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## IN (OR OUT OF) THE MARKETPLACE OF IDEAS: WARF V. GERON AND LESSONS FOR CANADA

MATTHEW HERDER<sup>1</sup>

### ABSTRACT

Four days after President George W. Bush addressed America regarding human embryonic stem cell (“hESC”) research in August 2001, a lawsuit was filed by the Wisconsin Alumni Research Foundation (“WARF”) against Geron Corporation (“Geron”). WARF holds patents in respect of hESC technologies pioneered by James Thomson. The parties were unable to negotiate licences for additional hESC types. In January 2002, WARF and Geron announced that a new agreement had been reached. This paper examines the antecedent question: should the hESC technologies have been patentable in the first place?

The reason for pursuing hESC research appears to be the possibility to improve human health. But hESC research also carries great economic potential. Express prioritization of these dual benefits is lacking. The practice of patenting hESC technologies provides a clue. The empirical support for the proposition that patent rights increase scientific innovation is minimal. Two arguments favour the status quo:

- (i) the researchers who ‘invent’ the technologies are entitled to a property right (Lockean argument); and,
- (ii) circumscribing access to secure investment is acceptable because an overall benefit is produced (utilitarian argument).

However, both arguments rest on dubious premises. Most notably, the “tragedy of the anticommons”, added transaction costs, and depreciated scientific creativity undermine the claim that a net benefit will accrue. Preserving the current regime therefore attaches higher priority to commercial interests. Two responses are left: modifying the patent system or

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placing hESC technologies in the public domain. Only the latter will ensure that the potential health benefits of hESC research are the top priority.

## I. INTRODUCTION

This comment takes a close look at a recent contractual dispute between a private corporation and a group of public researchers over an intellectual property rights licensing arrangement for various human embryonic stem cell (hESC) technologies. In this paper the public interest in hESC research is defined, and the claim that patents bolster the public interest is critically examined. Lockean property and utilitarian arguments are found to rest on dubious premises and fall short of providing sufficient justification to support patenting hESC technologies. Yet patenting hESC technologies is the present starting position. Inconsistent with the public interest, it appears that the potential economic benefits are given priority over the potential health benefits of hESC research. The likelihood and the means by which this might be reversed is briefly considered in the Canadian context.

## II. *WARF v. GERON*

### 1. The Licensing Agreement & The Federal Lawsuit

In 1996, the Wisconsin Alumni Research Foundation (“WARF”) entered into a contractual relationship with a private entity, Geron Corporation (“Geron”) of Menlo Park, California. Under the arrangement, Geron provided funding for a group of researchers at the University of Wisconsin-Madison headed by James Thomson, and in return WARF granted Geron a nonexclusive right to develop therapeutic and diagnostic products under the WARF primate stem cell patent.<sup>1</sup> In 1998, Thomson et al. made a scientific breakthrough, pioneering the derivation of stem cells from *human* blastocysts.<sup>2</sup>

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<sup>1</sup> Brief for Plaintiff at 18, Wisconsin Alumni Research Foundation v. Geron Corporation, D. Wisc. (F. Cir. 2001) (No. 01-C-0459).

<sup>2</sup> J.A. Thomson *et al.*, “Embryonic Stem Cell Lines Derived from Human Blastocysts” (1998) 282:5391 Science 1145.

Since that time there have been a number of developments. Thomson and his co-researchers have filed and have been granted patents pertaining to hESC research, which are held by WARF. They have also developed five viable hESC lines, which again, WARF holds. According to WARF, officials at Geron marveled at the prospect of the results of Thomson's research. In April 1999, WARF entered into a new agreement with Geron (the "1999 agreement or licence"), which licensed six cell types and methods relating to their production (*i.e.* derivation technologies) to the company for therapeutic and diagnostic applications, on an exclusive basis.<sup>3</sup> The licence agreement contained an option to add new cell types due to expire on March 31, 2001, which was subsequently extended to July 31, 2001.<sup>4</sup> In December 2000 the parties began to negotiate pursuant to this option. As well, the 1999 licence granted Geron certain rights relating to research products. Geron had insisted that those rights be exclusive, but WARF sought a compromise: only research products and services employing WARF technology

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<sup>3</sup> Brief for Plaintiff, *supra* note 1 at 19.

<sup>4</sup> The option, Section 2C of the 1999 agreement, attached as Exhibit A to WARF's amended complaint, reads as follows:

WARF hereby grants Geron the first option to negotiate an exclusive license for the addition of cell types to the Licensed Field. Geron may exercise its options under this Section 2C by providing WARF with written notice of its desire to add a cell type to the License Field including a Development Plan detailing Geron's plan and timeline for bringing Products to the market incorporating the new cell type and by paying WARF an upfront license fee to be negotiated in good faith between the parties factoring in commercially reasonable terms given the advancement of cell therapy in therapeutics and diagnostics and the value added by Geron. The terms of the exclusive license, other than the upfront license fee, shall be identical to the terms set forth in this Agreement, unless otherwise negotiated and agreed to by the parties. If the parties fail to agree on an upfront license fee for an additional cell type, WARF agrees that it will not offer such cell type to any third party on terms more favorable as a whole to such licensee than were offered to Geron hereunder for a period of eighteen (18) months from the date Geron first exercised its option to add a cell type to the Licensed Field. In the context of this Agreement, "terms more favorable as a whole" shall mean that the combination of the commercial terms, for example the license fee, royalty rate, milestones, minimum royalties, and other fees required as consideration for the rights granted under the license are not more favorable when taken together to the package offered to Geron. The option to add cell types shall expire on March 31, 2001 unless extended for an additional period by written agreement on terms mutually acceptable to the parties.

and incorporating Geron's own patented technology would be subject to an exclusive claim.<sup>5</sup>

In the midst of all this, the WARF researchers set up a non-profit corporation, WiCell Research Institute Inc. ("WiCell"), acting as a subsidiary of WARF and offering to distribute hESC technologies online to interested public researchers. Later, WiCell would play a key role in helping the National Institutes of Health create its "Human Embryonic Stem Cell Registry".<sup>6</sup>

On August 13, 2001, just four days after President George W. Bush addressed the American nation on the topic of hESC research,<sup>7</sup> a complaint seeking declaratory relief was filed at a federal court in Madison, Wisconsin by WARF against Geron. The disagreement had culminated on July 31, 2001 when Carl E. Gulbrandsen, the Managing Director of WARF, rejected Geron's unilateral attempt to exercise its "first option to negotiate" and lay claim to eleven additional cell types. In a letter dated August 1, 2001, Geron fired back. In marked contrast to WARF's interpretation, Geron interpreted the "Research Products" clause much more expansively:

Geron has exclusive rights to make, use and sell research tools that involve in some way one or more of the six cell types or derivatives therefrom and incorporate any other patented technology that Geron owns or has the right or license (exclusive or nonexclusive) to use.

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<sup>5</sup> Brief for the Plaintiff, *supra* note 1 at 19. "Research Products" are defined in Appendix A, ¶ E of the 1999 agreement, attached as Exhibit C to the amended complaint. The provision reads:

"Research Products" shall refer to and mean products or services that (i) are used in research as research tools which would infringe the claims of patented technology owned by Geron or which Geron has a right to license to use other than the Licensed Patent; and (ii) which employ, are in any way produced by the practice of, are identified using or arise out of any research involving the inventions claimed in the Licensed Patents or that would otherwise constitute infringement of any claims of the Licensed Patented Research Products specifically excludes the Materials.

<sup>6</sup> See National Institutes of Health (NIH), News Release, "National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement" (5 September 2001), online: National Institutes of Health <<http://www.nih.gov/news/pr/sep2001/od-05.htm>> (date accessed: 01/11/15). In November, the NIH launched the registry online, listing 11 participating entities and total of 64 hESC lines (now 72); see <<http://escr.nih.gov/>> (date accessed: 01/11/15).

<sup>7</sup> See "Text: Bush's Address on Stem Cell Research" *The New York Times* (10 August 2001) online: <<http://www.nytimes.com/>> (date accessed: 01/08/12).

This latter component is subject to change over time as Geron acquires additional proprietary rights, and the definition as presently structured would ultimately lead to complete exclusivity for Research Products within the Licensed Field. *We understand that this will make it quite difficult for WARF to grant licenses to other entities for Research Products, since the other entity could never be assured of the extent, or even the continued existence, of the rights granted to it.* Moreover, WARF would breach the terms of its agreement with Geron were it to grant rights that conflicted with those granted to Geron, even if the rights accrued retrospectively.<sup>8</sup> [emphasis added]

Thus, there were two main points at issue: WARF's further obligations to Geron (if any) pertaining to adding new cell types since the date for the option to be exercised had lapsed; and the scope of the "Research Products" clause in the 1999 agreement. John S. Skilton of Heller Ehrman White & McAuliffe LLP, counsel for WARF, explained that WARF wished to licence cell types to third parties but, based on Geron's interpretation of the clause, feared Geron's likely interference.<sup>9</sup> Skilton argued that this interpretation was entirely inconsistent with the intent of the parties and that WARF had met its duties under the licencing agreement. In support, he pointed to such cornerstones of contract law as rules of interpretation, good faith, and fair dealing in the amended complaint and brief filed at the Western District of Wisconsin Federal Court on September 24 and October 30 of 2001 respectively. But there is an overarching concern cited in both documents – the need to preserve the public interest in hESC research.

## 2. The New Agreement

On January 9, 2002, WARF and Geron announced that they resolved the federal lawsuit and have entered into a new licensing agreement for the "commercialization" of hESC technology.<sup>10</sup>

The statement released by WARF describing the new agreement reads, in part, as follows:

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<sup>8</sup> Amended Complaint for Declaratory Relief at 5-6., Wisconsin Alumni Research Foundation v. Geron Corporation, D. Wisc. (F. Cir. 2001) (No. 01-C-0459).

<sup>9</sup> *Ibid.*, at 6-7.

<sup>10</sup> Wisconsin Alumni Research Foundation, "WARF and Geron Resolve Lawsuit and Sign New License" (9 January 2002), online: WARF <<http://www.warf.ws/news/>> (date accessed: 02/01/09).

In the new license, Geron holds exclusive rights to develop therapeutic and diagnostic products from hESC-derived neural, cardiomyocyte and pancreatic islet cells. Geron also has non-exclusive rights to develop therapeutic and diagnostic products from hESC-derived hematopoietic, chondrocyte, and osteoblast cells. The agreement also grants Geron non-exclusive rights to develop research products in the following cell types: hepatocytes, neural cells, hematopoietic cells, osteoblasts, pancreatic islets and myocytes.

WARF and Geron have further agreed to grant research rights to existing hESC patents and patent filings to academic and governmental researchers without royalties or fees. WiCell Research Institute, a WARF subsidiary, will distribute the cell lines. Third party for-profit companies may form collaborations with Geron or obtain licenses to Geron's intellectual property on market terms.<sup>11</sup>

There are two key elements of this new deal. First, Geron's proprietary interest has been enlarged: the company acquired the rights to develop therapeutic and diagnostic applications for six cell types (three on an exclusive basis and three non-exclusively), and the rights to develop research products for six cell types on a non-exclusive basis. Second, WARF, under the auspices of WiCell, can grant research rights to public researchers on *existing* hESC patents and patent filings.

Avoiding litigation, which was likely to be long, is a good thing and not just to the immediate parties. The clause allowing WARF to supply hESC research materials to other researchers is significant. But is the resolution reached truly consistent with the public interest in hESC research? The new agreement does nothing, for instance, to preclude Geron from patenting, and thereby controlling access to, diagnostic or therapeutic applications with neural or cardiomyocyte cell types for neurological disorders or heart disease in the future.

### III. THE PUBLIC INTEREST IN EMBRYONIC STEM CELL RESEARCH

Even if the matter had seen the inside of a courtroom, with the weight of the U.S. President's decision emphasizing the importance of

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<sup>11</sup> *Ibid.*



hESC research on the court's shoulders, it is almost inconceivable to imagine a ruling against WARF. In any event, the scenario presents a perfect platform upon which to consider the antecedent question: should the hESC materials and technologies have been patentable and therefore licensable in the first place? WARF's counsel, of course, did not frame the public interest question in this manner. However, policy-makers in this global community need to consider this prior question to evaluate whether the public interest is served.

### 1. The Goal of hESC Research

In the wake of the 1998 Thomson experiments, the attention to hESC research in the media, the scientific literature, the philosophical/bioethical literature, and in the realm of public policy debates has been nothing short of stupefying. The research has been hailed as the basis for developing cures for a spectrum of conditions including Parkinson's disease, Alzheimer's disease, and diabetes to name only a few.<sup>12</sup> And, many have argued that we are morally bound to aggressively pursue this avenue of research.<sup>13</sup> Guidelines issued by various committees routinely opt to push the research agenda forward notwithstanding strong opposition to the destruction of embryos for the derivation of hESC lines, piecemeal regulation,<sup>14</sup> and the existence of less controversial alternatives (e.g. adult stem cell research).<sup>15</sup>

This suggests that the reason for pursuing hESC research is the possibility to alleviate a vast array of human suffering. It follows that hESC research should serve a social goal: increasing human health and well-being.<sup>16</sup> The potential for economic benefit should therefore be of secondary importance.

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<sup>12</sup> E.g., National Institutes of Health (NIH), *Stem Cells: Scientific Progress and Future Research Directions* (July 2001), online: NIH <<http://www.nih.gov/news/stemcell/scireport.htm>> (date accessed: 01/12/13).

<sup>13</sup> E.g., G. McGee & A. Caplan, "The Ethics and Politics of Small Sacrifices in Stem Cell Research" (1999) 9:2 *Kennedy Institute of Ethics Journal* 151 at 153.

<sup>14</sup> See generally, M. Herder, "The U.K. Model: setting the standard for embryonic stem cell research?" *Health L. Rev.* [forthcoming in 2002].

<sup>15</sup> E.g., G. Vogel "Can Adult Stem Cells Suffice?" (2001) 292:5523 *Science* 1820.

<sup>16</sup> One author has opined that this is always the goal when the research involves human biological materials. See E.R. Gold, "Making Room: Reintegrating Basic Research, Health Policy, and Ethics into Patent Law" in T. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) 63 at 65 [hereinafter "Making Room"].

Interestingly, hESC research policies and guidelines do not expressly recognize the dual benefits of this research. In this way, direct prioritization is avoided. Here, it is important to ask what is truly driving the research agenda? On one hand, the public is being asked to support hESC research because of its potential health benefits. And, there is a research community seemingly committed to realizing the health benefits of hESC research for society. But on the other hand, economic interests are protected: legislation and guidelines already in place or enduring the drafting process are typically silent on the issue of patentability.<sup>17</sup> Thus, while therapeutic applications remain years away, the process of commercialization is accelerating at a rapid rate. WARF and Geron are amongst the trailblazers.

Clearly, the public face given to hESC research concerns the health-oriented goal. Commercialization enthusiasts, WARF and Geron included, typically invoke the potential health benefits to support their position. But what guarantee exists that the potential health benefits are the primary impetus for hESC research? The absence of an explicit prioritization from any source is conspicuous. A closer inquiry into the present state of affairs may provide a measure of insight. Provided that the public interest in hESC research is represented by moving towards the goal of increasing health and well-being first and foremost, cogent arguments demonstrating that intellectual property rights facilitate that transition – not the transition from research tool to commercial product – are necessary.

## 2. Achieving Greater Health and Well-being

There is no definitive empirical support for the proposition that intellectual property rights increase scientific innovation.<sup>18</sup> Statements that posit such a positive correlation reflect little more than self-serving intuitions.<sup>19</sup> Why then does patenting hESC technologies constitute the starting position? Two main arguments appear to underlie this reality:

- (i) the researchers who through their labour ‘invent’ the technologies are entitled to an ownership right in respect of those technologies (Lockean argument); and,

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<sup>17</sup> Herder, *supra* note 14.

<sup>18</sup> “Making Room”, *supra* note 16 at 68.

<sup>19</sup> *Ibid.*

- (ii) circumscribing access to patented technologies in order to secure monetary investment is permissible because an overall benefit for the public good will be produced (utilitarian argument).<sup>20</sup>

In relation to the omnibus goal of hESC research, these two trains of thought operate quite differently. Whereas the utilitarian argument claims to increase the common good, the Lockean view only stipulates that burdens may not be imposed on third parties. In this analysis the common good need not be advanced. In this sense the Lockean argument is irrelevant to this essay's central criterion. Insofar as it does play a part in preserving the status quo, it is useful to examine it at least as a preliminary matter.

*(i) Locke's labour theory argument: a question of entitlement*

Increasingly, researchers in the biomedical field have regarded patent rights as entitlements.<sup>21</sup> Some have attributed this mindset shift to a top-down change in policy,<sup>22</sup> or law-and-norms working synergistically.<sup>23</sup> Others ascribe it to the maturation of biotechnological science itself.<sup>24</sup> Irrespective of the precise source of this change, it is a valuable exercise to delve into the logic behind this claim.

*(A) The Lonely Scientist*

Thomson *et al.* may believe the hESC technologies they have developed are patent-worthy, because they represent *their* ingenuity and *their* work. This is in line with Locke's theory, which aims to justify private property rights based upon notions of labour and desert.<sup>25</sup> However, this

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<sup>20</sup> K. Lebacqz, "Who 'Owns' Cells and Tissues?" (2001) 9 Health Care Analysis 353 at 358-59.

<sup>21</sup> M.A. Heller & R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280:5364 Science 698 at 698 [hereinafter "The Anticommons"].

<sup>22</sup> *E.g.*, R.S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research" (1996) 82 Va. L. Rev. 1663.

<sup>23</sup> *E.g.*, A.K. Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" (1999) 94 Nw. U.L. Rev. 77.

<sup>24</sup> E.R. Gold, "Finding common cause in the patent debate" (2000) 18 Nature Biotechnology 1217.

<sup>25</sup> J. Locke, *Two Treatises of Government*, Book II, Ch. 5, P. Laslet ed., 2nd ed. (Cambridge: Cambridge University Press, 1967).

view presupposes that the rights claimant is in fact claiming a right over his or her own labour. But scientific progress is an “interdependent social project”.<sup>26</sup> In other words, it is a communitarian (not an isolated) endeavor. By rewarding a single investigator or group of investigators, the patent system necessarily distorts the communitarian nature of this project. Hettinger poignantly describes this absurdity: “[a] person who relies on human intellectual history and makes a small modification to produce something of great value should no more receive what the market will bear than should the last person needed to lift a car receive full credit for lifting it”.<sup>27</sup> The work done by WARF researchers was a contribution, albeit an extremely significant one, in a greater scientific project to eradicate forms of human disease. Perhaps the cure for Alzheimer’s disease will be developed by one laboratory, but could that achievement be isolated from all previous efforts? In the language of the *Patent Act*,<sup>28</sup> the answer is a resounding ‘yes’, however, that does not mean it makes sense.

(B) *Discovery v. Invention*

The preceding view of scientific inquiry is perhaps too idealistic. To be sure, the practice of seeking patents for inventions seems deeply entrenched if not enforced in biomedical research culture.<sup>29</sup> But an important distinction should be kept in mind: scientific discovery versus scientific invention. It is more problematic to argue that a finite number of investigators *ought* to be rewarded by a patent for a scientific discovery as opposed to an invention.

On its surface, the current legislation in Canada reflects this thinking. The *Patent Act* stipulates that only “inventions” – “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” – are patentable.<sup>30</sup> This definitional

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<sup>26</sup> N. Brett, “Private Life: Biotechnology and the Public/Private Divide” (August 2001) at 16 [unpublished, part of the Legal Dimensions Initiative for the Law Commission of Canada] [hereinafter “The Public/Private Divide”].

<sup>27</sup> *Ibid.*, at 17 quoting E. Hettinger, “Justifying Intellectual Property” (1989) *Philosophy and Public Affairs* 18 at 38.

<sup>28</sup> R.S.C. 1985, c. P-4.

<sup>29</sup> Rai, *supra* note 23 at 109-11.

<sup>30</sup> *Patent Act*, *supra* note 28, s. 2.

requirement has been adhered to in prior case-law. For instance, in *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, Justice Lamer, held that “[t]he courts have regarded creations following the laws of nature as being mere discoveries the existence of which man [*sic*] has simply uncovered without thereby being able to claim he [*sic*] has invented them”.<sup>31</sup> Similarly, the trial judge in *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* maintained that “[a]nything that is merely a discovery is not patentable subject-matter”.<sup>32</sup>

Given that the source of hESC lines and types, embryos, exist in nature<sup>33</sup> how can they be patentable? The answer offered relates to the qualification Lamer J. put on his remarks in *Pioneer Hi-Bred* – “the nature of the intervention”<sup>34</sup> – *i.e.* the innovation occurs by deriving the hESC line or type.<sup>35</sup> Brett points out that the question whether it is invented gets collapsed into the question “is its usefulness a product of the invention?”<sup>36</sup>

So, only hESC lines and types that have been derived are patentable (*i.e.* hESC types in their pre-derived state in the embryo are not patentable because no intervention has taken place). But collapsing the question in this way skips a step. It does not follow that hESC lines or types are new, *i.e.* an invention, because a method of derivation has been constructed.<sup>37</sup> “The acceptance of this as a legitimate basis for the patenting of discoveries would provide a wide and slippery slope toward the privatization of whatever scientists find”.<sup>38</sup> This logical error is compounded by the very nature of intellectual property rights, which negatively impact third parties. For example, patents for a particular hESC line or type extend beyond the basic research to testing and therapeutic applications.<sup>39</sup> Alternative tests or therapies are less likely to

<sup>31</sup> (1989), 60 D.L.R. (4th) 223 at 231 [hereinafter *Pioneer Hi-Bred*].

<sup>32</sup> [1998] 3 F.C. 510 (T.D.) at para 26.

<sup>33</sup> Arguably, embryos created through in vitro fertilization do not exist in nature. Creating IVF embryos necessarily involves scientific intervention, but should the embryos themselves be patentable? Should the intervention be patentable? What is the difference?

<sup>34</sup> *Supra* note 31 at 231.

<sup>35</sup> “The Public/Private Divide”, *supra* note 26 at 26.

<sup>36</sup> *Ibid.*, at 22.

<sup>37</sup> See Brett, *supra* note 26 at 23.

<sup>38</sup> *Ibid.*, at 26.

<sup>39</sup> *Ibid.*, at 26-27. This is vividly illustrated by the recent actions of Myriad Genetics Corporation, which holds the patent on the ‘breast cancer genes’. It is attempting to charge a \$3000

be developed because of potential patent infringements.<sup>40</sup> Patent-holders can require fee-for-use of the controlled technologies or even prohibit researchers from improving the technologies throughout the designated period. Coupled with this discovery quality, this overbreadth runs counter to an argument in favour of these patents as of right.

In contrast, the processes for deriving hESC lines and types can be readily characterized as inventions. However, can a distinction between those processes and the materials they produce be drawn? Since hESC lines and types cannot exist absent derivation technologies, is an entitlement to patent the latter sufficient to support an entitlement, in effect, to the former? An ownership right that overreaches in this way requires added justification. Possibly the utilitarian argument is able to compensate.

*(ii) The utilitarian argument: patents will benefit the public good*

From a utilitarian perspective though, the preceding criticisms do not matter. So long as a patent has a net positive effect (*e.g.* the patent-holders construct a derivation process for a specific type of neural cell), imposing burdens on others (*e.g.* preventing other researchers from using that derivation technology to produce that neural cell type), even ‘harming’ others (*e.g.* obtaining embryos for experiments without informed consent), is justifiable. As mentioned at the outset, what remains hidden in this reasoning is the fact that the assumption that intellectual property rights facilitate scientific innovation is itself open to challenge. There are reasons to suggest that an overall increase in utility does not occur. If the other researchers referred to in the above example had access to the technology that is capable of producing that neural cell type, they may have developed a therapy for a neurological disorder before the patent-holders, or in a more cost-effective manner.

*(A) The “Tragedy of the Anti-commons” and Transaction Costs*

Intellectual property rights represent barriers for follow-on improvements. The effect of these barriers can differ depending upon whether the patents pertain to basic (“upstream”) research technologies or applied

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dollar fee for anyone who wants to be tested for the genes. See T. Caulfield & E.R. Gold, “The Dark Side of Gene Patenting” *The Ottawa Citizen* (21 November 2001) A19.

<sup>40</sup> “The Public/Private Divide”, *supra* note 26 at 27.

(“downstream”) research technologies. Whereas a patent relating to a downstream technology can preclude other researchers from improving upon that particular technology, patents on upstream technologies can preclude other researchers from improving or developing a whole host of technologies. The patents held by WARF are of the upstream variety – the relevant technologies will hopefully (from Geron’s point-of-view) serve as the basis for any number of (lucrative) applications. Recall the new licensing agreement. Geron aims to develop diagnostic and therapeutic applications in respect of six cell types.

Heller and Eisenberg have dubbed this phenomenon the “tragedy of the anticommons”:

The problem we identify is distinct from the routine underuse inherent in any well-functioning patent system. By conferring monopolies in discoveries, patents necessarily increase prices and restrict use – a cost society pays to motivate invention and disclosure. The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.<sup>41</sup>

Although the article focused upon the patenting of DNA sequences and expressed sequence tags (ESTs), Heller and Eisenberg’s analysis applies equally to hESC technologies. Downstream hESC research may involve multiple cell types so the tragedy of the anticommons can result where the patents for each cell type are held by multiple researchers. Alternatively, even if the rights to multiple cell types or the corresponding derivation processes are held collectively, the patent-holder can licence them on a per-item basis. Again the anticommons tragedy can ensue.

Heller and Eisenberg acknowledge that this tragedy may actually prove to be illusory as parties negotiating licensing agreements gain experience and patents continue to attract enough investment to support upstream research in the long term – the end may justify the means.<sup>42</sup> But three “structural concerns” inherent in the patent system provide added reason to doubt that overall utility will increase.<sup>43</sup> First, the interests of the parties may not coincide. Compare WARF and Geron:

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<sup>41</sup> “The Anticommons”, *supra* note 21 at 699.

<sup>42</sup> *Ibid.*, at 700.

<sup>43</sup> *Ibid.*

on one level, revenue motives (universities/institutions) and profit motives (corporations) can be at odds with one another. To maximize revenue, institutions need to licence non-exclusively to secure maximum royalties, unless the fee offered for a single exclusive licence is greater. From a corporation's perspective, monopolies offer the greatest return. More fundamentally, the parties may simply have different goals: Thomson *et al.* wanted to make available the basic research tools to other public researchers whereas Geron wanted to increase the value of its portfolio. The result of this underlying tension: negotiations over a new agreement were repeatedly frustrated and the parties became engaged in a federal lawsuit.

"Transaction costs" constitute the second identified impediment to net benefits.<sup>44</sup> In this arena standard licence terms are likely to be rare, such that negotiations may only take place on a case-by-case (or cell type by cell type) basis.<sup>45</sup> Each transaction therefore carries a cost, and the overall cost to a researcher rises in proportion to the number of patents that bear upon the chosen research agenda. Even where negotiations go smoothly and the subsequent research proves fruitful, transaction costs may be further exacerbated by "strategic behaviour", where "[t]he original patentee [uses] its patent as a "holdup" right, so as to appropriate as much of the value of the improvement as possible".<sup>46</sup>

Transaction costs are in part a function of valuation difficulties and this speaks directly to the third structural concern, namely "the cognitive biases among researchers".<sup>47</sup> Heller and Eisenberg suspect that researchers often overvalue their discoveries.<sup>48</sup> If a fraction of the promise associated with hESC research is realized, placing a monetary value upon an hESC line or type would seem impossible. Thus, regardless of whether these "inventions" are overvalued by the researcher, this uncertainty drastically undermines "the assumption that licencing agreements will be fairly easy to negotiate".<sup>49</sup> Indeed, *WARF v. Geron* offers a case in point.

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<sup>44</sup> *Ibid.*

<sup>45</sup> *Ibid.*

<sup>46</sup> Rai, *supra* note 23 at 128.

<sup>47</sup> "The Anticommons", *supra* note 21 at 701.

<sup>48</sup> *Ibid.*

<sup>49</sup> Rai, *supra* note 23 at 125.



*(B) Scientific Creativity*

The utilitarian argument is also undercut by what Rai refers to as “creativity costs”.<sup>50</sup> Contrary to assertions that coordination by a single rightsholder promotes efficient research and development, “progress in basic science occurs most quickly ... when different teams of scientists, working independently but with an awareness of each other’s efforts, use divergent approaches to the same problem”.<sup>51</sup> Since “many new technologies come into existence in relatively embryonic form”,<sup>52</sup> researcher independence is absolutely crucial. The WARF subsidiary, WiCell, did not appear to succumb to pressure from Geron. How often will that be the case?

Monopoly rights create added incentive for development, but this must be offset against these external creativity costs. Scientific creativity may also be constrained internally, by an organization’s own orientation. Given that patent-holders, particularly those in the private sector, are likely to pursue research that is profit-oriented while “necessary and good health research” does not always translate into financial gain,<sup>53</sup> (near) monopolies threaten to eliminate this other less-profitable research altogether. This surely does not factor positively into the utilitarian calculus. Not all hESC research will lead to life-saving therapies, yet where so little is known, can society afford for the research agenda to be limited by strict ‘bottom-line’ motives?

In sum, it is not clear that the intellectual property framework yields a net benefit to society. The point is buttressed where the research in question is funded wholly or partly, by public funds in which case patents, in effect, “require the public to pay twice for the same invention”.<sup>54</sup> Like the Lockean entitlement argument, the utilitarian view seems to assume more than it is worth. Consequently, the view that the potential health benefits of hESC research constitute the top priority is undermined.

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<sup>50</sup> *Ibid.*, at 136.

<sup>51</sup> *Ibid.*, at 124.

<sup>52</sup> *Ibid.*

<sup>53</sup> E.R. Gold, “Biomedical Patents and Ethics: A Canadian Solution” (2000) 45 McGill L.J. 413 at 429.

<sup>54</sup> Eisenberg, *supra* note 22 at 1666.

## IV. LESSONS FOR CANADA

The notion that intellectual property rights facilitate a move towards increased health and well-being through hESC research is not substantiated by convincing arguments. But a bigger problem remains. Other attacks surrounding the sanctity and special status of human biological materials for instance, have had no impact on patent policy.<sup>55</sup> Gold notes that industry proponents and patent critics tend to simply “argue past each other”.<sup>56</sup> In principle, the foregoing illustration should be more persuasive because it elucidates the weaknesses of the patent enthusiasts’ argument from within the patent scheme itself.

This new sphere of research is charged with controversy. The patent system provides a means for policy-makers to avoid confronting difficult value and ethical debates.<sup>57</sup> Canada has condoned hESC research within limits. But no real limit has been placed upon commercialization. It is important to recognize that this is essentially a choice, one which should not go unquestioned. The public interest in hESC research cannot be safeguarded where the market is gatekeeper.<sup>58</sup>

### 1. Modifying the Patent System

Intellectual property law is poorly fashioned to achieve the social goal of hESC research.<sup>59</sup> It may be possible to re-equip the patent system to address some of the concerns highlighted here. Three categories of responses include:

#### (i) Clarification of the Existing Criteria

Interpreting patents more narrowly in general may help to reduce transaction and creativity costs. A more focused approach involves stringently applying the “utility” requirement, so that ESTs of unknown function for example, would not be patentable.<sup>60</sup> On the other hand, the

<sup>55</sup> T. Caulfield, E.R. Gold, & M.K. Cho, “Patenting human genetic material: refocusing the debate” (2000) 1 *Nature Reviews Genetics* 227 [hereinafter “Patenting human genetic material”].

<sup>56</sup> E.R. Gold, “Moving the gene patent debate forward: A framework for achieving compromise between industry and civil society” (2000) 18 *Nature Biotechnology* 1319.

<sup>57</sup> “Making Room”, *supra* note 16 at 68.

<sup>58</sup> *Ibid.*, at 68-69.

<sup>59</sup> “Patenting human genetic material”, *supra* note 55 at 228.

<sup>60</sup> *Ibid.*, at 230.

processes invented to derive hESC lines and types are clearly useful. Thus, relying on a stricter application of the utility doctrine would not be sufficient to address the problems of access previously noted.

(ii) *Research Exemptions*

(A) *Experimental Use*

Fear of costly patent infringement litigation may preclude researchers from undertaking valuable research.<sup>61</sup> In the U.S., research that is not “purely philosophic” is potentially subject to such an attack.<sup>62</sup> Broadening the ambit of an experimental-use exception may allow a greater number of researchers to conduct basic research in emerging areas of science. There is precedent for doing so in the European communities.<sup>63</sup>

(B) *Reverse Doctrine of Equivalents*

Related to the experimental-use exemption, Merges has proposed employing the reverse doctrine of equivalents to facilitate negotiations between patent-holders and follow-on improvers where the invention is or operates in a substantially different manner than the patented invention.<sup>64</sup> Where a court finds a significant amount of “value-added” to the invention, infringement litigation should fail.<sup>65</sup>

(C) *Compulsory Licencing*

Gold suggests that compulsory licencing could be used with respect to “research tools such as ESTs, genes, and cell-lines”.<sup>66</sup> It operates by allowing “a third party to use a patented invention without permission by the patent holder for a reasonable fee”.<sup>67</sup> He notes that compulsory licencing is an attractive alternative for three main reasons: first, “a patent holder would not be able to prevent a competitor from using the tool since the competitor would not be entitled to a licence on commer-

<sup>61</sup> *Ibid.*

<sup>62</sup> “Making Room”, *supra* note 16 at 71.

<sup>63</sup> *Ibid.*

<sup>64</sup> R. Merges, “Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents” (1994) 62 *Tenn. L. Rev.* 75 at 81-82.

<sup>65</sup> Rai, *supra* note 23 citing R. Merges, “A Brief Note on Blocking Patents and Reverse Equivalents: Biotechnology as an Example” (1991) 73 *J. Pat. & Trademark Off. Soc’y* 878 at 887-88.

<sup>66</sup> “Making Room”, *supra* note 16 at 72.

<sup>67</sup> *Ibid.*

cial terms”; second, it “would prevent prohibitive or anti-competitive licencing terms with respect to basic technology”; and, third, compulsory licencing “would prevent the monopolization of early-stage technologies so that competition can take place with respect to end products”.<sup>68</sup> As a result, compulsory licencing may markedly reduce patent barriers to upstream research while preserving economic incentives at the other end.<sup>69</sup>

Gold’s view is pragmatic. Yet the health benefits of hESC research only become tangible to society at the application (diagnostic/therapeutic) end. Is the balance that Gold sketches therefore ill-advised? Further, a primary problem for both the compulsory licencing and experimental-use approaches concerns valuation. Given that researchers and industry actors with intimate knowledge of the state of the science and market respectively are not likely to agree upon the value of these materials, it is arguably futile to place the burden of formulating royalty figures on the judiciary.<sup>70</sup> With respect to the reverse doctrine of equivalents, the problem of transaction costs, which stifles research *ab initio*, is left unaddressed.<sup>71</sup>

### (iii) Activating a Public Order/Morality Exclusion

Knoppers has suggested that a public order or morality exclusion similar to the one employed by the European Patent Convention might be a means to deny patents where it would be contrary to public policy.<sup>72</sup> What would in fact be contrary to public policy is not clear. Not surprisingly, in Europe this provision has seldom been applied.<sup>73</sup> For example, the challenges against patenting the oncomouse using this provision failed.<sup>74</sup> In Canada, where the patentability of the oncomouse is still pending, courts have been loathe to give effect to patent officials’ attempts to implement public policy considerations.<sup>75</sup>

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<sup>68</sup> *Ibid.*

<sup>69</sup> *Ibid.*

<sup>70</sup> Rai, *supra* note 23 at 141-42.

<sup>71</sup> *Ibid.*, at 142.

<sup>72</sup> B.M. Knoppers, M. Hirtle, & K.C. Glass, “Commercialization of Genetic Research and Public Policy” (1999) 286:5448 *Science* 2277.

<sup>73</sup> *Ibid.*

<sup>74</sup> “Patenting human genetic material”, *supra* note 55 at 228.

<sup>75</sup> *E.g.*, *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* [2000] 4 F.C. 528 (C.A.).

## 2. Placing hESC Research in the Public Domain

### (i) *Non-Patentable Discoveries*

The most direct way to ensure access to hESC lines, types and derivation processes is to deny patents on those technologies altogether.<sup>76</sup> The circumstances described above – poorly constructed entitlement claims and unsubstantiated claims about a net increase in utility – warrant invoking this response for now. The other options constitute ad hoc attempts to minimize the challenges raised by new forms of biomedical research like hESC research.<sup>77</sup> Valuation problems are more or less eliminated once hESC research is placed in the public domain.<sup>78</sup> Where exclusive appropriation is not in the public interest, it is not evident why such subject matter should be patented at all.<sup>79</sup> In the instant case, WARF did favour a greater degree of access. Geron was more or less oblivious to equity considerations. But the litigation, had it gone ahead, would have been confined to a later stage. The public interest in hESC research would have been defined with specific attention to intellectual property parameters.

Fundamentally then, the three proposed modifications miss the point. Each fails to give express and meaningful priority to what should be the primary goal of hESC research: increased health and well-being. Absent the ability to judge the public interest in hESC research at the former stage, it is plainly illegitimate for that interest to rest (even in part) with a Federal Court in Wisconsin as a matter of fact.

### (ii) *The Recommendation of the Standing Committee on Health*

When the “Proposals for Legislation Governing Assisted Human Reproduction”<sup>80</sup> was introduced in May 2001, the Minister of Health simultaneously charged the Standing Committee on Health with critically evaluating the legislation. Six months later, the Committee made

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<sup>76</sup> “Making Room”, *supra* note 16 at 72.

<sup>77</sup> *Ibid.*, at 74.

<sup>78</sup> See A.K. Rai, “Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff” (2001) 95 *Nw. U.L. Rev.* 707 at 711.

<sup>79</sup> See Eisenberg, *supra* note 22 at 1725.

<sup>80</sup> Health Canada, *Proposals for Legislation Governing Assisted Human Reproduction* (May 2001), online: Health Canada <<http://www.hc-sc.gc.ca/english/pdf/reproduction/legislation.pdf>> (date accessed: 01/05/09) [hereinafter “Draft Legislation”].

several noteworthy recommendations. Perhaps most strikingly, the Committee made the following assertion:

The Committee is seriously concerned about the patentability of human material. We are deeply disturbed that the Patent Act does not specifically disallow patenting with respect to human genes, DNA sequences, and cell lines. Treating human biological components is repugnant to many of us. It entails their commodification and paves the way for their commercialization. Given the importance that this Committee attaches to the respect of human dignity and integrity, we urge that patents be denied in relation to human material. There should be particular emphasis on the ethical and social consequences of patenting human material as well as on the implications for the development and availability of related therapies and corresponding costs to health care delivery in this country.

Therefore, the Committee recommends that:

....

The Patent Act be amended to prohibit patenting of humans as well as any human materials.<sup>81</sup>

If this recommendation were acted upon, patents on hESC lines and types (but seemingly not derivation processes) would not be permissible in Canada. The Committee's position appears to be based on general concerns about the status of human life. This approach is indeed laudable, but in the past, has fallen on deaf ears. Challenging patent advocates on their level by engaging with the economic premises of their view may prove to be far more persuasive.<sup>82</sup>

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<sup>81</sup> House of Commons Canada, *Assisted Human Reproduction: Building Families* (December 2001), online: Standing Committee on Health <<http://www.parl.gc.ca/InfoDocCom/37/1/HEAL/Studies/Reports/healrp01-e.htm>> (date accessed: 01/12/13), at Section 12(iii), Recommendation 34.

<sup>82</sup> Lebacqz, *supra* note 20 at 357.

## V. CONCLUSION: PRIORITIZING THE BENEFITS OF hESC RESEARCH

The *WARF v. Geron* case at its most basic level concerns starting positions. The true effect of intellectual property rights on hESC research is difficult to decipher. The argument made here is that the burden to demonstrate that intellectual property rights actually aid in the development of diagnostic and therapeutic hESC applications, should lie on the pro-patent side.

What course the Canadian government will take is unclear. Equally, the present amicability of the WARF-Geron relationship may return to acrimony. But the answer to the question – who will profit – is certain if the situation stays the same. Researchers, whether public or private, will profit from hESC research. Perhaps this would be permissible if an overall health benefit accrues to society at large or the researchers had a bona fide entitlement claim. Both of these claims, however, rest on shaky grounds. Nonetheless, the Draft Legislation as it now stands, reinforces the priority on profit. The view that researchers (and funding corporations) should be able to profit is pervasive across nation-states.<sup>83</sup> All of this suggests that the potential economic benefits of hESC research are given higher priority.

If policy-makers instead choose to act, there are two primary paths which they may take. One alternative involves tinkering with the intellectual property system. The other alternative involves making hESC technologies non-patentable. Though a clear prioritization of health and economic benefits is not to be expected, choosing either one of these paths will be telling. To give the public face of hESC research meaning, hESC technologies will be exempted from the patent scheme. Conversely, if economic prospect is the primary driving force, modifications to the intellectual property framework will be enacted. In the latter scenario, it would be wise to take a more cautious stance regarding the potential health benefits of hESC research.

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<sup>83</sup> Herder, *supra* note 14. Notably, the same rationale was implicitly endorsed by the California Supreme Court in *Moore v. Regents of University of California*, 271 Cal. Rptr. 146 (Cal. 1990) cert. denied 111 S.Ct. 1388.