drug AZT, where the manufacturer charged such high prices that the majority of the patients infected with the HIV virus could not afford the treatment.<sup>111</sup>
36. A system of compulsory licensing could be imposed to alleviate the problem of patent-holders who refuse to license the rights to use their procedures.<sup>112</sup> Compulsory licensing might reduce the incentive to invent and innovate because the potential patentee is no longer guaranteed the freedom to charge a monopoly price.
37. One commentator, however, argues that other factors, such as cost, patient populations, geographical location, institutional biases, and payment methods, already serve to deny access to technological improvements.<sup>113</sup> Because not all patients have access to all technologies at the outset, the potential effect of medical process patents would be inconsequential in light of these other factors.<sup>114</sup>
38. The effect of medical process patents is perhaps inconsequential up to this point. This is mainly due to the fact that most patents issued to date are not considered basic health care requirements.<sup>115</sup> The current situation is likely to change depending on the outcome of Dr. Pallin's lawsuit. If he wins in court, a flood of medical process patents and infringement suits is likely, many possibly involving basic health care requirements.
39. Simply arguing that there are other factors that deny patients access to these procedures and that medical procedure patents are only one factor contributing to this process is unsatisfactory. In formulating policy, Congress should seek to reduce health care problems by increasing access, not reducing it. The crucial question

must be whether granting medical process patents will increase total public access to better health care.

d. Distortion of traditional norms of research

40. The scientific community encourages researchers to disseminate research results through publication.<sup>116</sup> Publication rewards those who make original contributions by conferring professional recognition.<sup>117</sup> This emphasis on originality creates pressure to publish as quickly as possible in order to avoid preemption by others who are conducting research on the same problems.<sup>118</sup> The patent system however, distorts this traditional incentive structure.
41. 35 U.S.C. § 102(b) precludes a patent from issuing where “the invention was ... described in a printed publication ... or in public use ... more than one year prior to the date of the application for patent.”<sup>119</sup> To preserve their patent rights, physicians might choose not to share their inventions. Consequently, allowing the patenting of medical procedures may retard traditional incentives for the development of new medical knowledge.<sup>120</sup> In addition, if physicians seek patents, a potential for bias in reporting research will be created in both in the professional literature and in the popular press.<sup>121</sup>
42. Once an inventor files a patent application, the inventor may publish the research results without impairing the prospects for patent protection on the inventions claimed in the patent application.<sup>122</sup> Notwithstanding the disclosure requirement of the patent laws, patent disclosure may occur considerably later than disclosure motivated solely by scientific norms and rewards, for two reasons.<sup>123</sup> First, patent applicants who are uncertain whether their inventions are patentable may choose to defer publication until a patent actually issues.<sup>124</sup> Second, the Patent Office may take several years to issue a patent, slowing the dissemination of information to the scientific community.<sup>125</sup> Under the letters of agreement signed on August 16, 1994 between the United States and Japan, any U.S. patent filed after January 1, 1996 will be made publicly available 18 months after its first priority date. This agreement will hasten the publication process, but an 18 month delay will still occur between the date of the invention and its publication.
43. For the most part, scientific research for the most part relies on many prior discoveries.<sup>126</sup> If researchers need to obtain licenses from prior inventors on whose work they build, royalties and transaction costs could quickly increase.<sup>127</sup>

44. Although scientists performing research using a patented procedure could claim the experimental use defense, granting a patent will have a deterrent effect on research outside the scope of the experimental use protection. Subsequent research that is arguably within the exception will also be deterred because the scope of the exception is unclear.<sup>128</sup>
45. Among academic researchers, the ideal is free access to information.<sup>129</sup> Communal ownership of information fosters key elements of academic research,<sup>130</sup> minimizes regulatory costs through effective peer review of freely published results,<sup>131</sup> and promotes the rapid and efficient dissemination of socially beneficial information through neutral academic publications.<sup>132</sup> The promise of potentially great financial reward seriously jeopardizes the willingness of researchers to cooperate with others in the development of competing or related research for fear of losing future patent rights.<sup>133</sup>
46. Private funding also will distort the research agenda of the scientific community.<sup>134</sup> If patents begin to issue on a large scale for medical procedures, research will focus more on what is profitable for the private funding sources and less on what society deems valuable.
47. Restricting information from peer review circumvents an important regulatory function. Patenting restricts “independent, unbiased evaluation by other investigators who might be denied a license to confirm or refute the observations of the group having the patent.”<sup>135</sup> For medical processes this is critical, because unlike drugs and devices that require pre-market testing by the Food and Drug Administration, “no independent agency has authority over the safety and efficacy of medical procedures.”<sup>136</sup>
  - e. Effect on physician-patient relationship
48. Some commentators have questioned the impact that medical procedure patents will have on the physician-patient relationship.<sup>137</sup> Their main concerns are that diffusion into the clinical context will be delayed,<sup>138</sup> patient costs will rise, a physician’s choice of appropriate diagnostic and therapeutic techniques will be limited,<sup>139</sup> and the privacy of the physician-patient relationship will be compromised.<sup>140</sup>
49. If a procedure is patented, a physician’s choice is limited in that the physician must become a licensee or refer the patient to another physician who is a licensee. The

effect of the patent on the physician's use of the procedure depends on the cost, availability, and ease of the licensing procedure.<sup>141</sup> The latter will become a nonissue if the problem of licensing is alleviated, as discussed above in Section IV.A.2.a. If a physician pays to become a licensee of a patented technology, the physician will have an interest in recovering his or her opportunity costs by promoting the licensed technology as frequently as possible.<sup>142</sup> This incentive destroys the physician's position as a neutral health care provider who selects the best treatment for the patient.

50. Requiring a physician to report to the patent holder each use of the patented procedure might intrude into the confidentiality of the physician-patient relationship,<sup>143</sup> although it should be noted that other entities require disclosure as well.<sup>144</sup>

### B. *Benefits of granting medical procedure patents*

#### 1. Increased dissemination of medical advances

51. Proponents of medical procedure patents argue that patenting encourages dissemination of medical advances.<sup>145</sup> Holders of several controversial medical procedure patents say they sought patents only after their attempts to seek traditional recognition failed.<sup>146</sup> Dr. George Lundberg, Editor in Chief of the *Journal of the American Medical Association* ("JAMA"), however, dismisses the lack of a publishing outlet as a motivation for seeking a patent, pointing out that thousands of peer-reviewed scientific and medical journals around the world provide an outlet for those who desire to publish.<sup>147</sup>
52. Holders of medical procedure patents argue that they profit deservedly from their contributions to medicine.<sup>148</sup> They argue that patenting a medical technique is no different from patenting a new drug or a surgical instrument.<sup>149</sup> They insist that any extra costs will be vastly outweighed by the benefits of disseminating medical innovations.<sup>150</sup>

#### 2. Incentives to innovate

53. Some patent experts say that exclusive rights are an important incentive for developing new techniques.<sup>151</sup> They argue that a patent award is often necessary to attract private research funding.<sup>152</sup> In the case of the SET patent, Dr. Buster said he was unable to obtain alternate funding for the research.<sup>153</sup> Dr. Buster contends that but for private investor financing, he could not have conducted the research

that led to SET. The National Institute of Health (“NIH”) and Dr. Buster refused to fund the research, and he could not charge private patients.<sup>154</sup> He further maintains that he would not have obtained funding if the investors stood no chance to profit from their investment by patenting and licensing the medical products and processes that resulted from his research.<sup>155</sup>

54. In the case of drugs and medical devices, the development costs associated with commercial production of many new medical products are so high that the resulting drugs and devices would not be available to consumers but for the patent award.<sup>156</sup> Private manufacturers may face economic disincentives that discourage research and development investment, because in the absence of a patent, competitors may simply copy the product and undercut its price.<sup>157</sup>
55. A case in point is the balloon catheter, developed by the staff at Cedars-Sinai hospital.<sup>158</sup> A medical publication described the catheter but the device was not patented.<sup>159</sup> Although the catheter was fully operational, little was done to make it widely available until medical product manufacturers developed patents to improve it.<sup>160</sup> What this illustration reveals is that publishing a medical discovery rather than patenting it may delay rather than hasten its availability to the medical community.<sup>161</sup>
56. In this scenario, patients must choose between limited access to new drugs and devices or monopoly prices for these new drugs and devices. Patents on drugs and medical devices are different from patents on medical procedures in that incentives for innovation and investment in research, development, and marketing are necessary in the case of drugs and medical devices but not in the case of medical procedures.<sup>162</sup>
57. Surgeons develop many medical procedures in hospitals. Because these procedures often involve new medical products, for-profit companies might still be willing to fund research if the research involves a patentable drug or device. It is not a necessary conclusion that but for medical procedure patents, the public will not obtain the benefit of these procedures.
58. Similarly, hospitals, universities, colleges, and nonprofit research institutions use patents to generate income through licensing.<sup>163</sup> The generated income enables researchers to conduct further research, adding funds to decreasing grant allocations and federal and state medical insurance reimbursements.<sup>164</sup> Unfortunately, most medical patents are not owned by nonprofit

organizations. Of 423 patents issued in January 1987, only twenty-three were issued to hospitals, universities, colleges, or nonprofit research institutions. Another advantage of private funding is that it protects against the vicissitudes of political support for federal research.<sup>165</sup>

### *C. Cost and benefit analysis*

59. Medical procedures may be divided into two categories for the purpose of economic analysis. Category one includes medical procedures invented and developed by physician-practitioners in the course of their practice. Category two includes medical procedures developed by physician-researchers in the course of their research, using either federal funds, private funds, or both. It can fairly be said that the lure of a patent will not induce physicians in category one to become significantly more inventive in the course of their practice. As discussed above in Section IV.A.2.d., physicians gain an edge over their colleagues by disclosing newly invented procedures. Even if medical procedures are unpatentable, it is unlikely that physician-practitioners will choose not to reveal a new procedure. That the promise of a patent grant will make the physician-researcher more inventive is also unlikely. Like a research and development firm, the investing firm most likely will ask the physician to sign a contract so that any invention resulting from the firm's investment will be assigned to the firm. As a result, the benefit of a patent is mostly in the form of increased private funding. In the face of decreasing federal funding,<sup>166</sup> the importance of private funding cannot be ignored. But the promise of a medical procedure patent is not the only way to encourage private investment. Many procedures are developed along with new devices or drugs. For those procedures, the firms will likely make the investment even if the procedure is unpatentable, provided that the accompanying drugs or devices are patentable.
60. The only inventions and innovations that the promise of a patent would encourage are new procedures that do not employ patentable devices or drugs. As discussed in Section III above, if the demand for these procedures is high, the price that society must pay in the form of cumulative royalty fees is correspondingly high, and the objection to patentability strong. In these cases, society would be better off economically if the government were to fund the research for these procedures entirely. Society would save by not paying royalty fees for the procedures, either in the form of increased insurance costs or increased taxes due to increased Medicare and Medicaid spending. These savings would likely more than compensate the initial federal investment. The savings should at least equal the



amount of royalty fee profits a company would have made if the company had funded the research and secured a patent on the medical procedure.

61. For procedures for which demand is low and costs high, society loses the benefit of the procedure if there is no adequate federal funding and no promise of a patent grant to induce its invention. Even if medical procedure patents are available, firms driven by the profit motive will only invest in procedures when sufficient demand exists for the firms to turn a profit.
62. Because it is administratively impossible to distinguish between these two categories of medical procedures,<sup>167</sup> all medical procedures would have to be patented to secure the benefit of a small subset of medical procedures. As discussed above in Section IV.A., enormous sacrifices would be required in the form of impediments to medical research, distortion of traditional research norms, decreased accessibility to health care, distortion of the physician-patient relationship, and enforcement problems. From this perspective, the economic costs of granting patents for medical procedures clearly outweigh the benefits. If the cost of invention is greater than the benefit represented by future cumulative demand, society would be better off economically if the procedure were not invented or developed.
63. It may seem unfair to single out physicians and deny them patents on medical procedures. In reality, however, the beneficiaries of patents are most often companies and not individuals. Scientists performing basic research do not enjoy the benefit of the patent system because principles of nature are not patentable,<sup>168</sup> and no significant objections have been raised to the lack of incentive this situation creates in the theoretical scientific disciplines.
64. If one were to begin from the position that one who invents or innovates deserves a patent, then the exclusion of medical procedures from patentability would perhaps seem indefensible. But, as discussed above in Section III, the constitutional mandate is to promote the progress of the useful arts. Granting patents for medical procedures would promote invention and innovation in only a small subset of procedures, yet the aggregate cost to the health care system of medical procedure patents would be enormous. As discussed above in Section IV.A.2.d., most medical procedures would be disclosed even without a patent because of the incentives provided by existing norms in the medical field. Even though medical technology might be improved through patent grants, medicine as a tool to

improve health care would not. The constitutional goal of patent law is not achieved if the improvement of medical technology occurs at the expense of quality health care.<sup>169</sup>

## V. PROPOSED SOLUTIONS

65. Not all scientific innovations qualify for patents. Unpatentable subject matter includes principles, laws of nature, physical phenomena, abstract ideas,<sup>170</sup> and products of nature. As discussed above in Section II.A., courts have not clearly decided whether medical procedures are patentable. In light of the judicial trend towards patentability, it is doubtful that courts will hold medical procedures *per se* unpatentable.<sup>171</sup> As in other areas, any changes in patent policy will need to come from Congress.
66. In the past, Congress has created statutory exceptions to patentability in the public interest. For instance, inventions useful to utilize fissionable material or weapons grade materials are statutorily unpatentable.<sup>172</sup> The government may also deny a patent when an invention contains technology relating to weapons systems.<sup>173</sup> Moreover, the patent grant generally is not absolute. For example, the Department of Agriculture may grant compulsory licenses “where necessary in order to insure an adequate supply of fiber, food or feed ... [if] the owner is unwilling or unable ... to supply the public needs ... at a price which may reasonably be deemed fair.”<sup>174</sup> In exchange for this license, the patentee is entitled to reasonable compensation from the government.<sup>175</sup> A provision of the Clean Air Act of 1970 allows the Attorney General to order a patentee to license a patent for an invention necessary to comply with the requirements of the Act when alternate technologies do not exist and failure to license would tend to create a monopoly in the affected line of commerce.<sup>176</sup> A federal procedure statute also provides for compulsory licensing of patents to the United States.<sup>177</sup>
67. Congress has created exclusions to patentability in the past when the public interest has required it. In the case of medical procedure patents, society would be better off if Congress excluded medical procedures from patentability.
68. Some commentators have proposed a statutorily mandated universal licensing scheme,<sup>178</sup> under which the price of the patent would be judicially determined, the patent holder could not deny a license to any physician wishing to employ the patented procedure, and the patent-holder’s relief in court would be limited to

reasonable unpaid licensing fees.<sup>179</sup> This solution, however, only solves the enforcement and accessibility problems and does not address the related issues of distortion of the traditional norms of research and adverse effects on physician-patient relationships.<sup>180</sup> The only solution that encompasses all the concerns discussed above in Section IV is a statutory exclusion from patentability of all medical procedures. In light of these problems, and because patenting medical procedures is unjustifiable in light of patent policy, medical procedures should be statutorily excluded from patentability.

## VI. CONCLUSION

69. The patent system is a notable exception to a legal system that favors free competition. The goal of patent law is not to reward an individual for invention or innovation but to increase resources for society. Where a patent grant decreases rather than increases resources for members of society, the patent monopoly is unjustifiable. In the case of medical procedures, physician-practitioners will continue to develop procedures absent the promise of a patent. In the subset of cases where a patent would encourage the development of new procedures, physician-researchers may more cheaply provide an incentive to develop procedures. The procedures that accompany profitable and patentable devices or drugs will be developed even if the procedures themselves are not patentable.
70. If medical procedures remain patentable, society may gain the benefit of medical procedures that do not have accompanying profitable and patentable devices or drugs, but society will pay the price in the form of significant increases in health care costs, accessibility and enforcement problems, and distortion of medical research and patient-physician relationships. As a result, society will be better off if Congress excludes medical procedures from patentability.

## ENDNOTES

<sup>1</sup> This paper defines “medical procedures” to include procedures for the purpose of treatment and diagnosis of a human or animal condition, regardless of whether the condition is a medically-defined disease. This definition encompasses surgical methods, injection methods, and other treatment or diagnostic methods in which the subject is a human being or an animal. *Compare In Re Goldenberg*, 22 C.P.R.3d 159 (Comm’r of Patents 1988), (the Canadian Commissioner of Patents holding that a diagnostic method that involved injecting an imaging agent into the patient’s bloodstream was not subject to the medical-treatment exclusion from patentability). The Canadian Supreme Court has also strictly construed the exclusion from patentability of medical treatment of humans and animals. *Immunomedics Major Patent Issued in Canada; Broad Patent for Cancer Imaging*, P.R. NEWSWIRE, Nov. 28, 1993, at 1128N4041.

<sup>2</sup> Brian McCormick, *Just Reward or Just Plain Wrong? Specter of Royalties From Method Patents Stirs Debate*, 37 AM. MED NEWS 3, 3 (Sept. 5, 1994).

<sup>3</sup> *Id.* Examples of patents include a method of administering insulin, U.S. Patent No. 5,320,094, a new method of diagnosing a heart-beat disorder, U.S. Patent No. 4,960,129, a method for treating allergies, U.S. Patent No. 5,116,612, a method for surrogate embryo transfer, U.S. Patent No. 4,816,257, a method for making a self-sealing episcleral incision used in cataract surgery, U.S. Patent No. 5,080,111, and a method of treating arthritis, U.S. Patent No. 5,026,538.

<sup>4</sup> Statement of F. T. Jay Watkins, President, Origin Medsystems Inc., Jane Applegate, *Surgery: The Mother of Invention*, L.A. TIMES, Apr. 5, 1991, at D3.

<sup>5</sup> McCormick, *supra* note 2, at 3.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 4.

<sup>8</sup> U.S. Patent No. 5,080,111. The procedure uses a curved incision instead of sutures. McCormick, *supra* note 2, at 4.

<sup>9</sup> McCormick, *supra* note 2, at 4.

<sup>10</sup> *Id.* Dr. Pallin suggests that physicians who use his procedure be charged annually, based on the number of procedures they performed in the previous year. *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263, 264-65 (1990).

<sup>13</sup> *Id.* at 265.

<sup>14</sup> 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

<sup>15</sup> *Id.* at 882.

<sup>16</sup> The new force or principle brought to light must be embodied and set to work, and can be patented only in connection or combination with the means by which, or the medium through which, it operates. *Neither the natural functions of an animal upon which or through which it may be designed to operate, nor any of the useful purposes to which it may be applied, can form any essential parts of the combination, however they may illustrate and establish its usefulness.*

*Id.* at 884 (emphasis added).

<sup>17</sup> 1 DONALD S. CHISUM, PATENTS, § 1.03[3], at 1-71 (1994) [hereinafter CHISUM].

<sup>18</sup> *Ex Parte Brinkerhoff*, 27 J. PAT. OFF. SOC'Y 797 (1883).

<sup>19</sup> *Id.* at 797-98. See also CHISUM, *supra* note 17, at 1-72 (many old-method patents were on medical instruments and had "method of using" claims).

- <sup>20</sup> 27 J. PAT. OFF. SOC'Y at 798 (citing 17 F. Cas. 879).
- <sup>21</sup> 43 F.2d 628 (S.D.N.Y. 1930).
- <sup>22</sup> 96 F. Supp. 689 (D. Md. 1951), *aff'd* 193 F.2d 58 (4th Cir. 1951).
- <sup>23</sup> 96 F. Supp. at 694-95.
- <sup>24</sup> *Id.* at 691.
- <sup>25</sup> *Id.* at 695.
- <sup>26</sup> See, e.g., *Ex parte* Campbell, 99 U.S.P.Q. 51, 53-54 (Pat. Off. Bd. App. 1952) (upholding patentability of a process for combating clotting of blood in human beings, which consists of administering a regulated amount of a specific compound to a human being, on grounds that the process involves a mental step because it states that regulation of the quantity of the compound administered at later intervals is based on the blood prothrombin level following administration of blood at earlier intervals); *Ex parte* Kettering, 35 U.S.P.Q. 342, 343 (Pat. Off. Bd. App. 1936) (holding a process for creating fever in a human body is patentable although the ultimate purpose is to cure disease); *Ex parte* Wappler, 26 U.S.P.Q. 191, 191-92 (1934) (holding a method of shrinking living tissue is patentable even though completion of the process is simply dependent upon the operation of natural forces, where the claims on appeal are not directed to the treatment of any specific disease and the procedure outlined is sufficiently certain to avoid criticism under the *Brinkerhoff* case); see also *Becton-Dickenson v. Scherer*, 106 F. Supp. 665 (E.D. Mich. 1952), *aff'd* 211 F.2d 835 (6th Cir. 1954); *Ellis v. Coe*, 49 U.S.P.Q. 232, 232-33 (D.D.C. 1941) (methods and apparatus for determining a characteristic of living animal tissue are patentable although the claims consist of controlling the forces of nature to effect a new result, where the invention involves more than a mere mental concept).
- <sup>27</sup> 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954); Cf. *Ex parte* Balzarini, 21 U.S.P.Q.2d 1892, 1898 (Bd. Pat. App. & Int'f 1991) (claims for method of treating human cells, by use of a compound effective to inhibit the replication and effect of HIV in human cells, rejected by examiner as indefinite and excessive in scope and unclear in that the phrase human cells may encompass a human host, granted by the Board, which disagreed with the examiner that the claims were indefinite); *Chemetron Corp. v. Airco, Inc.*, 198 U.S.P.Q. 119 (N.D. Ill. 1976) (describing a patent on a method for removing drainage from the bodies of patients recovering from gastro-intestinal surgery; the issue of whether the invention was patentable subject matter was not raised).
- <sup>28</sup> *Ex Parte* Scherer, 103 U.S.P.Q. 107.
- <sup>29</sup> *Id.* at 108.
- <sup>30</sup> *Id.* at 109.
- <sup>31</sup> *Id.* at 110.
- <sup>32</sup> *Id.*
- <sup>33</sup> See CHISUM, *supra* note 17, § 1.03[3].

- <sup>34</sup> Agreement On Trade-Related Aspects of Intellectual Property Rights, Including Trade In Counterfeit Goods, Final Act Embodying The Results Of The Uruguay Round Of Multilateral Trade Negotiations, Apr. 15, 1994, art. 27 § 3(a), 33 I.L.M. 1, 83-111.
- <sup>35</sup> *Id.*
- <sup>36</sup> North American Free Trade Agreement, Dec. 17, 1992, art. 1709, § 3(a), 32 I.L.M. 605, 670-81.
- <sup>37</sup> United Kingdom Patents Act, 1977, pt. I, § 1(1)(c) (Eng.). The 1977 revisions of the British statute are modeled after the European Convention (Munich 1973) as amended, 1979 O.J. 3 (Dec. 21, 1978). The European Convention defines a patentable subject as an invention susceptible to industrial application and provides that “[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application.” *Id.* art 52(4).
- <sup>38</sup> Patent Act, R.S.C. ch. P-4, § 2 (1985) (Can.).
- <sup>39</sup> 8 C.P.R.2d 202 (S.C.C. 1972) (Can.); for a discussion of Canadian law on this topic see Food and Drug Law Group, Blake, Cassels & Graydon, *Developments in Canadian Law Relating to Food, Drugs, Devices, and Cosmetics as of December 1992*, 49 FOOD, DRUG & COSM. L.J. 323 (1994).
- <sup>40</sup> *Tennessee Eastman*, 8 C.P.R.2d 202.
- <sup>41</sup> U.S. CONST. art. I, § 8, cl. 8; see Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 808 (1988).
- <sup>42</sup> Merges, *supra* note 41, at 808.
- <sup>43</sup> WARD S. BOWMAN, JR., PATENT AND ANTITRUST LAW 2 (1973).
- <sup>44</sup> *Id.* at 2-3.
- <sup>45</sup> Merges, *supra* note 41, at 807.
- <sup>46</sup> *Id.*
- <sup>47</sup> *Id.*
- <sup>48</sup> *Griffith Rubber Mills v. Hoffar*, 313 F.2d 1, 3 (9th Cir. 1963) (“Patents are issued not for private benefit but for the public good; they grant a monopoly for a limited period as an incentive to the disclosure of innovations which in the end will add to the fund of freely available knowledge.”); ROBERT P. BENKO, PROTECTING INTELLECTUAL PROPERTY RIGHTS: ISSUES AND CONTROVERSIES 16-21 (1987) (discussing various economic theories underlying the patent system); Evan Ackiron, Note, *Patents For Critical Pharmaceutical, The AZT Case*, 17 AM. J.L. & MED. 145, 149 (1991).
- <sup>49</sup> *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829) (reasoning that promotion of the progress of science and the useful arts is the “main object” and that rewarding inventors is secondary and merely a means to that end).
- <sup>50</sup> *Mercoird Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944).

<sup>51</sup> Ackiron, *supra* note 48, at 149.

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

<sup>53</sup> BOWMAN, *supra* note 43, at 3-4 (arguing that without the temporary monopoly under the patent grant, there would be an insufficient profit incentive to produce the invention; because an invention is profitable only if consumers are willing to pay what the patentee charges, consumers are better off than they would be without the invention); Ackiron, *supra* note 48, at 149.

<sup>54</sup> Ackiron, *supra* note 48, at 149.

<sup>55</sup> Yusing Ko, Note, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L. J. 777, 791-92 (1992).

<sup>56</sup> *Id.*; see also FREDERICK M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 443-44 (2nd ed. 1980); William F. Baxter, *Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis*, 76 YALE L.J. 267, 268-69 (1966).

<sup>57</sup> See, e.g., BOWMAN, *supra* note 43, at 17.

<sup>58</sup> SCHERER, *supra* note 56, at 444-46.

<sup>59</sup> Ackiron, *supra* note 48, at 150.

<sup>60</sup> See *Katz v. Horni Signal Mfg. Corp.*, 145 F.2d 961, 961 (2d Cir. 1944) (noting that great scientists, such as Faraday, are generally not motivated by intellectual property incentives), *cert. denied*, 324 U.S. 882 (1945); *Martin v. Wyeth, Inc.*, 96 F. Supp. 689, 695 (D. Md. 1951) (arguing that physicians' ethics are inconsistent with restrictive patent monopolies), *aff'd*, 193 F.2d 58 (4th Cir. 1951); Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1666 (1993) (arguing that a patent monopoly may not be necessary as an incentive to invest in those forms of germ-life therapy that might be desirable).

<sup>61</sup> Robert K. Merton, *The Normative Structure of Science*, in *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS* 999, 267-68, 272-76 (1973).

<sup>62</sup> *Id.* at 273.

<sup>63</sup> *Id.*

<sup>64</sup> JOSEPH A. SCHUMPETER, *CAPITALISM, SOCIALISM AND DEMOCRACY* 81-110 (3d. ed. 1950); *Merges*, *supra* note 41, at 807.

<sup>65</sup> Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1161 (1991).

<sup>66</sup> *Id.* at 1162.

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 1161.

<sup>69</sup> *Id.* For example, Dr. Pallin's patent on a method of performing cataract surgery, see *supra* notes 8-11 and accompanying text, is a high-demand procedure. Arguably, the method would have been developed by Dr. Pallin or another ophthalmologist in the course of practice even absent the promise of a patent grant. Thus, the overall allocative and productive efficiency in the area of cataract surgery is decreased due to the patent grant in this particular case.

<sup>70</sup> Burch, *supra* note 65, at 1161. With the notable exception of Dr. Pallin's incision method patent, see *supra* notes 8-11 and accompanying text, the medical procedure patents that have been issued up to the present point have been of low demand.

<sup>71</sup> Burch, *supra* note 65, at 1161 n.114.

<sup>72</sup> *Id.* at 1161-62.

<sup>73</sup> McCormick, *supra* note 2, at 3(3).

<sup>74</sup> Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1.

<sup>75</sup> McCormick, *supra* note 2, at 3(3).

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

<sup>77</sup> Felsenthal, *supra* note 74, at B1; *Contra Letters to the Editor: An Unethical Objection to My Surgical Patent*, WALL ST. J., Oct. 24, 1994, at A15 (Dr. Pallin arguing that his proposed royalty of two dollars represents only two-tenths of a percent of the cost of the operation and that since the new technique does away with a nineteen dollar suture, a net savings of seventeen dollars for each patient is created, resulting in seventeen million dollars per year saved by the Medicare administration). According to the AAO and the AMA, Dr. Pallin should not have secured a patent for the method. Thus, under the views of AAO and AMA, if Dr. Pallin prevails in court, the additional cost to Medicare alone would be two million dollars a year.

<sup>78</sup> McCormick, *supra* note 2, at 3(3).

<sup>79</sup> Beverly Merz, *Stock Breeding Techniques Applied to Human Infertility*, 250 J. AM. MED. ASS'N 1257, 1257 (1983).

<sup>80</sup> George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting*, 14 HASTINGS CENTER REP. 25 (1984).

<sup>81</sup> *Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 98th Cong., 2d Sess. 350-59 (1984) [hereinafter *Hearings*].

<sup>82</sup> Harris Brotman, *Human Embryo Transplants*, N.Y. TIMES, Jan. 8, 1984, § 6, at 42.

<sup>83</sup> McCormick, *supra* note 2, at 3(3). Lonnie Bristow, president-elect of the AMA, states: "Doctors have always shared information with one another because we feel that's the hallmark of a profession. Our role isn't to secrete information away." Felsenthal, *supra* note 74, at B1.

<sup>84</sup> McCormick, *supra* note 2, at 3(3).

<sup>85</sup> *Id.*



86 Brotman, *supra* note 82, at 42.

87 *Id.*

88 McCormick, *supra* note 2, at 3(3).

89 *E.g.*, the American Academy of Ophthalmology, the world's largest association of medical eye doctors, opposes medical method patents such as that issued to Dr. Pallin. *Letter to the Editor: Doctors Group Opposes Medical Method patents*, WALL ST. J., Sept. 6, 1994, at A13 (letter by H. Dunbar Hoskins Jr., M.D., Executive Vice President of the American Academy of Ophthalmology) [hereinafter *Hoskins' Letter*].

90 *Id.*

91 *Id.*

92 McCormick, *supra* note 2, at 3(3).

93 Brotman, *supra* note 82, at 42.

94 Professor George Annas of Boston University's School of Medicine and Public Health claims that medical procedures generally cannot be monitored without invading the privacy of doctors and patients. Felsenthal, *supra* note 74, at B6.

95 *Id.*

96 *Id.*

97 Statement of James Longacre, a lawyer for Dr. Pallin. McCormick, *supra* note 2, at 3(3).

98 *Id.*

99 *Id.*

100 See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1246-47 (Fed. Cir. 1989).

101 *City of Milwaukee v. Activated Sludge*, 69 F.2d 577, 593 (7th Cir. 1934), *cert. denied*, 293 U.S. 576 (1934) (denying an injunction, requested by patentee of a sewage treatment process, against the City of Milwaukee, because it would have effectively forced the municipality to dump raw sewage into Lake Michigan).

102 601 F. Supp. 964 (C.D. Cal. 1986), *aff'd*, 794 F.2d 1561 (Fed. Cir. 1986).

103 *Shiley*, 601 F. Supp. at 971.

104 *Id.*

105 Burch, *supra* note 65, at 1158-59. The problem is especially compounded for medical processes that are in high demand. *Id.* at 1158.

106 Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 217 (1987) (arguing that the patent system will influence the behavior of research scientists

more effectively if it takes into account the norms and incentives that guide behavior in the scientific community).

107 *Id.* at 217-18.

108 *Id.* at 218.

109 *Id.*

110 Annas, *supra* note 80, at 26.

111 Ackiron, *supra* note 48, at 145.

112 A court's refusal to grant an injunction because of public interest when there is a likelihood of patent infringement has the same effect as granting a compulsory license. See discussion *supra* section IV.A.1.

113 Timothy J. McCoy, *Biomedical Process Patents*, 13 J. LEGAL MED. 501 (1992).

114 *Id.*

115 *Id.* at 511. See also, Annas, *supra* note 80, at 25.

116 Eisenberg, *supra* note 106, at 181.

117 ROBERT K. MERTON, *Priorities in Scientific Discovery*, in THE SOCIOLOGY OF SCIENCE 999, 286 (1973).

118 ROBERT K. MERTON, *Behavior Patterns of Scientists*, in THE SOCIOLOGY OF SCIENCE 999, 325-27 (1973).

119 35 U.S.C. § 102(b) (1988).

120 Burch, *supra* note 65, at 1139.

121 Annas, *supra* note 80, at 26.

122 Eisenberg, *supra* note 106, at 216.

123 *Id.*

124 *Id.* Publication prior to that time is risky because the inventor forfeits secrecy without any assurance of obtaining patent rights. *Id.*

125 *Id.*

126 *Id.* at 217.

127 *Id.*

128 *Id.* at 218.

129 *Id.* at 181-84.

130 *Id.*

131 *Id.*

132 *Id.*

133 McCoy, *supra* note 113, at 513.

134 Eisenberg, *supra* note 106, at 230-31.

135 Annas, *supra* note 80, at 26.

136 *Id.*

137 *See, e.g.,* Hearings, *supra* note 81, in which Georgetown University Kennedy Institute Bioethics Center Director LeRoy Walters states: "My question concerns a specific proposed use of the patent system, namely, to require that all physicians wishing to employ a medical procedure that is potentially useful to their patients must purchase a license before being authorized to perform the procedure."

138 *Id.*

139 Burch, *supra* note 65, at 1139.

140 *Id.*

141 *Id.* at 1154.

142 McCoy, *supra* note 113, at 514 (arguing that physician autonomy is not a valid argument against medical process patents because health care economics and non-patent issues of personal economic reward play a powerful role in the individual treatment decisions of physicians, and because medical malpractice is heavily regulated in the United States).

143 Burch, *supra* note 65, at 1154.

144 *Id.* at 1155. A patient's insurance company typically requires a detailed disclosure of the nature of the patient's medical condition; government-funded health care benefits also require some level of disclosure. *Id.*

145 McCormick, *supra* note 2, at 3(3).

146 *Id.* Dr. Samuel Pallin initially wrote an article on using a curved incision to perform cataract surgery without sutures, but after a journal derided his research as "old news," he sought and secured the patent he is now attempting to enforce. *Id.* Dr. John Stephens' efforts to publish the use of ultrasound to determine the gender of a fetus date back to 1983, years before he began the process through which he finally secured a patent for that use. *Id.*

147 *Id.*

148 *Id.*

149 Felsenthal, *supra* note 74, at B1 (statement of Dr. Pallin).

150 McCormick, *supra* note 2, at 3(3).

151 Felsenthal, *supra* note 74, at B1 (Professor Roger Schechter of George Washington University stating that critics “believe that these new techniques should be freely available, without even considering that maybe the techniques wouldn’t exist in the first place unless there was a patent to encourage them.”).

152 Burch, *supra* note 65, at 1158.

153 Annas, *supra* note 80, at 25. The funding from Fertility and Genetics Research was about \$500,000 in total. *Id.*

154 *Id.*

155 *Id.* at 25-26.

156 A. Bloomberg et al., *Patenting Medical Technology: “To Promote the Progress of Science and Useful Arts,”* 317 NEW ENG. J. MED. 565, 566-67 (Aug. 27, 1987). “Congress determined that the pharmaceutical industry is unique in its need to have incentives to undertake costly research and development activities.” Ackiron, *supra* note 48, at 158 (citing Congressional records on the Orphan Drug Act: H.R. REP. NO. 840, 97th Cong., 2d Sess. 6 (1982)).

157 Bloomberg, *supra* note 156, at 566-67.

158 *Id.* at 567.

159 *Id.*

160 *Id.*

161 *Id.*

162 Statement of Dr. Hoskins, Executive Vice President of the American Academy of Ophthalmology, *Hoskins’ Letter*, *supra* note 89, at A13.

163 Bloomberg, *supra* note 156, at 566.

164 *Id.* Under Cedars-Sinai’s hospital patent policy, royalty income is shared with its inventors.

165 Eisenberg, *supra* note 106, at 231.

166 *See generally* COMMITTEE ON POLICIES FOR ALLOCATING HEALTH SCIENCES RESEARCH FUNDS, FUNDING HEALTH SCIENCES RESEARCH (1990).

167 For public health reasons, it is also more objectionable to issue a patent for a life-saving medical procedure. An equally good argument, however, can be made for medical procedures that drastically improve patients’ quality of life, such as a procedure that cures blindness. Drawing the line between these types of procedures could bring great administrative costs that outweigh the benefits of increased innovation. Furthermore, drawing this line, between procedures that save lives and improve quality of life and procedures that do not, distorts the incentive structure because it is precisely the life-saving and quality-improving procedures that society would like to encourage.

<sup>168</sup> Parker v. Flook, 437 U.S. 584, 593 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (holding that a mathematical algorithm is a method of calculation analogous to a mental process, hence not patentable).

<sup>169</sup> It could perhaps be argued that in the long run, after the expiration of the patent grant, the benefit of the increased invention and innovation would eventually catch up and outweigh the current cost to the health care system. That is likely to occur when existing or future demand for the procedure is high. In that case, society would still be better off if the government invested in the invention.

<sup>170</sup> Parker, 437 U.S. at 593; Gottschalk, 409 U.S. at 67.

<sup>171</sup> See, e.g., Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) (evaluating whether bacteria is patentable subject matter and basing the decision on the statutory language and on congressional intent).

<sup>172</sup> 42 U.S.C. § 2181 (1988).

<sup>173</sup> 35 U.S.C. § 181 (1988). The applicant is compensated for the damages caused by the secrecy order and the government's use of the invention. *Id.* § 183.

<sup>174</sup> Plant Variety Protection Act, 7 U.S.C. § 2404 (1988).

<sup>175</sup> 28 U.S.C. § 1498 (1988).

<sup>176</sup> Clean Air Act, 42 U.S.C. § 7608 (1988).

<sup>177</sup> 28 U.S.C. § 1498 (1988). This statute codifies the eminent domain power of the federal government and has been interpreted as providing the patentee's sole remedy for federal infringement, barring injunctions, royalties, and punitive damages for willful infringement. See TVI Energy Corp. v. Blane, 806 F.2d 1057 (Fed. Cir. 1986).

<sup>178</sup> See Burch, *supra* note 65, at 1167.

<sup>179</sup> *Id.* at 1166-69.

<sup>180</sup> See discussion *supra* Section IV.A.