2008

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EMBRYONIC STEM CELLS, INTELLECTUAL PROPERTY, AND PATENTS: ETHICAL CONCERNS

Samuel Packer, M.D.*

I. INTRODUCTION

The ethical issues surrounding the research involving embryonic stem cells can be traced back to the principles of Kant, Mill, Rawls, and other philosophers. As with all ethical principles, they tend to be absolute and vague. Thus, when society faces new technology, there is a need for ethical analysis. Ethical analysis deals with dilemmas that occur when the resolution to an issue brings into play two or more conflicting principles. When discussing stem cell ethics, we must further accept that an ethical analysis will include healthcare, research, and business, and that each will have specific ethical concerns. Thus, we have the usual social ethics of freedom—respect for the individual (Kant), respect for the group (Mill), and for justice (Rawls); and we add the ethical issues of medicine—autonomy, beneficence, non-maleficence, justice, and the norms and values of religion and politics. It is worth noting that science and the idea of progress emerged recently (sixteenth century) and that "[p]rogress involves a judgment of value . . . [and] there is inevitably an ethical element. . . . [that] implies that . . . [it] flows in a desirable

* The Arthur and Arlene Levine Professor of Clinical Ophthalmology, New York University School of Medicine; Chair, Ethics Committee North Shore University Hospital and Long Island Jewish Medical Center.


2. See generally JOHN STUART MILL, ON LIBERTY (Alburey Castell ed., Harlan Davidson, Inc. 1947) (1859) (emphasizing that one of the critical elements of liberty is the freedom to express one's own opinions).

A basic understanding of the ethical principles involved in the stem cell debates will not necessarily get us to socially acceptable answers because of the pluralistic values that exist in society. For example, even arguments based on deontology will differ, whether one believes in a theological basis for analysis with the source being the will or laws of God versus another monistic deontology, such as Kant’s, where acts are judged by their universalizability. Thus, specifics, or particulars, deserve attention, as does the consensus that will be needed for the political process to achieve a socially acceptable solution that is not just a pyrrhic victory for the strong. The need for ethical alignment, as opposed to economic alignment, and preferably for the alignment of both is the subject of this Article. The complexity is due to the many stakeholders and the many areas, both ethical and non-ethical, that relate to stem cell research. These include: national and international political systems, legal systems, healthcare systems, research efforts that are both government-supported and non-government-supported, various views of different religious groups, and basic philosophical and ethical understandings of when life begins and the dignity of life and who decides and how to decide—to mention just a few of the specific areas that require alignment.

How societies deal with the acquisition of new knowledge and the processes that enable society to use this new knowledge speak to the concern of social ethics—what kind of people are we? Are we good or are we bad?

II. ETHICS

A. Basics: Values and Dilemmas

From the principles mentioned above, values are generated for individuals and groups to function in an agreed manner. Since groups evolve with different values and prioritize them differently depending on the situation, dilemmas arise. Typical ethical values include respect for life, law, freedom, and health. In healthcare, autonomy, beneficence, and


justice are the expected norms. Society functions smoothly and its citizens prosper when there is agreement as to social norms and these social norms are prioritized fairly and consistently. Dilemmas occur when individuals or groups feel that a particular value/norm is more important than does another individual or group. For instance, with stem cell research, the issue of when life begins or the definition of life may be based on different values and not on some scientific definition. Thus, there is a need for a dialogue that attempts to clarify these differences and seek consensus. Fundamental questions may exist, such as whether a society should have a theocracy or a democracy and, by extension, whether a society can have both. The point is that the latter—that is, two types of government, theocratic and democratic, in one society—seems improbable, but having individuals or groups within a society differ regarding religious versus secular beliefs seems likely. Since the latter is probable, we need to understand the basis for disagreements and attempt through understanding to allow for these debates to facilitate the making of a consensus that allows society to prosper. Theocracies place more moral value on respect for authority, loyalty, and spiritual purity, while democracies value harm and fairness among the other values mentioned above.\(^6\)

The critical issues here are health and life. Some view research and the creation of new knowledge as requiring acceptance by various groups within society. Others view research as a responsibility of those who create new knowledge—researchers. These ethical debates require particulars to do any sort of reasonable analysis. A casuistic approach is one that attempts to deal with specific situations and use ethics and logic, but leads to action rather than analytic paralysis.\(^7\) Stem cell research represents a new technology with important and unique dilemmas that are added to the usual dilemmas presented by new technology; specifically, there are the religious issues that relate to definitions of life and respect for the sanctity of life. Thus, there is a need for a basic agreement and consensus—not unanimity—as to what defines life and personhood and when there is a soul. Here we must address some basic philosophical questions and admit to the philosophy upon which we are basing actions; for example, utilitarianism versus individualism, liberalism versus conservatism, or other social and political philosophies. Do we want more government or less government? Do we want the answers to come from the marketplace or

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6. Id. at 1000 fig.1.  
from academia? Gaining economic alignment will be much easier than gaining philosophical alignment, especially when one appreciates the international scope of stem cell issues. It is important to recognize and accept the fact that time is a factor in the feelings that society has about new technology. A recent poll survey asked, among other questions, whether "[i]t is morally acceptable to do medical research using stem cells obtained from human embryos."8 In 2002, fifty-two percent felt that it was acceptable, and in 2008, sixty-two percent felt that it was acceptable.9 Other questions that related to moral values and religion showed a significant change over the seven years.10

B. Professionalism: Medicine, Law, Religion, and Educators

Added to the complexity of analyzing the basic social-ethical dilemmas, there are additional ethical areas that should be represented in any discussion of stem cell research. These include the ethical precepts of the professions. The "learned" professions of medicine, law, and clergy have adopted the ethical principles of respect for autonomy, beneficence, non-maleficence, and justice.11 The rationale that emerged historically is critical to understand so that any trade-offs that occur when analyzing an ethical dilemma are not simplified. These professions were elevated from trades over thousands of years, primarily because society felt that it would be better protected if these professions acted in the best interests of citizens who were in vulnerable circumstances. Those in need of healthcare, legal help, or religious guidance were felt to be vulnerable, and therefore special privileges were granted to these professions if they would act according to an agreed to social covenant—that is, a contract. This fiduciary role for physicians, lawyers, and clergy evolved legally with licensure, codes of ethics, and external and internal mechanisms of compliance. Codes of ethics attempt to insure the premises of the profession and seek consistency in behavior that benefits society without acting as a trade guild.12 This fiduciary role

9. Id.
10. Id.
may be looked at legally or ethically. Both views point to a responsibility to act in the best interest of the vulnerable.

Although the "learned" professions were the first to attain social status and license, other professions have recently sought and earned similar status. This has required the fulfilling of the major tenets of a profession, as opposed to a trade. The major characteristics of a profession include: "First, a rather extensive training is required . . . . Second, the training involves a significant intellectual component . . . [as] providing advice rather than things is a characteristic feature of the professions . . . . Third, the trained ability provides . . . services important to the organized functioning of society."

Thus, nurses, teachers, professors, engineers, and others have attained social acceptance as professionals. The religious connections to early medicine and the congruence of moral beliefs have been noted:

"Non-Christian physicians in the ancient world and middle ages—Egyptian, Hebrew, Moslem, Indian and Chinese—were also members of moral communities each with its own religious or quasi-religious binding force. What is remarkable is the congruence of ethical precepts among physicians who held widely disparate world-views. This suggests something intrinsic to the morality of medicine as a human activity that in some way transcends culture, religion, and historical era. But still, neither the Christian nor non-Christian physicians explicitly developed the idea of a moral community with definitive collective obligations to society . . . ."\(^\text{14}\)

Therefore it is helpful to appreciate that religious differences did not preclude the acceptance of the basic moral code of the professions. The recent political decisions to restrict federal funding of stem cell research in the United States did little to improve dialogue between the many interested parties. The freedom of religious groups to lobby for their views is accepted in a free society. However, the basic tenets of American democracy are that the government will represent a pluralistic society and not favor one group over another.\(^\text{15}\) The strong views presented by President George W. Bush and echoed by Dr. Leon Kass, the former Chair of the President's Bioethics Council,\(^\text{16}\) need to be taken

\(^{13}\) Bayles, supra note 11, at 28.
\(^{14}\) Pellegrino, supra note 11, at 207 (footnote omitted).
as important but perhaps not representative. Kass’s lecture reflects a view that is the opposite of one that should represent a pluralistic society or one that represents a democratic government. The anti-science rhetoric ignores the fact that “after stripping away the hyperbole, one finds that it took a dedicated independent researcher, aided by desperate patients, before a reluctant drug company delivered on the promise of its proprietary product.”

As a profession, law has also promised society that it would act in the individual’s best interest and uphold its promises to society. In the latter role, its practitioners serve individuals (clients, patients, and research subjects) and groups (biomedical technology companies, university research laboratories, etc.) and, as judges, act to uphold the values within society. Whether these values include those moral values that relate to the issues surrounding stem cell research remains uncertain. Professor Derek Morgan states that, “[s]cientific citizenship requires that law develop a moral vision and vocabulary so that we shape the moral dimensions of the emergent bioeconomy.” This will place the courts in the position to adjudicate, as well as possibly uphold regulations that present moral dilemmas. One of the specific dilemmas is between the value of choice (market-driven access) and the value of human dignity (who decides when life begins).

It is not that choice is unimportant but that, as a value in the art of medicine, it can come to be overvalued: knowing the price of everything and the value of nothing, as Oscar Wilde observed, is the hallmark of the cynic who degrades and devalues the potential and possible roles and rotes of the doctor, who is becoming more and more a partner to the scientific business enterprise in conjunction with the scientist.


18. See David DeGrazia, Moral Status, Human Identity, and Early Embryos: A Critique of the President’s Approach, 34 J.L. MED. & ETHICS 49, 56 (2006) (noting the opposing viewpoints on cloning for biomedical research in society and the impact this strife has on policy-making).


21. Id. at 86.
The progress of stem cell research warrants an early look, before therapies emerge, at the ethical issues that may be critical. Hans Jonas has called for "scientific futurology," and the legal system has called for "lengthened foresight." Some see health as representing a human freedom, and therefore, choice might take precedence in analyzing any legal restrictive regulation. The value of freedom may not fare well in an ethical analysis where progress is looked upon as a more important value. The latter would be supported by many, including researchers, the bioeconomic interests in markets, and politics—including utilitarian thinking, which emphasizes the greatest good for the greatest number. Thus, moral reflection will be required at many levels and by many stakeholders and stockholders. In addition, it is essential to consider the pluralistic perspective due to different religious values and the political influence of religious groups. This will require a respect for and inclusion of the various religious moral perspectives on the stem cell debate. This will include the values felt to be important with defining the beginning of life and the conundrum presented with dignitarian absolutist views, such as Kant and certain Catholic perspectives.23

III. KNOWLEDGE, SCIENCE, TECHNOLOGY, AND PROGRESS

Stem cell research is not the first area of research to have ethical concerns that overlap science and religion. The birth control pill and in vitro fertilization preceded stem cell research with many of the same ethical issues that some would argue still exist and are reemerging with stem cell research.24 The stem cell "wars" bring to the table many of the same opponents once again.25 The justification of government intervention—as occurred with President George W. Bush's federal restrictions on federal funding of stem cell research—has been

22. Id. at 85.
23. See KANT, supra note 1, at 45-46 ("Now I say: man and generally any rational being exists as an end in himself, not merely as a means to be arbitrarily used by this or that will, but in all his actions, whether they concern himself or other rational beings, must be always regarded at the same time as an end. . . . Accordingly the practical imperative will be as follows: So act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as means only."); see also Michael R. Prieur et al., Stem Cell Research in a Catholic Institution: Yes or No?, 16 KENNEDY INST. ETHICS J. 73, 74 (2006) (exploring whether Catholic healthcare facilities could participate in stem cell research without running afoul of Catholic teachings regarding conception and personhood).
25. See HEROLD, supra note 24, at 30-32.
challenged, and several states have decided to fund stem cell research because of the actions of the federal government. This may represent a seismic shift in how medical research is done in the United States and may cause a "Balkanization" of research. It is important to recognize that government officials are influenced by their personal religious beliefs, as well as those of political supporters. In addition, commercial interests in the potential business opportunities offered by any new technology bring other players to the political table. In this way, California formed an agency to promote stem cell research and to have the citizens of California be the financial beneficiaries of any commercial profit. This creates new ethical conundrums for other states and for other societies. Also, it seems intuitive that an unintended economic consequence of restricting research will be that other countries take advantage of the opportunity. As has been noted, "even in areas of strong moral opposition, science can often develop in the shadow of the law, with the market eventually compelling both moral concerns and legal prohibitions to decline."

The Bayh-Dole University and Small Business Patent Procedures Act ("Bayh-Dole Act") and the Stevenson-Wydler Technology Innovation Act ("Stevenson-Wydler Act") attempt to have society benefit from research that receives government funding—that is, they attempt to increase technology transfer. This has had good and bad consequences, often depending on one’s social and political views. With the desire to have the commercialization of new technology occur more


27. See James W. Fossett et al., Federalism & Bioethics: States and Moral Pluralism, 37 HASTINGS CENTER REP. 24, 34 (2007) (noting that the "moral and political complexity" of bioethical issues will make establishing national standards difficult and thus most policy decisions will remain with the states).

29. Spar & Harrington, supra note 24, at 543.
32. See Arti K. Rai & Rebecca S. Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, 66 LAW & CONTEMP. PROBS. 289, 290 (2003) (explaining that the legislative goal of these two Acts was to "promote widespread utilization of federally-sponsored inventions").
efficiently, the result was an enormous increase of patents from medical schools and a concurrent significant increase in expenditures to establish administrative offices to handle these efforts. As Part IV will discuss, the negative effects from commercializing universities has been realized. The social and economic consequences have been discussed by many and are more often negative. Professor Arti K. Rai states that "the benefits of granting intellectual property rights in research are significantly diminished by the losses in creativity and high transaction costs that such grants generate and...norm-like mechanisms for addressing transaction costs are unlikely to be successful." However, it has been historically noted, especially for the United States, that "[w]ith a society secular in motive, dynamic in economy, scientific in intellectual interest, it was inevitable that its political institutions should reflect these dominant drives."

IV. INSTITUTIONS: ACADEMIC AND INDUSTRY

Conflicts of interest exist throughout society and impact on any discussion involving an issue as complex as stem cell research. Research conflicts of interest have impacted society historically and both laws and professional codes of ethics have attempted to improve the behavior of those involved in discovery. The conflicts that researchers have include conflicts between revealing the truth and seeking academic advancement; between representing self and being the advocate/agent of the research subject; and between loyalty to self, to institution, to corporate sponsor, and to society. Superimposed on these conflicts are

33. Pierre Azoulay et al., The Anatomy of Medical School Patenting, 357 NEW ENG. J. MED. 2049, 2052 (2007) ("The number of patents granted to medical school faculty increased from 122 in 1976 to 2175 in 2003 . . .").

34. See DEREK BOK, UNIVERSITIES IN THE MARKETPLACE 75-76 (2003) (suggesting that the commercialization of university research compromises the integrity of research conclusions and increases the public's level of skepticism).

35. See Rai & Eisenberg, supra note 32, at 310 (arguing that while patents have allowed universities to profit, they may actually restrict subsequent research and development). See generally ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2004).


37. BURY, supra note 4, at XXXV.


those caused by institutional conflicts, such as when companies invest financially in institutions or when institutions have a board of trustees that represents both industry and the university or medical center. The ability of universities and medical centers to achieve monetary gains from patents has been exaggerated and certainly has had unintended pernicious consequences. And these activities seem to have created a potential for loss of social promises. Those promises relate to a covenant between institutions of higher learning and society, where the expectation is that the institutions of higher learning will have a primary purpose of preserving and transferring knowledge and creating new knowledge. The tacit understanding is that universities are not to become businesses because society would suffer. Professor Yochai Benkler points to several open access activities to demonstrate the benefits: for example, the Massachusetts Institute of Technology’s (“MIT’s”) Open Courseware Initiative and the South African project, Free High School Science Texts.

Government offers another superimposed layer for conflicts. Leaders of government may be influenced by special interest groups, such that allocation of financial resources is effected. These outside groups may include biotechnology companies, the pharmaceutical industry, academia, or religious groups. Laws, such as the Bayh-Dole Act and the Stevenson-Wylde Act, and policies, such as those enacted under the Bush Administration, have had intended and unintended consequences. The intent of law is to be just; however, when political manipulation occurs, society suffers. The stem cell issues that need resolution will be affected by these conflicts and require an

40. See Susan H. Ehringhaus et al., Responses of Medical Schools to Institutional Conflicts of Interest, 299 JAMA 665, 665 (2008); see also Annetine C. Gelijns & Samuel O. Thier, Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections, 287 JAMA 72, 72 (2002).
42. See BENKLER, supra note 41, at 348.
43. Id. at 326-27.
unraveling and subsequent alignment of interests that are morally sound.\textsuperscript{47} The Bayh-Dole Act and ensuing decisions in case law impacted existing social norms of cooperation within academia and changed the behavior of researchers to being more commercial—that is, more secretive—and less academic.\textsuperscript{48} Not all went along with the direction of being pushed by government and industry; some universities resisted. The contrast in behavior can be seen with gene patents, where the researchers Georges Köhler and Cesar Milstein felt that it would be ethically wrong for them to seek a patent, whereas Dr. Craig Venter sought patents on thousands of gene fragments.\textsuperscript{49} MIT, Harvard, and Stanford are attempting to show some restraint in seeking patents.\textsuperscript{50} Professor Rebecca Eisenberg points out that “the traditional American conception of academic freedom is ill-suited to the task of protecting academic values in externally sponsored research.”\textsuperscript{51} Rai further points out that Eisenberg feels “progress in basic science occurs most quickly not when it is coordinated by a single entity (such as a patent holder) but, rather, when different teams of scientists, working independently but with an awareness of each other’s efforts, use divergent approaches to the same problem.”\textsuperscript{52} This certainly is consistent with Benkler’s views and also philosopher Francis Fukuyama’s view that decreased trust (from diminished communality) increases transactional costs.\textsuperscript{53}

V. INTELLECTUAL PROPERTY AND PATENTS

A. General

A basic ethical dilemma exists for society when considering intellectual property and socially legal mechanisms for restricting the use of knowledge. In the United States, Thomas Jefferson is the
President who helped launch the patent system with specific ideas in mind.

Jefferson wanted to encourage inventiveness and progress within the context of a free-market economic system. At the same time, he wanted inventions to benefit society. To achieve this, Jefferson incorporated two critical features into patent law. First, a patent provides the inventor with a form of ownership over the invention for a limited time. Second, a patent is granted only if the inventor reveals and describes the invention. The purpose of these features of patent law was to ensure that "the public may have the full [free and unrestrained] benefit [of the invention] after the expiration of the patent term."

The opposite of legal intellectual property rights, such as patents, is the concept of open access. Benkler explores the ramifications of any restriction to open access from a legal, economic, and cultural perspective. He compares the industrial information economy that favors strong protection of intellectual property with the networked information economy that favors open access and no legal restrictions. He purports that just a market-driven solution to intellectual property is not in the best interest of the creation of knowledge. The multiple ways that knowledge is created mandate an inclusive rather than an exclusive system. Thus, laws should not create exclusive regulations that decrease the dissemination of knowledge and therefore decrease the creation of new knowledge.

This is especially critical at a major starting point of the creation of knowledge, such as the institutions of higher learning. Some of these institutions have been "captured" by industry and function as agents of industry rather than agents of society. The problems with academic-industry relationships have received considerable attention. Most are concerned about its potential to diminish the societal functions of a university. Others feel that technology transfer does the most social

55. BENKLER, supra note 41, at 60-61.
56. Id. at 1-5, 37-38.
57. Id. at 37-38.
58. Id. at 315.
59. See BOK, supra note 34, at 155-56 (noting that technology has made industry and science inseparable).
60. See generally Ehringhaus et al., supra note 40 (providing the first comprehensive study of institutional conflicts of interest in medical schools in the United States); Gelijns & Thier, supra note 40 (discussing the interplay between medical inventions and industry).

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good, in that society may benefit from the works within institutions of higher learning and national laboratories. Thus, the Bayh-Dole Act and the Stevenson-Wynder Act did much to encourage relationships between academia and industry and caused an enormous increase in patenting activity within universities and government laboratories. A result is that the resources of institutions of higher learning—both public and private—are being inappropriately utilized. "One concern relates to the effects of increased academic patenting and licensing activity on the values and culture of medical schools." This becomes critical if "scientists working at noncommercial research institutes funded by nonprofit educational institutions and government grants produce most of our basic science," and such efforts produce knowledge that is intended to sell something and make money. "The efficiency of regulating information, knowledge, and cultural production through strong copyright and patent is not only theoretically ambiguous, it also lacks empirical basis."

Although this Article is not about the economic issues that relate to intellectual property law, Benkler does note that "the reality of both theory and empirics in the economics of intellectual property is that both in theory and as far as empirical evidence shows, there is remarkably little support in economics for regulating information, knowledge, and cultural production through the tools of intellectual property law." He points to many successful business efforts that were accomplished through open access. These include Linux (IBM), Slashdot, PLoS, Wikipedia, and SETI@home. The power of the Internet is realized with "commons-based peer production" that is based on "a new modality of organizing production: radically decentralized, collaborative, and nonproprietary; based on sharing resources and outputs among widely distributed, loosely connected individuals who cooperate with each other without relying on either market signals or managerial commands." This description fits the description of perhaps an ideal but truthful

62. Azoulay et al., supra note 33, at 2050.
63. BENKLER, supra note 41, at 35.
64. Id. at 38.
65. Id. at 39.
66. Id. at 33, 46, 76, 82, 313.
67. Id.
68. Id. at 60.
understanding that "[s]cience is built by many people contributing incrementally—not operating on market signals, not being handed their research marching orders by a boss—independently deciding what to research, bringing their collaboration together, and creating science."69

This type of collaboration was seen in the International HapMap Project for mapping the human genome,70 which does not seem very different from stem cell research. Benkler further elaborates on the cultural values, such as freedom and health, of a cooperative society rather than a totally commercialized society that successfully invades our institutions of learning.71

It is also worth noting that the United States and Europe have particularly strong intellectual property laws and that this has a negative effect on the health of poorer countries. Sir Hugh Laddie, United Kingdom High Court Patents Judge, stated that "[f]or too long IPRs [(intellectual property rights)] have been regarded as food for the rich countries and poison for poor countries."72 He hoped that new government policy would change this.73 A more detailed look at the patent system in the United States can be found in the works of Adam Jaffe and Josh Lerner, who feel that a major problem resides in the details of how the United States Patent and Trademark Office ("PTO") functions.74 "The undesirable manifestations of current policy can be understood as the inevitable consequences of inventors, their attorneys, and competing firms' exploitation of the incentives that changes in policy and practice over the last two decades have inadvertently created."75 They also note that "[t]here are no easy solutions to the problems of running a patent system. There is an inherent trade-off [(ethical dilemma)] in this system, between rewarding innovators and burdening commerce, competition, and other inventors."76 They agree with Benkler that there is a link between the economic incentives to

69. Id. at 63.
71. BENKLER, supra note 41, at 14.
73. Id.
74. JAFFE & LERNER, supra note 35, at 2.
76. JAFFE & LERNER, supra note 35, at 79.
patent and the health of society. Jaffe and Lerner are both economists and note that

[e]conomists have often been perceived as hostile to the patent system. We do not consider ourselves anti-patent. We are just anti-bad patents, and anti-blackmail made feasible by a court system stacked against those who challenge the bad patents. We want a patent system that can be presumed valid, because a valid patent system is vital to the continued health of innovation, and, hence, economic growth and prosperity.

Thus, Jaffe and Lerner feel that the patent system is bad, but can be fixed. Examples of the areas of the United States patent system that need correction include: (1) industry-capture of the PTO due to the fees paid to the PTO for the patent process and therefore the need for more financial resources from government and not from industry so as to reduce conflicts of interest (Does the PTO work for the public or for industry?); (2) a court system (particularly the Court of Appeals for the Federal Circuit) that favors industry and therefore the need for more skilled judges and specially appointed masters “to decide technical issues of novelty and obviousness”; and (3) pre-grant opposition (input from the public) and effective reexamination. Benkler feels that we need a patent system that adheres to the concepts of freedom. More information freedom would allow for a nonproprietary information system to also flourish, such as increased open access to new information that would allow society to benefit from both proprietary and nonproprietary economic models. Professor Lee Silver also feels that “[t]he larger the number of independent scientists working on a problem—collaborating, competing, and exchanging information—the faster progress is made.” Professor Baruch Brody offers additional suggestions to modify patent laws so as to respect social values. A new method of peer review of patents using the Internet is being tried in the United States and Europe, including the United Kingdom. This “peer to patent” process hopes to address some of the concerns that exist with the

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77. See BENKLER, supra note 41, at 310-12.
78. JAFFE & LERNER, supra note 35, at 207.
79. Id. at 206.
80. BENKLER, supra note 41, at 130.
81. Id. at 145-46.
82. SILVER, supra note 54, at 318-19.
83. Baruch Brody, Intellectual Property and Biotechnology: The U.S. Internal Experience—Part II (pt. 2), 16 KENNEDY INST. ETHICS J. 105, 125 (2006) (listing several recommendations, including “limiting the patenting of research tools and/or... providing a research exception to patent protection”).
present system, such as "prior art" assessment done only by one patent office examiner with limited time and sometimes limited expertise.  

Another concern with the proliferation of patents is the problem of the "anticommons." An "anticommons" occurs "when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use." Thus, "more [intellectual property] rights may lead paradoxically to fewer useful products for improving human health." The example below captures most of the bad that comes from patenting new technology and the costs to academia and to society.

B. Stem Cells

Over 8334 stem cell patents have been issued as of March 2009 by the PTO. This will ineluctably lead to increased costs for research and restriction of access to scientific information. Does society benefit from this? The evolving story of Dr. James Thomson’s discoveries and the three patents sought by the Wisconsin Alumni Research Foundation ("WARF") hint at some of the potential problems with patenting of stem cells. The public interest groups Public Patent Foundation and the Foundation for Taxpayer and Consumer Rights challenged the validity of the three WARF patents. Dr. Thomson's work received private funding from the Geron Corporation, which received exclusive commercial rights to selective human embryonic stem cells. Many negative issues have been raised for a long time regarding the problems that patents have caused. The economic consequences of protecting

86. Id. at 701.  
89. Brody, supra note 83, at 122.
intellectual property with patents are different than those resulting from protecting physical property. This has to do with the original economic concepts surrounding patents. The Thomson patents allow WARF to mandate money from anyone who wants to use their stem cells, thus increasing the cost of research and restricting the research to only those who can afford to pay. It should be noted that different financial arrangements have been made to accommodate the furor over the broad reach and financial impact of these patents. This accommodation was primarily for research to be done in universities or national laboratories. The effect has not been assessed as it is still too early, but many are still upset with the extent of the patents.

These patents also restrict research because of the increased costs associated with obtaining patents, per primum; again, this economically disenfranchises the poorer university or country. It may also lead to research that seeks exclusive patents so as to satisfy the corporate sponsor and to increase secrecy. "Property rights can limit the distribution of intellectual property and can draw excessive resources into the creation of intellectual property, and away from other socially valuable activities, by the phenomenon of rent seeking." However, as far as the WARF patents, the issue of patent continuation has yet to be resolved in the courts. Professor Russell Korobkin takes another look at the WARF patents and expresses concern over the impact on the broad nature of the patents and the ability of WARF to seek a "$100,000 up-front fee and a $25,000 annual maintenance fee from companies wishing to buy commercial licenses." He then clarifies the separation of patents and intellectual property created with public funding and the need to commercialize new discoveries so that society may benefit.

While patent rights are necessary to encourage socially beneficial scientific research, the need is reduced when public funding underwrites the costs of innovation. In this situation, the incentive of patent protection is unnecessary to encourage the production of basic science, but it remains necessary to encourage private industry to invest. Both the federal Bayh-Dole Act and CIRM's intellectual property policies are inattentive to this subtlety because they allow

92. Id. at 123.
93. See Laddie, supra note 72, at 7.
grantees to patent all government-funded inventions, rather than just the types of inventions for which the incentive is necessary to assure that the innovation reaches the market.\textsuperscript{97}

In addition, the patents to date have not resolved the critical question as to the definition of pluripotency.\textsuperscript{98}

The federal restrictions in the United States on funding for stem cell research have led to states creating funding mechanisms for stem cell research in a very inconsistent and perhaps economically costly manner. California, New York, and other states have formed entities that have been funded with taxpayer monies, ($3 billion for California and $660 million for New York).\textsuperscript{99} To deal with these complex issues, newly formed government agencies had to be established; in California, it is the California Institute for Regenerative Medicine ("CIRM") and in New York, it is the Empire State Stem Cell Board ("ESSC").\textsuperscript{100} Some view this as positive, although with some reservations, and warn that:

Bioethicists are often interested mostly in national standards and institutions, but state governments have historically overseen a wide range of bioethical issues and share responsibility with the federal government for still others. States ought to have an important role. By allowing for multiple outcomes, the American federal system allows a better fit between public opinion and public policies.\textsuperscript{101}

They further encourage that an "[a]wareness of the decentralized and complicated institutional and political machinery that governs bioethical decision-making in this country would make bioethical discussions more immediately relevant to public debates about these issues."\textsuperscript{102} In addition, differences in patent practices between the United States and European countries further complicate related issues, such as economics, politics, and religion. The European Patent Office ("EPO"), through their Opposition Division ("OD"),

\textsuperscript{97} Id. at 260-61.
\textsuperscript{98} Vrtovec & Scott, supra note 95, at 393-94.
\textsuperscript{100} CIRM, supra note 26; NYSTEM, supra note 26; see also CAL. COUNCIL ON SCI. & TECH. INTELLECTUAL PROP. STUDY GROUP, POLICY FRAMEWORK FOR INTELLECTUAL PROPERTY DERIVED FROM STATE-FUNDED RESEARCH: FINAL REPORT TO THE CALIFORNIA LEGISLATURE AND GOVERNOR OF THE STATE OF CALIFORNIA 7 (2006), available at http://www.ccst.us/publications/2006/IPFinalES.pdf.
\textsuperscript{101} Fossett et al., supra note 27, at 24.
\textsuperscript{102} Id. at 34.
held that the [human embryonic stem cell] patent contravened a rule that had been transposed directly from Article 6(2)(c), namely, the prohibition on "uses of human embryos for industrial or commercial purpose." Even in the absence of a uniform moral approach to human ES cells in Europe, the OD reasoned that the rule "... has to be interpreted broadly to encompass not only the industrial or commercial use of human embryos but also the human ES cells retrieved therefrom by destruction of human embryos." 103

VI. RESOLVING ETHICAL DILEMMAS AND CONFLICTS OF INTEREST

The premise of this Article is that values lie at the foundation of the stem cell debate. These values emanate from science, medicine, and religion. A strategy for gaining consensus exists if we can combine pluralism and particularism, as Wallace has proposed:

The views that values are irreducibly plural and sometimes incompatible (pluralism) and that attention to the concrete circumstances in which practical problems arise is necessary ... (particularism) indicate a certain understanding of practical knowledge. On the latter view, such knowledge consists in an accumulation of ways of solving problems that experience has shown to be better rather than worse for certain purposes. ... Such practical knowledge includes matters classified as moral. 104

The many ways that disagreements have been solved within and between societies have included: (1) merely adapting to progress, either social or scientific; (2) creating new social mores; and (3) creating new laws and, occasionally, war.

The principles and rules of law that exist in a pluralistic world are challenged when new technology emerges.

What one should do in concrete situations in which such considerations conflict ... is to seek a way to modify the principles in such a way that (1) one can observe them both, (2) the roles, that is, the

103. Aurora Plomer et al., Commentary, Challenges to Human Embryonic Stem Cell Patents, 2 CELL STEM CELL 13, 15 (2008). See generally R. Stephen Crespi, Patenting and Ethics—A Dubious Connection, 85 J. PAT. & TRADEMARK OFF. SOC’Y 31 (2003). He notes that the European Patent Convention Article 53(a) "excludes from patentability any invention ‘the publication or exploitation of which is contrary to morality or ordre public.’" Id. at 32. He also finds that the European Group of Ethical Advisers to the European Commission has "side-stepped the most difficult questions and has settled for devising its own patentability criteria, of which the key opinion is that only stem cells that have been modified by in vitro treatment or genetic modification can be considered fit subject matter for patents." Id. at 47.

104. JAMES D. WALLACE, ETHICAL NORMS, PARTICULAR CASES 7-8 (1996).
purposes of the principles in the activity at hand are preserved, and (3)
the modification occasions a minimum of disruption elsewhere.105

This has occurred to some degree with advances in reproductive
technology, birth control pills, and in vitro fertilization. Although these
suggestions are helpful, the issues at hand, such as the definition of
when life begins and sanctity of life and the disparate views held by a
minority, mandate a level of moral analysis that must accept that “[t]here
is a powerful intellectual temptation to suppose that morality consists in
a body of principles or rules that unambiguously indicate the right thing
to do in every circumstance.”106 What will be required is for leaders who
represent entities, both religious and non-religious, to come together
and, through extensive dialogue, to reach consensus that allows for
respect of the pluralistic constituencies and social progress. “Whether
this happens, however, depends upon the richness of their practical
knowledge, their ingenuity and courage, and the difficulty of the
problems.”107

A. Religious

The religious debate over stem cell research revolves around the
definition(s) of life and when it begins. This Article does not deal with
these issues in any great detail; however, the relationship of knowledge
and religion is worth noting. It is stated in Ecclesiastes 1:18: “For in
much wisdom is much grief: and he that increaseth knowledge increaseth
sorrow.”108 However, progress in some religious philosophies
seems to allow an appreciation of the lack of conflict between scientific
progress and religion. Francis Bacon also notes in his early essays
(written in approximately 1589) that religious concerns were still
present: “that the aspiring to overmuch knowledge was the original
temptation and sin whereupon ensued the fall of man: that knowledge
hath in it somewhat of the serpent, and therefore where it entereth into a
man it makes him swell.”109 Bacon cites Solomon’s censure, “‘[t]hat
there is no end of making books, and that much reading is weariness of
the flesh,’” and “‘[t]hat in spacious knowledge there is much
contristation [(sadness)], and that he that increaseth knowledge

105. Id. at 20.
106. Id. at 21.
107. Id. at 45.
108. Ecclesiastes 1:18 (King James).
109. FRANCIS BACON, THE ADVANCEMENT OF LEARNING AND NEW ATLANTIS 6 (Arthur
St. Paul, in Colossians 2:8, gives another caveat cited by Bacon: “Beware lest any man spoil you through philosophy and vain deceit, after the tradition of men, after the rudiments of the world, and not after Christ.” Bacon states that “experience demonstrates how learned men have been arch-heretics, how learned times have been inclined to atheism, and how the contemplation of second causes doth derogate from our dependence upon God, who is the first cause.” Bacon then proceeds to plead the case that science is not against religion and is a benefit to society.

These same religious fears regarding science—here stem cell research—continue. Professor Prieur and his co-authors state: “Catholic teaching permits neither the creation nor the destruction of human embryos for the purposes of research. However, stem cell lines derived from human embryonic tissue now exist and research currently is being done in some centers using these cell lines.” The authors continue with a religious caution:

Science also could be on the verge of a spectacular disaster by tampering with the core essentials of human life and its reproduction at the genetic and cellular level. This tension exists in a culture that values efficiency, haste, technology, and expediency, often at the expense of other values such as the dignity of the human person, respect for the mystery of life, human limitations including death, and, ultimately, the plan of the Creator.

One could be concerned that not much has changed. This debate has been further updated in the recent writings of scholars D.W. Brock, Jan Deckers, Mina Alikani, and others. The exact definition of embryo remains a problem, although several authors have tried to address this issue with some of the recent scientific discoveries considered. Researcher David de Kretser states,

However, I have no doubt that techniques will become available to remove the need for human eggs to make the induced pluripotent stem
cells from adult human cells. This will further remove the ethical dilemmas, since if eggs or zygotes are not used, the collection of induced pluripotent stem cells cannot progress to form an embryo or implant into the uterus since these cells do not have the capacity to form a placenta.

... Even if there is a small chance of these pluripotent cells giving rise to an embryo, it would be difficult to argue that any or indeed every adult cell should be given the status of a potential embryo.\textsuperscript{118}

However, recent scientific research has shown that new techniques such as retro-engineering allow skin cells to attain embryo-like potential and altered nuclear transfer may help to answer some, but not all, of the religious concerns.\textsuperscript{119}

B. Conflicts of Interest for Academia and Industry

An improved, more respectful, socially responsible relationship is needed between academia and industry. Society will not prosper if the social purposes of universities and government laboratories are not fulfilled because resources are diverted for market profits and not for social benefits. Similarly, a better balance is needed regarding commercialization of knowledge. It is not always the best for society to have restrictions to access of new knowledge. Society has witnessed the pharmaceutical industry preferentially seek out profit-making drugs, such as Viagra.\textsuperscript{120} They have a fiduciary responsibility to stockholders to do just that and no stockholder would accept diminished financial return so that the company could do more socially responsible research. This may well happen with stem cell research, if it becomes "Viagrified"; that is, preferentially focuses on treatments to improve performance, appearance, etc. We need to resolve the dilemma that commercialization now presents to academia. Former President of Harvard University Derek Bok points out the negative effects that commercialization has had on that institution, and it is likely to be similar at other institutions of


higher learning. The marketplace is not the solution for every social need, and society, through political action, must represent the entire citizenry and not just the powerful interest groups, such as the biotech and pharmaceutical industries. These industries will continue to apply all legal means to gain profitable positions in the potential commercialization of products from stem cell research.

C. The Law and Society

Recently, changes have been suggested that revolve around patent law, the PTO, and its procedures, as well as changes in social norms. Rai prefers a solution that includes both changes in the law and changes in social norms of behavior. This might lead to more appropriate use of patents and improve relationships between academia and industry, if both accept these changes. He emphasizes, as does Wallace, the importance of being pragmatic and dealing with particulars. Bioethicist David Resnik offers specific suggestions as to how to deal with stem cells patents. These include eight suggestions regarding property rights, such as, "[i]t should be legal to patent ES cells, products, and related technologies. . . . [b]ut [p]atents on ES cells, products, and related technologies should not be excessively broad." Donald Willison and Stuart MacLeod point out that an Ontario report on genetics, testing, and gene patenting suggested several changes to Canadian law. European law differs significantly from United States law regarding embryonic stem cell research and patents. Article 6(2)(c) of the European Patent Convention states that "uses of human embryos for industrial or commercial purposes" is not permitted to be patented. Professor Joseph Stiglitz suggests a medical prize fund, which might allow monies for more socially important research as opposed to more commercially suitable research.

121. BOK, supra note 34, at 199-205.
122. See JAFFE & LERNER, supra note 35, at 170-207; Rai, supra note 36, at 137-44.
123. Rai, supra note 36, at 144-51.
124. WALLACE, supra note 104, at 7-8.
125. Rai, supra note 36, at 152.
128. Plomer et al., supra note 103, at 15 (footnote omitted).
VII. ETHICAL ALIGNMENT

A. Freedoms

Ethical alignment is more simply dealt with by eliminating some ethical views. For instance, the possibility of viewing healthcare law as mainly an issue of consumerism would obviate complex analysis. However, health is at the core of “what makes a life livable”¹³⁰ and can be realized in its centrality to the Human Development Index (“HDI”). “The HDI tries to capture the capacity of people to live long and healthy lives . . . .”¹³¹ In addition, there is a need for international alignment from a legal and moral perspective. Each nation state may develop laws that have unintended consequences and represent narrow views and limited philosophical underpinning. As noted by Dr. Henk ten Have:

“This [neutral] language [of bioethics] seems itself to represent the specific moral language of a specific moral community, particularly the (neo) liberal community with universal and equal respect and self-determining freedom as its hypergoods. Upon analysis, bioethics is apparently itself the cultural expression of the political norms of liberalism and individualism, characteristic of North American society.”¹³²

Ethical alignment should extend beyond geographic borders. Also, understanding the many loci of decisionmaking within each society becomes essential if a dialogue is to be meaningful.¹³³ Religious groups and secular players represent sources of political influence through lobbying and political contributions. Other pressure groups include businesses that seek to profit from new technology and universities and government laboratories performing basic research and seeking financial interest through patents and protection of intellectual property. Finally, one must ask who along this long line of stakeholders represents society and has the wisdom to make choices that benefit society.

Where does good public policy emanate from? The need for “smart regulators” represents a point of view that is not respected by many and the need to understand the role of actions by government other than regulations requires better understanding. Scientific progress that is

¹³⁰ BENKLER, supra note 41, at 309.
¹³¹ Id. at 310.
¹³² Morgan, supra note 20, at 80 (footnote omitted) (quoting Dr. ten Have).
supported by government—that is, taxpayer money—deserves accountability; but the question is whether the government merely represents an aggregate view of commercial interests without an ethically principled interpretation of its actions. The United States government, through the National Academy of Sciences, has initiated an effort to address some of the social concerns with the formation of the Committee on Guidelines for Human Embryonic Stem Cell Research. If the benefits of stem cell research are limited because patents reduce the potential of poorer populations from gaining access to its benefits, we will have further fragmentation of the world.

B. Religion

The divergent religious views have created varying views of stem cell research. Disagreement exists over fundamental beliefs of the definition of life and when it begins, the definition of a soul, issues of afterlife, and concepts of the cycle of life. This is seen in the different views of the world’s religions. Some have very different views of afterlife or the lack of it, and thus the answers to questions about the beginning and end of life may vary. Silver states that “[c]ommunal codification of spiritual beliefs is one definition of religion. So to understand the relationship between spirituality and science, we must understand religion in all its various guises.” He also notes that there are over 10,000 individual religions, with Christianity having 33,830 denominations. In the United States, the intermingling of religion and politics came to the surface with the President’s Council on Bioethics. Former Chair Leon Kass championed the mysteries of religion and the sanctity of life as reasons for not funding embryonic stem cell research. Many have written to confront his view as being wrong from many viewpoints.


135. See id. at 47-49 (noting that Islam, Judaism, and some Protestant denominations “do not recognize the human embryo before 40 days after conception as an entity that should be accorded the same moral status as a person”).

136. SILVER, supra note 54, at 19.

137. Id.

138. See generally Kass, supra note 16 (asserting that scientific advances in the realm of stem cell research is a threat to traditional religious values).

139. See, e.g., SILVER, supra note 54, at 54-55; DeGrazia, supra note 18, at 56.
C. Respecting Critical Moral Values in a Pluralistic Society and Preserving Democracy

From a philosophical view:

[W]e must give up "the . . . hope that somehow, somewhere, a magic philosophical formula will be devised that will enable serious philosophical minds to pierce, once and for all, the fog of indecision that attends ampliative governance when it is engaged with norms that broadly and deeply give form to our life and thought. The agitation, doubt, indecision, controversy, etc., are not ailments suffered, not symptoms of disease, but normally signs of health."

The divergent views can be seen in the articles by Brock and Deckers, as well as Professors Bonnie Steinbock and David DeGrazia, over embryos and personhood. As noted with reproductive potential, the philosophical debate will not always allow all parties to agree, and it is necessary to respect all views if a consensus is to be reached.

The question is how we approach solving the complex issues raised by stem cell research and its potential applications. I propose that a sociological view of values may allow for dialogue that bridges some of the differences and may allow for consensus. Jonathan Haidt and Jesse Graham present just such a view. They have proposed a "social intuitionist" model for the different moral views that exist in the world. This work is built on and extends the works of Lawrence Kohlberg, Carol Gilligan, and Richard Shweder and his

140. WALLACE, supra note 104, at 162-63 (footnote omitted) (quoting Frederick L. Will).
141. See generally Brock, supra note 115 (rejecting both the moral and political arguments against human embryonic stem cell research).
142. See generally Deckers, supra note 116 (responding to Brock's claims regarding the status of human embryos).
143. See generally Bonnie Steinbock, The Morality of Killing Human Embryos, 34 J.L. MED. & ETHICS 26, 34 (2006) ("[I]t is permissible to use human embryos in research that kills them because embryos lack moral status.").
144. See generally DeGrazia, supra note 18 (concluding that the Bush Administration's opposition to cloning and embryonic stem cell research was incorrect).
146. Id. at 100.
148. See generally CAROL GILLIGAN, IN A DIFFERENT VOICE: PSYCHOLOGICAL THEORY AND WOMEN'S DEVELOPMENT (1982) (reporting research that "provide[s], in the field of human development, a clearer representation of women's development").
coauthors. Shweder has three areas for his moral discourse: the ethics of autonomy, community, and divinity. The five psychological systems for moral evaluation that Haidt and Graham include are: (1) harm/care; (2) fairness/reciprocity; (3) ingroup/loyalty; (4) authority/respect; and (5) purity/sanctity.

The harm/care dyad evolved from the Kohlberg-Gilligan debates that related to early moral education (gender differences) and has obvious connection to healthcare and professionalism. Fairness/reciprocity represents the second value system that liberals view as essential in a "good" society. The last three value systems are critical to the stem cell "wars" as they represent the value systems of religious groups and political conservatives. Haidt and Graham note that the five foundation theory "offers a surprisingly simple explanation of the 'culture war' going on in the United States, and in other democracies." For ethical alignment to occur so as to move stem cell research forward more effectively, all parties will benefit from recognizing all of the five moral foundations so that we "can open up a door in the wall that separates liberals and conservatives when they try to discuss moral issues." This will not be easy: "[m]obility and diversity make a morality based on shared valuation of traditions and institutions quite difficult." Haidt and Graham perhaps ignore political correctness when they divide the foundational values into tribal and non-tribal. The former are harms and fairness, and the latter include loyalty, authority and respect, and purity. Defining principles alone is not likely to lead to consensus. This occurred when an attempt was made to establish a global bioethics. A major reason for the failure was the differences between the secular and the religious views. Haidt and Graham's values point out the dichotomy of values between tribal and

149. Richard A. Shweder et al., The "Big Three" of Morality (Autonomy, Community, Divinity) and the "Big Three" Explanations of Suffering, in MORALITY AND HEALTH 128, 129 (Allan M. Brandt & Paul Rozin eds., 1997).

150. Id.
151. Haidt & Graham, supra note 145, at 99.
152. Id. at 100-01.
153. Id. at 104-05.
154. Id. at 105-06.
155. Id. at 107.
156. Id. at 113.
157. Id.
158. Id. at 102. Haidt and Graham use the phrase "ethic of community," which encompasses "a collection of institutions, families, tribes, guilds or other groups." Id.
non-tribal groups. The former preferentially value loyalty, authority/respect, and purity over harm and fairness, and the latter do the opposite. As noted above, this can be seen in moral decisionmaking when one compares political liberals and conservatives. And certainly this is worth considering in solving some of the differences in the world that are clearly more than just political. It should be pointed out that all potentially important variables are not discussed here. For instance, moral evaluation skills were at first not thought to be influenced by gender and were later found to be a critical variable. Thus, other variables, such as age, education, and geography, may be important. Therefore, any conversation concerning stem cell research must begin with principles, but quickly look for common ground in particulars that may be facilitated by discussing the values in a nonjudgmental manner. And this will occur “only if science, religion, and politics can find common ground.” Science needs to exist with intellectual freedom and integrity, divergent religious views need to be considered, respected, and integrated into the policies of a democratic society, and the political system (executive, judicial and legislative branches) has to act to create laws and regulations that are “calibrated” so as to be appropriate for the complex issues raised with innovative science. This is certainly not meant to exclude other efforts to deal with the divergent views regarding stem cell research.

VIII. CONCLUSION

This Article has focused on the ethical issues surrounding stem cell research. They have involved the areas of social values and norms, society’s views of science, technology, and progress, and the social responsibility that institutions, such as universities, have to society as compared to the institutions that are market-driven. These impact knowledge, science, and progress. The ethical dilemmas and conflicts of interest are discussed but emphasis is placed on the need for ethical as well as economic alignment of all stakeholders.

Finally, a proposal for understanding the moral differences is given based on the works of Haidt and Graham and others. The need to have an understanding of the different moral values of participants in the stem

160. Id. at 104-05.
161. See GILLIGAN, supra note 148, at 2; KOHLBERG, supra note 147, at 349.
162. WALLACE, supra note 104, at 7-8.
163. SILVER, supra note 54, at 130.
164. KOROBKIN, supra note 96, at 261.
165. See Cribb et al., supra note 47, at 359.
cell “wars” is emphasized in that it may facilitate bridging a moral divide and enable a consensus that will benefit society.