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THE COMMERCIALIZATION OF HUMAN GENETICS: FUTURE POLICY CONCERNS

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SUMMARY

The Human Genome Project may be the most commercially driven large scale scientific endeavor in the history of mankind. Since its inception, in the early 1990's, genetics and biotechnology have been increasingly cast as an important part of our economic future. This paper seeks to highlight a number of the benefits and concerns associated with the commercialization of genetics and genetic research with particular emphasis on the commercialization of the research environment and gene patents. The author notes that the commercialization of the university environment may lead to a reduction in pubic trust and decreased enthusiasm for the products of the "genetic revolution". In some countries, including Canada, there is a growing conflict between the typically "pro-patent" innovation policy and the necessity to reduce the cost of publicly funded health care.

I. Introduction

It is arguable that the mapping of the human genome has been the most commercially driven large scale scientific venture in history. Other major scientific endeavours have been closely tied to other, non-scientific, social agenda. The Manhattan Project was driven by explicit military aims and the race to the moon was motivated, at least in part, by Cold War paranoia. But few scientific endeavours have been so closely tied with the private sector and the profit motive as the mapping of the genome.

Key words: Human Genome Project – Genetics – Commercialization - Health policy - Patent

The Human Genome Project (HGP) was not sold to government funding agencies or the public as purely a mechanism of economic growth, but largely as a scientific project that would lead to major health care breakthroughs[1]. However, since the start of the HGP in the early 1990s, genetics and biotechnology have increasingly been cast as an important part of our economic future. Of course, this is partly due to the fact that, in our progressively "knowledge based" economy, universities and university researchers are, in general, becoming more closely aligned with the private sector. That said, it is hard to deny that the science of genetics has been at the focal point of the commercialization of the biomedical research[2]. Some have gone so far to suggest that, from an economic perspective, we are at the dawn of the "biotech century".

This commercialization trend has elicited enthusiasm, skepticism and outright condemnation[3]. This brief paper seeks to highlight, rather than critique, a number of the benefits and concerns associated with the commercialization of genetics and genetic research. Not all concerns and benefits are canvassed. Rather, this paper focuses on two general areas, the commercialization of the research environment and gene patents. The goal is to illustrate the growing tension between pro-commercialization policies and other social agendas, such as access to publicly funded health care. As more and more gene based products leave the laboratory and make their way into the clinic, the issues associated with the commercialization process seem likely to become more acute. In this paper, for instance, I note how the commercialization of the university environment may lead to a reduction in both the trust the public places in genetic researchers and the enthusiasm the public has for the products of the "genetic revolution." Likewise, in some countries, there is growing conflict between innovation policy - which is generally "pro" gene patents - and the desire of governments to reduce the cost of publically financed health care.

This paper is not meant to place the commercialization process in an unfavorable light. On the contrary, there are many sound reasons for the heavy involvement of the private sector in genetic research. However, if we are to fully benefit from the

tremendous advances occurring in the field of genetics, it is essential for policy makers to understand the possible adverse implication of commercial forces in this context.

II. Commercializing the Research Environment

The "genetic revolution" is occurring at a time when the ties between private industry and the biomedical research community have never been stronger or so explicitly encouraged[4]. The impact of this trend obviously has implications well beyond the area of genetic research. Nevertheless, the promotion of industry/academic researcher collaborations is a phenomenon that is setting the tone for much of the work done in human genetics. Indeed, though many countries, including Canada and the US, have increased public spending on biomedical research, the financial commitment of the private sector has increased at a faster rate. As noted by Pilar Ossorio, "the share of research supported by the public funds has decreased and the share supported by private funds has increased"[5].

In Canada, both the provincial and federal governments have policy arms designed to facilitate public/private collaboration in the area of biomedical research. Even national, publically financed, granting entities encourage and, in some cases, require partnerships with the private sector. The enabling legislation of the Canadian Institutes of Health Research (CIHR), Canada's primary public funder of biomedical research, states that the goals of the CIHR are to *"encourag[e] innovation, facilitat[e] the commercialization of health research in Canada and promot[e] economic development through health research in Canada."*[6] Genome Canada, a recently established and publically funded national research program, requires researchers to obtain matching funds, largely from the private sector, on a dollar for dollar basis[7]. Similar research funding policies can be identified throughout the world[8].

i) The Benefits

There are numerous valid justifications for this trend toward public/private partnerships - particularly in the area of genetics. Governments throughout the world are understandably excited

about the economic potential of biotechnology. In Canada, it is currently the fastest growing sector of the economy[9]. Governments have an interest in and, at least some would argue, an obligation to stimulate economic growth and diversification[10]. Close links between academic researchers and industry have been identified as an important factor in the growth of a technology industry. As such, policies which facilitate these relationships are viewed by industry and by those within government responsible for the innovation agenda as a sensible component of economic policy.

Another rationale for public/private partnerships is the fact that the private sector plays an essential role in the production and dissemination of technological innovations - be they drugs, diagnostic procedures or medical devices. That is, in a market based economy, the private sector will inevitably be needed in order to get the products of genetic revolution into the hands of health care providers and patients. Though publicly funded clinical and research laboratories will inevitably play an important role in the delivery of genetic services, the development and implementation of broadly based therapeutic interventions, such as in the emerging field of pharmacogenetics[11], require a heavy committment from industry[12].

Finally, from the perspective of public funding agencies, such as the CIHR and Genome Canada, public/private partnerships are viewed as one way of leveraging public research dollars and bringing more funding into the research setting. Given the chronically underfunded state of public granting agencies, it is not surprising that governments and universities enthusiastically pursue and promote partnerships that generate alternate funding sources.

ii) Risks and Concerns: Maintaining the Public Trust

Of course, numerous ethical, legal and social issues have also been associated with the commercialization of the research environment. While a comprehensive analysis of these concerns is beyond the scope of this paper[13], it is worth noting that the possible adverse effects of a close relationships between industry and academia has been the subject of increased public scrutiny[14]. Below we consider just a few of the more commonly noted issues.

First, not all of the benefits of genetic research require market distribution. Indeed, perhaps the most valuable and widespread benefit that will flow from the genetic revolution is the increase in basic knowledge about human development, biology and disease. As recently noted by Francis Collins and Alan Guttmacher:

> *"the greatest payoff from understanding the human genome is likely to be an illumination of the molecular pathogenesis of disorders that are currently poorly understood"*[15].

It is not clear, however, whether relationships with industry will necessarily promote this type of fundamental work. Indeed, several commentators have noted that close relationships with industry have the potential to skew the direction of biomedical research away from basic research to that which is likely to have a "commercializable" outcome[16]. Thus, there is a concern that funding for much needed "basic" research will be lost in the push to find industry partners and promote research with a commercial application.

Another growing concern in this context relates to the creation of new opportunities for conflicts of interest - particularly in relation to clinical research[17]. Numerous high profile conflict of interest dilemmas have thrust the issues associated with industry sponsored research into the public spotlight[18]. For example, the death of a young man, Jesse Gelsinger, involved in a gene therapy protocol raised questions about the close ties of the researchers and an industry sponsor and whether financial consideration had an inappropriate impact on the running of the protocol[19]. Specifically, both the principal investigator and the Dean of the University of Pennsylvania medical school, the relevant institution, had an equity interest in a company with a stake in the gene vector being tested[20]. Yet another example is the protracted dispute arising at the Toronto Sick Children's Hospital between Dr. Nancy Olivieri and Apotex Inc. wherein

Apotex Inc. threatened to bring legal action against Dr. Olivieri when she took steps to inform patients enrolled in clinical trials that the treatment drug may be causing life-threatening side-effects. Apotex Inc. objected to the disclosure of such information by Dr. Olivieri to her patients or to the public on the basis that the disclosure was a breach of the clinical research agreement between Dr. Olivieri and Apotex Inc.[21]. Not surprisingly, such events have led to a call for significant reforms in relation to how industry/university collaborations are structured[22].

Other frequently articulated concerns associated with the commercialization of university research include: the loss of the independent academic voice; erosion of an appropriate teaching atmosphere; a decrease in data sharing between researchers; and, perhaps most important, the reduction in the trust the public places in academic research[23].

Survey research in Canada has demonstrated that the public places a high degree of trust in academic researchers but less in those associated with industry. For example, one study found that 80% of Canadians thought that university researchers funded by grants were very or somewhat credible while 65% felt the same about university researchers working for biotechnology companies[24]. Follow up focus group work led the authors of this survey to conclude that:

> *"Most people rest their assessment of credibility on the degree to which the person or institution is perceived to be at arm's length and independent of controlling and/or funding influencers. The source of the funding seems to be the critical test"*[25].

A loss of public trust in the conduct, integrity and outcome of research would have tremendously adverse implications for industry, university and, ultimately, society[26]. As more and more genetic technologies leave the laboratory and make their way into clinical use, policy makers will need to become increasingly sensitive to the ramifications that a loss of public trust may have on the acceptance of a given technology. As we have seen in the context of genetically modified food products, a lack of trust in public institutions can have a profound impact on the utilization and, for that matter, the commercialization of a genetic in-

novations. Though it is clear, at least in Canada, that the public strongly supports human genetic research[27], at least some commentators believe there is still a potential for a backlash[28]. Currently, the public believes researchers are motivated by the desire to find cures not make money[29] - which is undoubtedly true. However, as the line between commerce and research becomes increasingly blurred, the public's comfort level may diminish.

There are many good reasons for university and government policy makers to seriously consider and meaningfully address the social, legal and ethical issues associated with industry/academia collaborations[30]. But it should not be forgotten that the erosion of public trust associated with these arrangements might make it more difficult to achieve a number of the very goals of the commercialization agenda - such as the production of a more vibrant biotechnology market.

III. Patents and the Human Genome

We now turn to a discussion of gene patents. Patents are viewed as key element of the commercialization process. However, from the beginning of the Human Genome Project, human gene patents have also stirred a high degree of social controversy[31]. From claims that they infringe notions of human dignity to charges of bio-piracy, human gene patents have been frequently criticized[32]. Nevertheless, from the perspective of patent offices in Europe, Japan, the US and Canada, there has never really been any legal issue. Human gene "inventions" are patentable so long as they satisfy the basic criteria of national patent regimes - the invention must be new, non-obvious and useful. And since the internationally influential US Supreme Court case of *Diamond v. Chakrabarty* in 1980[33], where an oil eating bacterium was found patentable, there has been little that has not been viewed as potentially patentable. In most jurisdictions, social issues, such as concerns about human dignity, have had little impact on this approach to the patenting process. Indeed, as of the year 2000, over 25,000 DNA-based patents had been issued in the US alone[34].

In Canada, as in many countries, governments and universities explicitly encourage the patenting process. For example, at the University of Alberta, the number of patents or patent appli-

cations upon which an academic is named as an inventor or co-inventor must be disclosed on each faculty members' annual report - the more patents, the better. Governments also use the number of patents held by local researchers and industry as a barometer of the health and potential of the region's technology sector. Governments and universities often offer grants and other forms of assistance to facilitate the patenting of innovations[35]. To a large degree, at least from the perspective of the industry arm of government, human gene patents are viewed as a good thing.

i) The Benefits

Again, as with the push to commercialize generally, there are a number of valid policy justifications for the enthusiasm that many (but not all) in government have toward human gene patents. For example, patents have long been viewed as an essential part of the innovation process - particularly in biotechnology. As noted by Cook-Deegan and McCormack,

> *"[n]o other sector of the economy depends as much on strong patent protection" as the pharmaceutical and biotechnology industries"*[36].

Patents are designed to encourage innovation by granting the inventor a time-limited monopoly over his/her invention (in Canada, the patent term is 20 years). This monopoly protection is especially important in relation to biotechnology industry, where big profits can often be decades removed from an actual biomedical discovery. Without gene patents, it would be more difficult to attract private sector investment. As such, gene patenting is viewed, rightly or not, as an essential element of the commercialization process and is embedded in the ethos of the biotechnology industry. Some commentators, such as Joseph Strauss, have gone so far as to suggest that the existence of a vibrant biotechnology industry is closely associated with the availability of a strong patent regime. Straus cites the *"shift of nearly all industrial R&D activities in the field of biotechnology from Europe to the United States and Japan"* as evidence of the influence of patents on the growth of the biotechnology sector[37]. Such

commentary has led those in government to conclude that the promotion of gene patents is simply good economic policy.

It has also been noted that there may be social and ethical justifications beyond the potential economic impact of patents[38]. One of the rationales for existence of patents is to facilitate the disclosure of useful information. In exchange for the monopoly control of an invention, the inventor must provide a detailed description of his/her invention. Such information will, it is hoped, lead to further innovations and technological developments[39].

ii) General Social Concerns and Gene Patents: Emerging Policy Conflicts?

Of course, gene patents have long been associated with a wide variety of social policy dilemmas, ranging from moral concerns[40] to practical legal issues[41] to the impact of gene patents on the research environment and the distribution of technologies[42].

For example, despite the support that patents receive from industry and much of the research community, there is growing concern that patents may actually *deter* innovation rather than stimulate it - at least in the context of human genetics. Because the human genome is largely a finite resource, the concern is that the proliferation of gene patents will slow or stop researchers from working on particular regions of the genome for fear of infringing an existing patent[43].

Likewise, some commentators have noted that upstream patents on "inventions," such as expressed sequence tags, might slow or, even, block the development of practical, downstream, inventions, including gene tests and therapeutics[44].

An example of a more speculative (but nevertheless legitimate) concern is the idea that gene patenting will facilitate an increasingly market driven view of disease, disability and normality. Corporate entities that own human gene patents would clearly benefit from a broad definition of "disease" and a narrow definition of "normalcy." As argued by Martone:

> *"Once the marketplace has exclusive rights over the development of products related to genetic material, the marketplace can then redefine the hu-*

man persons to standards that will create demands for products that the market can develop"[45].

From the perspective of this paper, one of the most interesting social concerns is the impact that gene patents may have on the management of publically funded health care systems[46]. That is, might gene patents actually make it more difficult for citizens to access and benefit from the very innovations that gene patents are meant encourage? A number of authors, including Mildred Cho from Stanford University[47], have raised the issue but few policy makers have taken note. However, in Canada, a recent controversy involving Myriad Genetics' patents on the BRCA1/2 genes and associated testing technology led to significant political action.

In the summer of 2001, Myriad Genetics decided to take steps to enforce its patents over the BRCA1/2 genes. Provincial health care ministries in Canada were told by Myriad that all future genetic testing that utilizes the BRCA1/2 genes must be done through Myriad's laboratories. The Myriad test is quite expensive as compared to the testing process already being done in Canada. Indeed, Myriad charges more than $3800 CND per test. As a result, a number of Canadian provinces have stated that the public system cannot afford the Myriad test. Several provinces have taken the position that they will either ignore or fight the patent[48]. In defending Ontario's decision to challenge the rights of private companies to patent genes, control their use by others, and reap profits from virtually all diagnostic and therapeutic treatments that are based on the gene or a portion of the gene disclosed in the patent, Premier Mike Harris has stated that:

> *The benefits of a world-wide effort such as the human genome project should not be the property of a handful of people or companies. Our genetic heritage belongs to everyone. We must share the benefits fairly and do what we can to make genetic tests and therapies affordable and accessible*[49].

With respect to this issue, Mr. Harris asserts that *"[n]ow is the time to ask questions about how this new frontier will be settled and who will own it"*[50]. In other jurisdictions, such as Europe,

Myriad's decision to enforce its patent rights has generated a similar policy response[51].

The issue of access to potentially beneficial health care services is also clearly important to the public. One study found that though 63% of the surveyed Canadians saw more benefits than risks associated with gene patents, focus group analysis found access to medically necessary technologies to be the most significant concern of the public in relation to patents. Canadians seem to understand the economic justifications for patents - that is, patents are meant to stimulate innovation - but in the context of health care, equity remains the paramount social value[52].

What makes this concern so interesting is that it explicitly puts two practical, high priority and immediate governmental policies - access to affordable health care and the promotion of innovation and the economy - in direct conflict. Over the past few decades, containing the cost of publically funded health care systems has been a key policy issue for most OECD countries[53]. In Canada, it has long been the single most important political topic, for both the federal and provincial governments[54].

In the meantime, as noted throughout this paper, governments and universities have been enthusiastically promoting the patenting and commercialization process. But because patents grant the inventor a 20 year monopoly control over the invention, patent holders are able to charge a premium. In fact, this is one of the rationales for the 20 year monopoly granted by patents - it allows inventors to recoup the costs of research and earn a reward for being the first to produce the innovation. This may also mean, however, that the cost of accessing the technology may become prohibitively high, as was the situation with the Myriad dilemma. And this cost dilemma is likely to magnify with the introduction of "multi-plex" testing and pharmacogenetics - two emerging clinical application which could implicate numerous or even dozens of gene patents with each clinical application. Moreover, if one accepts the arguments made by commentators like Martone, noted above, gene patenting may also drive up the cost of healthcare by facilitating an inappropriate market driven expansion of the consumption of gene technologies.

These health care cost and access concerns have created the odd situation where government is both vigorously promoting gene patents and fighting the logical implications of those very same patents. Indeed, Myriad Genetics is doing exactly what those promoting patenting and the commercialization of the research environment want. Myriad is simply commercialization a genetic "innovation."

V. The Policy Conflict

In general, the countries that are heavily invested in genetic research can be described as liberal democracies with market based economies. As such, the extensive involvement of the private sector in genetic research is both inevitable, unavoidable and essential. The private sector will naturally seek to exploit market opportunities, and there are few as big as the genetic revolution. That said, governments obviously have an important role to play in shaping the commercialization environment. To date, a predominant theme of government policy - at least from the industry and research sectors of government - has been to promote the commercialization process. But as the products of the genetic revolution begin to reach the marketplace, it is becoming apparent that government commercialization policies have the potential to adversely impact, paradoxically, the very goals of the commercialization agenda - that is, the production and dissemination of innovative genetic technologies.

There are a many good reasons to deal with the social concerns associated with the commercialization of genetic technologies[55]. And commercialization policies should not be reformed for the sole purpose of facilitating market access and acceptance of new technologies. Obviously, government policies in the area of genetics must carefully balance a variety of laudable, often conflicting, social goals including, inter alia, the stimulation of the economy, the creation of a sustainable public health care system, the promotion of human dignity and the protection of vulnerable populations. However, there is a clear need to for governments to start considering a better harmonization of commercialization policy and other social policy. Such steps seem essential to the development of a long term biotechnology strategy.

In fact, some authors have speculated that the waning public support of biotechnology[56] is not necessarily a reaction to the science or a specific technology but to a growing distrust of public and private institutions. As noted by Hampel, et al.:

> *"[W]hat on the surface appears to be a rejection of technology turns out, when taking a thorough (analytical) look, to be an indication of a loss of trust in the social mechanisms which are to - and should - promote, control and guide development"*[57].

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Articoli/*Articles*

ETHICAL DEBATE ON STEM CELL RESEARCH AND ROMAN CATHOLIC INSIGHTS

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SUMMARY

The paper examines four important topics surfaced in the ethical debate concerning stem cell research. After having briefly considered, first, scientific and, second, therapeutic expectations as well as, third, the possible sources of stem cells, finally the issues related to embryonic stem cells receive a greater attention. Three insights from the Roman Catholic moral tradition are proposed as possibly related to this issue in particular. First, we refer to those conditions that allow for research on cells taken from organs or tissues as well as from aborted fetuses. Recent decisions taken in the USA and Germany concerning stem cell research are read in relation to this first insight. Second, the definition of what is material cooperation appears to be relevant. Third, the emphasis on social justice and the promotion of the common good express concerns shared within society.

Expectations

The current research concerning stem cells captures our attention for its novelty and opportunities. It could allow us to increase our understanding of cell differentiation process, how it is controlled and how we could reproduce it. This is expected to transform biology and medicine. Further, even more relevant are the possible benefits we could gain from therapeutic applications that would be based on knowing the characteristics of these cells. Each of these benefits is largely expected and strongly welcomed—as it has been confirmed by the increasing media frenzy on stem cells, and their potential uses, in the recent months.

The first element that characterizes the ethical debate is, therefore, the fact that stem cells seem to offer to us the possi-

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