IS IT JUSTIFIED TO PATENT HUMAN GENETIC RESOURCES?

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Abstract

In the past century, the scope of patentable objects has greatly expanded. Patents are now being granted on living organisms, human biological material and genes. What are the consequences of such practices for scientific research and health care? One of the fundamental philosophical questions behind this issue is the following: are we justified in patenting human genetic material? An examination of the traditional philosophical justification of intellectual property will allow us to critically explore whether or not this practice is ethically justifiable. It will be argued that the consequentialist justification of intellectual property requires, in this present case, that we modify the patent regimes in order to maximise social benefits and minimize public burdens.

Au cours du siècle dernier, le nombre d'objets brevetés s'est grandement accru. Il est maintenant possible de breveter des organismes vivants, du matériel biologique et des gènes humains. Quelles sont les conséquences d'une telle pratique sur la recherche scientifique et sur les soins de santé ? Cette nouvelle réalité soulève parmi maintes questions fondamentales, la suivante: le brevetage du matériel génétique humain est-il justifié? En examinant les justifications philosophiques qui légitiment l'utilisation des brevets nous pourrons nous demander si l'application de brevets sur les gènes humains est justifiable sur le plan éthique. Nous verrons en quoi les arguments de Locke ainsi que ceux de nature conséquentialistes exigent, dans le présent cas, que l'on modifie les politiques de brevetability afin d'équilibrer les bénéfices et les inconvénients.

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SECTION I: INTRODUCTION

In the past century we have observed a rapid development of biological sciences. This new knowledge has generated a number of fascinating and controversial applications. From the control of plants and animal breeding to the eugenic practices of certain political regimes, this science has changed the way we perceive, encounter, and manipulate the world surrounding us. This science, and its biotechnological applications, is generating many ethical and social conundrums. The transformations occurring in this field have brought members from all spheres of society to investigate ethical, legal and social issues that relate to this new reality. The private appropriation of living organisms and human biological material is one of the outcomes of this science which has raised many concerns. Why is it that a scientist or a company can patent a gene? Is this privatisation adversely affecting public health and research for new cures? Should human genes be considered the heritage of all of humankind? The question that interests us here is the philosophical justification behind the appropriation of biotechnological inventions. Why is it that we grant patent rights on human genetic material? Is there an adequate philosophical and ethical justification to allow the private appropriation of human genes?

To examine these questions we will first explore the traditional philosophical justifications behind property rights. The structure of the patent regimes will also be reviewed. Next, I will review the conditions that must be met to make an acceptable patent claim. Before examining the consequences of the privatisation of human genetic material, a history of controversial patents on biological material is

presented. Finally, I will consider whether the philosophical justification of intellectual property rights allow for such a practice considering the adverse effects presented.

In what follows, two traditional philosophical justifications of intellectual property rights are presented. The first, the Lockean theory of private property, provides an intellectual basis for the justification of property rights. According to this theory an individual can possess a thing when he mixes his labour with a good. The additional value that derives from labour belongs to the individual that generated it. This conception of property can be applied to abstract objects such as ideas and inventions. The second justification -the most commonly referred to rationale in the legal system- is the utilitarian framework. Under this rubric, intellectual property rights should be granted to innovators to promote the progress of science and useful arts.

Patent regimes introduce conditions that must be met before a temporary monopoly is granted on an invention. An invention must be useful, novel and non-obvious in order for its claimant to receive an exclusive right on the given product. Under the European regime, a number of particularities circumscribe further the patentable subject matter. A special clause allows patent officers to dismiss a patent claim based on the fact that it is contrary to morality. Certain types of objects, such as processes for cloning human beings, have been explicitly banned from that patent regime. The international legislative structure also brings about a number of particular elements.

Since biotechnology is a relatively recent field of work, I will focus my attention upon particular prototypes of biotechnological inventions.

During the 20th century, new types of patent claims have emerged. Organic objects are now being patented. The patenting of living organisms has raised many controversies over the part 100 years. Breeded plants, according to Mendelian biology, were the first type of living organism to be patented. In the 1970s, a claim on a modified living microorganism was presented to the USPTO. This was a very important patent application. The Diamond v. Chakrabarty case was eventually brought to the US Supreme Court. The Supreme Court declared that this microorganism was indeed a patentable subject matter. This legal precedent legitimised the patent on higher life forms. The controversial Harvard "Oncomouse" was patented on the basis of this precedent. In the 1990s, the human genome became the new target for private interest. The race to decrypt the human genome raised the question about the patentability of human genes. The issue of the race was an important one: would the private sector monopolise this information?

This appropriation of genetic material has generated a number of unfortunate social effects. The monopolisation of human genetic material raises new challenges for the protection of human research subjects. This new trend also affects the scientific community. Information sharing in biotechnological fields, very important for the progress of the sciences, is being dramatically modified by the presence of patent rights. The presence of potential patents also influences the type of research that

scientists choose to conduct. Further, the attribution of broad patents on genes increases the risk of infringement when research is conducted. This consumes time and financial resources that could otherwise be spent on scientific research. Finally, it is observed that these temporary monopolies granted on genetic material also affect the quality of medical care.

The question is obvious: are the justifications of intellectual property rights sufficiently convincing that they allow such practices, considering the adverse effects presented here? I will argue that the Lockean justification is not sufficient to justify existing patent practices. The strength of the argument stating that labour entails property rights must be evaluated in this particular context. Should this right be limited when moral concerns arise? Does this argument justify the appropriation of the entire object or only of the added value? Must this right be balanced proportionally to work contributed? These questions bring us to interrogate the validity of this justification.

The much-praised utilitarian framework also brings us to question the application of patents on genes. Utilitarianism demands that the patent system be beneficial for society. It should increase the production of useful arts and sciences . Yet, if gene patents are not producing the benefits expected in the patent bargain we must reconsider the legitimacy of this type of policy. It has been argued that patents on genetic material are not necessarily good for business; a number of firms use DNA in their research and are discouraged by licenses fees. Further, these patents actually reduce the amount of information available in the public domain. There can be no

such thing as an ideally beneficial patent system though presumably some systems are better to other. Still, in order to justify patents the benefits must outweigh the burdens. For this reason, it is necessary that we amend actual patent practices on human genetic material.

In order to fulfil the requirements of a utilitarian framework, the patent regimes must adapt to meet the present challenges. I will recommend the introduction of a morality clause, supported by an ethics review board, could be an assurance of the acceptability of the patenting of human genetic resources. Further, an effective critical review will allow the public to participate in the evaluation of ethical concerns. Also, the scope of the patent claims on genes should be narrowed. To balance the benefits and the burdens, exemptions for experimental research and compulsory licensing for public health purposes, should be installed. Finally, the principle of justice demands that benefit sharing be implemented.

SECTION II: PHILOSOPHIES OF INTELLECTUAL PROPERTY

Abstract objects are non-tangible goods such as ideas and information. These objects are non-exclusive because they can be at many places at the same time. There is no marginal cost in providing that object to more than one user. Applying the status of intellectual property to this type of good can seem controversial. It is not clear why one should have exclusivity rights on an idea. This seems even more contentious when we note that laws of nature cannot be subject to such appropriation under the law. How can we justify, on philosophical grounds, the presence of intellectual property? This is the first question one must ask before analysing the application of such rights to human genetic material. An investigation of the classic arguments will help us analyse the appropriation of this type of biotechnological material. First, the Lockean justification of property will be explored. Then, the utilitarian reasoning behind intellectual property will be considered.

2.1 LOCKEAN JUSTIFICATION OF PROPERTY

Philosophical attempts to justify intellectual property often refer to John Locke's theory of property. In the *Treaty of the Civil Government* the theory of natural right is the rationale behind private property.[1] Humans own their body and the product that it generates is consequently theirs. Property is justified because labour adds values to things; the additional value belongs to the individual that produced it. Private prope-

rty can also be justified by holding that the individual's work should be rewarded since labour is something all wish to avoid. In the case of both arguments, certain types of abstract objects cannot be appropriated depending on their nature and the nature of what is considered to be the intellectual common.

The doctrine of natural law establishes that God has created the world in such a way that, in the state of nature, things of this world are shared in common by humankind. The notion of private ownership, which may seem contrary to natural law[2], is founded on the assumption that every man has property of his own person. Hence, the labour he generates belongs to him. Consequently, whenever a person mixes his labour with something in the common he therefore makes it his property. The institution of private ownership derives from the value added by labour. In Chapter 5 of the Second Treatise, Locke states that "what so ever he removes out of the state of that nature hath provided, and left it in, he hath mixed with his labour, and joined to it something that is his own, and thereby makes it his property."[3]

Two conditions limit, in this theory of property, the appropriation of common goods. First, there must be enough goods to ensure that every one can appropriate the objects of his labour without infringing upon the goods that have been appropriated by somebody else. The appropriation of goods is conditional upon leaving in the common enough for the other members of the common. This "enough and as good"

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[1] Locke, *Two Treatises of Government*, Laslett, Cambridge, 1988.
[2] To find a discussion regarding this tension see: Drahos, *A Philosophy of Intellectual Property*, Dartmouth, 1996.

[3] Locke, *Two Treatises of Government*, Laslett, Cambridge, 1988, chap. 5, paragraph 30.

condition is an equal opportunity provision leading to a distribution based on merit. The second condition requires that no individual take more from the common he or she can use to their advantage. "As much as any one can make use of to any advantage of life before it spoils."[4] This condition prohibits the accumulation of property to a point where some of it is destroyed without being used.

Different types of arguments derived from this theory of property can justify intellectual property rights. The labour theory can be applied to ideas if it is recognised that their creation requires intellectual labour. If work is implied in the creation of abstract objects, people have the right of enjoying the fruit of their labour even if the given object is not physical.

The **avoidance view of labour**[5] can serve as a justification for intellectual property rights. In this view, labour is defined as an unpleasant activity that is non-desirable in and of itself. It is observable that we generally have to discipline our selves to work. Labour is something which people avoid or want to avoid; labour is an activity one does because one absolutely must. Further, it can be thought that labour is so unpleasant that an individual must be encouraged to do so or receive benefit from performing such an activity, otherwise he would not perform that task. Production of intellectual objects can be seen as a form of labour. Even if many people who spend

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[4] Ibid.

[5] Becker,L., "The Labour Theory of Property Acquisition", *Journal of Philosophy*, 653, 1976.

time producing ideas prefer this activity to manual labour; one must make an effort to do such work. 'Idea making' may, in this sense, be viewed as labour in the same way as manual labour. The production of ideas should therefore be rewarded since it is a form of labour.[6] This argument is used, in its instrumental form, by legislators to justify patent rights.

The **value-added theory**[7] of intellectual property can also be derived from the Lockean view of property. If labour produces something of value to other individuals, then the one who has laboured should be rewarded. The production of abstract objects that enhance the public good make the creator worthy of reward. The provision of reward can be treated as a normative proposition: individuals should receive rewards for the contribution they make to the public good, notwithstanding if that motivates their work or not. Rewards should be allotted simply because it is the morally right thing to do. On the other hand, this claim can also be used as a consequentialist argument. The use of intellectual property rights as rewards for the labour involved in such work contributes to the creative process and encourages individuals to contribute to the public good. This approach, as in the case of the avoidance theory, has been an important justification of intellectual property rights in legal theory.

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[6] This claim can be founded on two grounds. The normative position states that labour should be rewarded because there is an ethical imperative. The instrumental position demands that labour be rewarded because of the effect of such rewards.

[7] Becker,L., "The Moral Basis of Property Rights", *Nomos22: Property*, New York: New York University Press, 1980.

At this point an essential question remains: does the production of intellectual ideas require labour? It can be said that the creation of intellectual objects requires two steps: first, the creation of ideas and, second, the application of the idea to create the product. Yet, we have difficulty when we try to formulate a clear separation between these two moments. In a number of cases it may seem that the idea did not require labour. Rather, only the execution required labour. This might invite us to consider these two moments as a single event. The patent law is congruous with this vision where the creation of ideas and their application is seen as one event. The existing intellectual property regimes grant property rights only to inventions that have been sufficiently executed. For example, a mere formula cannot be patented; it must able to be applied to a particular use and have a demonstrable utility. In this sense, it is the execution that is rewarded and which protects the idea. This way the labour behind the idea does not need to be recognised.[8] Moreover, this approach allows the balancing of the need for free access to ideas and recognises the importance of rewards for the creators.

Another question must be raised regarding this theory of intellectual property. What is the nature of the 'intellectual commons' from which these ideas are derived? The nature of the intellectual common will have an impact on the intellectual property regime judged appropriate. It is clear that Locke's idea of the Common[9] applies to

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[8] This particular dichotomy is explicit in the case of copyrights where it is the content of the entire work that is protected rather than the underlying idea.

[9] The idea of the common is described in the beginning of chapter five of *The Second Treaty of the Government*. In the state of nature goods are held in common through a grant from God. The individuals must convert these goods into private property by exerting labour upon them. In the

intellectual objects. In fact, this type of object responds more adequately to the description that Locke gives of the object held in common than physical objects do. Abstract objects are never exhausted; it is always possible for another person to access that object even if someone else is using it. Also, these objects are never spoiled, the particular formula or technique is always good no matter how often it has been utilised. By their nature they suit more naturally the idea of commonality.

Based on the theory advanced by the *Treaty of the Civil Government,* the doctrine of mixing labour as the motive for property, when applied to intellectual objects, can be interpreted in such a way that it depletes the common intellectual objects.[10] If the intellectual commons is a set of discoverable abstract objects, a strong view would hold that only the two conditions that regulate the appropriation of these objects - the 'enough and as good' criteria and the non-waste condition - are to limit the appropriation. Hence, under such a structure the IPR would have a much greater extension. Since these ideas are the result of one's labour, the time limit would not be necessary and all intellectual objects could be submitted to this property structure. Property rights on new creations are admissible since by installing a property right on a new substance that is created, one is not depriving others from its use, since it could not have been used at all if the person responsible had not found it. For this argument to be acceptable, the patent must be limited in time, since it is possible that another individual would have eventually found it and hence rendered it available.

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common there is no scarcity, essentially because of the limited of human capacity of appropriating them. Locke specifies that it is illegitimate to spoil goods of the common.

[10] Drahos, *A Philosophy of Intellectual Property*, Darthmouth, Brookfield, 1996.

By creating an infinite property right that individual would be unjustly excluding others from this good in the common.[11]

Both common and extraordinary ideas that are part of the intellectual common cannot be granted property status in the actual practice of law. This is implicit to the argument supporting the enough or as good criteria. In the case of everyday abstract objects, as an essential part of the common, they cannot be subject to property rights. Objects such as the idea of washing the car every weekend or adding paprika to a quiche to add colour may not be subjected to property rights. These abstract objects are too useful and would require a tremendous transfer of wealth if they were to be privatised. At the other end of the spectrum, extraordinary abstract objects are also excluded from IP. Extraordinary ideas are those that disclose facts about the world such as the Pythagorean theorem; they cannot/should not be appropriated. You cannot legally monopolise the idea but you can monopolise a technology that is developed with this idea.

Because of this vast possibility of interpretation of the Lockean doctrine, its application as a foundational stone of IPR is controversial yet very useful. In many courts the instrumental argument of reward for labour is often cited, as is also the reward for production of new social goods. This theory has certainly greatly influenced the legal regimes and the discussions that have structured them.

[11] Hughes, J., "The Philosophy of Intellectual Property", *Geo. Law Journal*, 287, 1988.

2.2 UTILITARIAN JUSTIFICATION OF INTELLECTUAL PROPERTY

The most frequently referred to justification of IPR is the utilitarian argument. Utilitarianism is based on the work of Jeremy Bentham and John Stuart Mill. It argues that the guiding principle to achieve appropriate actions is to attain the greatest good for the greatest number. Many intellectual property regimes ground their legal structure on this type of philosophical justification. The US constitution refers to this type of argument when it states that IPR exists "to promote the progress of science and useful arts."[12] Most contemporary writers refer to the wealth maximising criterion, which advocates that lawmakers choose the system of law that maximises wealth.[13]

The utilitarian view suggests that intellectual labourers should be given IPR as an incentive for the creation of socially optimal output. Without this incentive, individuals would not be as interested in the creation of these goods. No one would engage in original development of products and of techniques since others could mimic them and benefit at the expense of the creator. The nature of the preceding arguments is intrinsically paradoxical. It argues that patents intend to advance the progress of useful arts yet it recommends doing that by restricting the availability and use of intellectual products. Hence, the question is not whether intellectual property rights provide incentives for original works. Rather, we should ask if they

[12] Constitution of the United States of America, available at http://www.law.cornell.edu/constitution/constitution.table.html

[13] Posner, R., *Economic Analysis of Law*, Boston, Brown, 1986 can serve as an example of this view.

increase the availability and use of intellectual objects more than they restrict this availability and use. The policy makers have to make an optimum balance between the power of exclusive rights to stimulate the creation of inventions and works of art and, on the other hand, the need for widespread public enjoyment of those creations.

Under the auspices of utilitarianism, an appropriate patent law is one that engenders the most incentive to create while allowing the shortest monopoly in order to create the maximum social benefits. This is the **incentive theory** of intellectual property rights. William Nordhaus[14] offers such a treatment of patent laws. He notices that each increase in duration of patent law stimulates an increase in inventive activities. The resultant welfare includes the producer's surplus associated with the distribution of the intellectual product. Yet, social welfare is reduced by administrative cost and higher prices of intellectual products. Such products may have been produced even in the absence of enhanced incentive. Patent longevity should be increased to the point where the marginal benefits equal the marginal costs in an incentive theory perspective.

In this sense, it can be said that patent laws are constructed to **reward researchers** by encouraging them to continue creating new products.[15] By knowing that the result of their work will be protected, individuals will feel more secure about investing

[14] Nordhaus, W., "Invention Growth and Welfare: a Theoretical Treatment of Technological Change", *MIT Press,* 1998.

[15] Schrecker, T., Wellington, A., *Patenting of Higher life forms and Human Biological Materials: An introduction to the issues*, CBAC, revised in 2001, available at http://www.cbac-cccb.ca/documents/en/PHL_BioHuman_Schrecker.pdf

their time and energies in such an activity. It is clear that without patent laws some people would tend to take advantage of the mental efforts of others rather than investing in an original idea themselves. The problem of the free rider shows that without intellectual property rights to protect creation and inventions from being appropriated by others, inventors and investors would be less likely to bring those creations forward from the workshop or the lab bench to the market place. This would therefore reduce the number of new intellectual products created. Further, the goods available to society would be reduced.

It is also maintained, on a utilitarian basis, that without exclusive rights, no one will be willing to invest in research and development. The research processes are very expensive and, as noted, it is possible that other individuals or groups might attempt to benefit from copying or imitating the innovation realised by another individual. For a group to finance a given project, it must have reasonable chances of benefiting from its investment. Patents must protect inventions to permit a maximum of investments in research. Patents encourage investment in research and increases the amount of money members of society will invest in this area. Further, the monies gained from the patents induced by research and development can be re-injected in further research. This situation is favourable for the economy and also for the public that benefits from the goods released from these scientific investigations.

On the other hand, it can be held that the primary purpose of our patent system is not to reward or encourage individual creators or investors but instead to serve as a tool

to further advance the arts and sciences.[16] The inducement of patent law requires that all the content of an invention be rendered available in the public domain. The presence of patents diffuses scientific information. The disclosure obligation present in patent laws allows the rapid advances of knowledge since science advances more rapidly if researchers enjoy free access to knowledge. In this sense, patents are not a certificate of merit, but an incentive to disclose. Hence, patent laws are installed because they allow the disclosure of information that increase scientific innovation and improvement. This, consequently, will allow the public to access a larger number of new inventions.

One must note that by its nature, utilitarian theory demands that in the calculation of burdens and benefits the counter effects of a given issue be considered. In the case of IPR at least two structural counter effects can be identified. [17] First, it can be argued that the state's intervention in the form of intellectual property rights provides the patent holder with a first mover advantage that allows that individual to acquire huge parts of the markets. This provides an unjust advantage and allows the establishment of market entry barriers against competitors. These barriers destabilise the free market, a structure that permits, according to certain constraints, an appropriate distribution of wealth. The second mover advantage implies that firms following the innovator are more efficient in making innovations that respond to market needs than the original inventor. It is a mistake to hold that they do so by saving huge costs.

[16] Hettinger, E., "Justifying Intellectual Property", in *Intellectual Property: Moral, Legal and International Dilemmas,* Rowman and Littlefield, 1997.

[17] Thumm, N., *Intellectual Property Rights*, Physica-Verlag, 2000.

They must invest huge amounts of money to develop that new technology. In that sense the patent law restricts further innovations by increasing the cost of R & D of second mover companies, which reduces the availability of goods that respond to market need.

The Lockean and the utilitarian models have been very influential in the common law regimes. The importance given to the appropriation of the fruits of one's labour is a component of the justification of private property, and consequently of capitalism. The utilitarian argument lies at the foundation, as we specified, of the US patent act, where patents are granted to an individual in order to further the advancement of the arts and sciences. Yet, behind the utilitarian argument the notion of reward for labour, as a normative component, is certainly justifying the pragmatic use of this type of discourse. This dual justification is used in the construction of the judicial system. These justifications can help us to reflect on the present appropriation of human genetic resources. Under these frameworks can this type of material be legitimately appropriated? Before addressing this issue we will draw a portrait of the basis of the intellectual property right regimes in Canada, the United States and Europe and consider the challenges that lie behind the patenting of such objects.

SECTION III: THE PATENT SYSTEM

In this section, it is important to draw a portrait of the patent system to understand how and why problems arise when human genetic material is patented. The appreciation of the distinctions between the legal frameworks of the different major actors on the international scene is important since the United States and the European Union both have included in the construction of their patent systems specific aspects. These particularities change the ethical issues that stem from patenting new biotechnological inventions. Further, when a nation addresses the issue of patent law, it must take into consideration international legislature, and thus this also will be examined. Finally, confusions may occur when the public misunderstands the nature of biotechnological inventions and patents. For that reason, it is important to clarify the type of human biotechnological objects that are eligible under current patent systems.

Patents are exclusive rights granted to the inventor or the inventor's legal representative, for a limited period of time, on new products or process. In the *Canada Patent Act* it is stated that under its jurisdiction falls "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."[18] In Canada, the government agency responsible for granting patents is the Canadian

[18] Canada Patent Act, section II, available at http://laws.justice.gc.ca/en/P-4/

Intellectual Property Office (CIPO).[19] A patent gives the holder the right to prevent others in his country from manufacturing, using or selling the patented invention. In Canada, the contents of a patent application must be disclosed no later than 18 months after the application is filed, whether or not a patent is awarded.[20] The decision rests with the commissioner, who has the authority to grant or reject a patent application as long as that authority respects the *Patent Act* and previous court decisions. The patent application must meet a set of conditions. The inventions must be useful, novel, and non-obvious. Also, an invention must be described in sufficient detail in the application . All these conditions must be met for a patent to be granted on a new invention. Since 1989, patents are enforceable for a period of 20 years from the filing date.[21] The commercial use or exploitation of an invention that is under the scope of a patent without an authorisation from the patent holder is called an infringement.

For an invention to be patentable it must have a significant **utility**. In order to be considered as meeting the utility condition an industrial value is required. A product that has no practical application in industry, trade or commerce is not considered useful. Further, a process, which only has aesthetic appeal or intellectual meaning, does not meet the utility criterion.[22] This requirement applies to all biotechnological

[19] Information regarding this agency are available at http://cipo.gc.ca/

[20] Canada Patent Act, section II, available at http://laws.justice.gc.ca/en/P-4/

[21] Ibid.

[22] Frendo, M., *Intellectual Property Protection for Biotechnological Innovations*, Industry Canada, 2001.

patent claims. Patent and trademark offices have issued recommendations to clarify how this standard is to be pragmatically put in to effect. For example, in January 2001, the USPTO issued new guidelines to the effect that: "you can patent a gene but only if it meets a three-prong test of utility-that is, having specific, credible and substantial use."[23]

The **novelty** criterion addresses the issue of human intervention and uniqueness of the created product. For this condition to be met, it must be verified that there is no record of the same product being patented. Further, this invention must not have been previously disclosed by another individual than the applicant in a forum prior to the applicant's filing date.

The **non-obviousness** condition demands that the object presented result from human ingenuity. The filed invention must not be something already apparent to a person skilled in the art or science to which it relates.[24] A mere discovery cannot be patented; further, "products of nature" cannot be subject to patenting.[25] This non-obviousness condition may be difficult to meet since it involves a number of steps. First, the patent applicant must clearly identify the innovation claim in the application. Second, he must determine the information used in this creation process that was previously public knowledge. Then, he must specify whom, in that field,

[23] Schrecker, T., Wellington, A., *Patenting of Higher Life Forms and Human Biological Materials: An Introduction to the Issues,* CBAC, revised in 2001 available at http://www.cbac-cccb.ca/documents/en/PHL_BioHuman_Schrecker.pdf

[24] Frendo, M., *Intellectual Property Protection for Biotechnological Innovations*, Industry Canada, 2001.

[25] Ibid.

was likely to know this information before the application. Finally, the commissioner must evaluate the difference between the common knowledge and the claimed innovation. This entire process must be followed to establish if an innovation is to be judged non-obvious.

Finally, it is important that the invention be described in sufficient detail to enable one skilled in the field to use it for the stated purpose. This requirement is particularly important since one of the fundamental goals of patent law is to ensure that the public acquires information in exchange for the exclusivity granted to the patent holder.

It must be noted that certain things cannot be received under the current patent system. Scientific principles and abstract theorems are not considered patentable inventions.[26] For example, Einstein's discovery of the formula $E = mc^2$ could not have been attributed a patent. This classification scheme is based on the important distinction between discovery and inventions. One must note that, however important, information itself cannot be patented.[27] Medical or surgical treatments, schemes or plans, or methods for doing business are not patentable either. Further, an inventive step is essential to enable eligibility to patent. The entire DNA of a cell cannot be patented. Rather, it must be purified and be reproducible in the form which make it commercially useful.[28] The particularities related to biotechnological patents

[26] Canada Patent Act, section II, sub-section 27(8) available at http://laws.justice.gc.ca/en/P-4/
[27] EPC, article 52(2); Canadian Patent Act, cP-4, article 52.
[28] Some critics argue that this should not be the case because the inventive step is not substantial enough to justify granting IP protection to the product of that research.

will be further discussed in section 2.3. It must be specified that a patent grant does not imply that this particular invention is desirable[29] or that it should be commercialised.

3.1 DISTICTIONS BETWEEN EUROPEAN AND AMERICAN PATENT LAWS

Without providing a comprehensive comparative law review, tracing the similarities and differences between the European and American patent laws, certain particularities must be examined since they are of interest in the present philosophical investigation. The European, and a certain number of other patent regimes such as the Japanese, has included an *ordre public* clause. This clause is labelled a "morality clause". Europeans have also excluded from patentability certain types of biological inventions from patentability. These particularities modify the role of the patent office and the significance of patents.

Patent applications can be rejected, under certain national laws, if they are considered contrary to the *ordre public* or morality. The United States, Canadian, and Australian law does not include such a clause.[30] The European Policy Centre

[29] In the EPC a morality clause is included and could be understood as a tool to reject patents that are inappropriate, but this clause is a not sufficiently broad to include all inventions that could be considered non-desirable.

[30] Schrecker, T., Wellington, A., *Patenting of Higher Life Forms and Human Biological Materials: An Introduction to the Issues*, CBAC, revised in 2001, available at http://www.cbac-cccb.ca/documents/en/PHL_BioHuman_Schrecker.pdf

(EPC) prohibits the granting of patents which would be contrary to *ordre public* or morality, but it must not take such action merely because it is prohibited by law or regulation in some or all of the contracting states.[31] The European Patent Office must take into consideration Article 53(a) that prohibits patents on any invention that is contrary to public order or morality. Further, the European parliament explicitly considers certain biologically based inventions to be immoral and thus not subject to patent protection.[32] For example, they have ruled out patents on

- the human body, at the various stages of its formation and development
- processes for cloning human beings
- processes for modifying the germ line genetic identity of human beings
- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

3.2 INTERNATIONAL PATENT LAWS

Patents laws are now binding parts of international agreements. In Canada, we are subject to a number of agreements, such as the North American Free Trade Agreement (NAFTA) and the World Trade Organisation (WTO). The WTO reached an agreement in 1994 which includes Trade Related Aspects of Intellectual Property

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[31] European Patent Convention, available at http://www.european-patent-office.org/legal/epc/index.html

[32] Gold, R., *Patenting Life Forms: An International Comparison,* CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/IPPHL_IntComparison.pdf

Rights (TRIPs), which set boundaries to national intellectual property standards.[33] These international regulatory structures influence and dictate the organisation of national patent systems. The TRIPS Agreement, which was a product of the Uruguay Round of trade talks, binds all members of the World Trade Organisation. It sets mandatory minimum standards for national protection of intellectual property that require states to implement a common and often expanded set of intellectual property protections. It also imposes enforcement measures, including potential trade sanctions against nations that do not comply with these standards.[34]

TRIPs and other international agreements aim to protect the patent system.

> "Patents shall be available for any new inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Patents shall be available and patent rights enjoyable without discrimination as to the place of the invention, the field of technology and whether products are imported or locally produced."[35]

This type of structure creates a tool to facilitate commercial exchanges between different members of the organisation.

Still, this type of legislation imposes certain limits so that countries do not set forth measures that could undermine the width of the system.

> "It is not possible, however, to introduce additional criteria to the determination of whether to grant a patent over an invention. International trade law ensures that the standard of novelty, inventive

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[33] Ibid.

[34] UN Economic and Social Council, *Approaching Intellectual Property as a Human Right: Obligations Related to Article 15 (1) (c), E/C.12/2000/12*, Washington, November 2000.

[35] TRIPs, article 27, available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm; NAFTA chapter 17, article 1709, available at http://www.nafta-sec-alena.org/english/index.htm

> step, and industrial application are the only ones that a country can apply in determining whether to grant a patent."[36]

This stipulation can halt a government from creating rules that would discriminate against particular types of inventions. Still, members may exclude diagnostic, therapeutic and surgical methods for the treatment of human or animals; plants and animals other than microorganisms.

International trade law allows countries to exclude from protection inventions that if commercialised would violate *ordre public* or *morality* from patent protection. The article section 27 (2) of TRIPs states that

> "members may exclude from patentability inventions, the prevention with their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect humans, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."[37]

3.3 CLARIFICATIONS RELATED TO BIOTECHNOLOGICAL INVENTIONS

Biotechnologies have significantly developed in the past 10 years. In order to discuss the ethical issues related to new inventions based on human genetic material, we must understand what they are and which technologies have been considered patentable.

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[36] TRIPs article 29(1), available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

[37] TRIPs article 27(2) available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

The very important 1980s case of Diamond v. Chakrabarty[38] states that patent laws extend to "any process, machine manufacture or composition of matter."[39] The court has declared that if the invention has required human intervention it falls outside the category 'product of nature' and hence can be patented. It was decided that genes could be patented based on the same type of arguments used to justify the patenting of chemical compounds. Isolated or purified DNA sequences evade the "product of nature" clause.

In Canada, genes can be subject to patent application. There are various ways in which rights can be asserted over DNA sequences. Many patents will contain claims to more than one method of using a DNA sequence. Four types of applications DNA sequences can be subject to patent claims.[40] 1) **Diagnostic testing**: allows the identification of faulty genes based on knowledge of the structure of a gene. 2) **Research tools:** knowledge of the genetic code can help in the identification of targets for which new drugs could be designed. 3) **Gene therapy**: the aim is to replace a faulty gene with a normal gene, this approach is being developed for the treatment of many diseases including cystic fibrosis. 4) **Therapeutic products to be used as medicines:** distinctive therapeutic use has been identified for protein encoded by the DNA sequence.

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[38] Diamond v. Chakrabarty, 447 U.S., 303; Hefferson, T., "Patent Law- Diamond v. Chakrabarty - the US Supreme Court Rules that Living Matter is Patentable", *North Carolina Law Review*, 1001, 1980; Dorn, B., "Chakrabarty in the Era of Genomics", *Journal of Technology Law and Policy*, 4, 2000.

[39] Ibid.

[40] Frendo, M., *Intellectual Property Protection for Biotechnological Innovations*, Industry Canada, 2001.

Genes or DNA sequences can appear in a number of different forms in patent claims. For example, a claimant can solicit a patent on an individual mutation known to cause disease, or on a genetic polymorphism, a variation between people that are not associated with a disease and those who are. They can also submit a patent application on an entire transcribed gene known as cDNA,[41] or nucleic acid probes that are fragments of DNA used to locate particular parts of DNA sequences. Amongst other claims that assert rights over DNA we find testing kits that are used for detecting genetic mutation. DNA and RNA can be patented if they meet the mandatory criteria of utility, novelty and non-obviousness. "As such a claim for a gene sequence in a patent application could be granted as long as the sequence has been isolated or purified from its natural state, has no previously known existence and has an established function."[42] DNA sequences are treated in the same manner as any naturally occurring molecules. Patents can be sought for sequences in isolated form or with a change in the nucleotide sequence.

Patent applications can also be filed on a number of promising **gene therapies**. Gene therapy is a new experimental approach that aims at treating, curing, or ultimately preventing disease by changing the expression of a person's genes.[43] Two types of gene therapy methods are presently being studied. Somatic cell gene therapy seeks to affect the individual non-reproductive cells. In other words the genome of the

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[42]Ibid.

[43]Human Genome Project, Gene therapy, available at http://www.ornl.gov/hgmis/medicine/genetherapy.html

individual is changed but this cannot be passed along to the next generation. On the other hand, germ line cell therapy has the potential of affecting the future offspring. This type of intervention affects the sperm and/or eggs of the parent in order to pass that particular change to the offspring.

Patenting the **human body** is a very important and delicate issue. It seems that the human body is not patentable but there is no clause for this in the *Canadian Patent Act* and no court has yet been confronted with this issue. Many argue that a body could not fulfil the condition of non-obviousness. Further, it could be argued that such a patent would violate the inalienable right to life, liberty and security of the person under the current Canadian Charter of Rights and Freedom.[44] Human body parts cannot be patented in their natural form because of the criteria of novelty. But questions can be raised regarding modified body parts such as limbs; organs and tissues isolated from the body and genetically altered. The Canadian position on this issue will be influenced by the recent result of the appeal concerning the case of Harvard's oncomouse in which it was decided that living organisms cannot be patented under the current *Patent Act*.[45]

There has been general public concern over the moral appropriateness of private property over any kind of human material. It is argued that many concerns arise from

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[44] Tigerstrom, Barbara, *Human Rights Issues Related to the Patenting of Human Biological Material*, CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf

[45] The verdict pronounced by the Supreme Court of Canada regarding the Harvard Onco-Mouse is available at http://www.lexum.umontreal.ca/csc-scc/en/rec/html/harvard.en.html

the fact that individuals confuse the notion of patenting genes and that of owning a person.[46] A certain number of individuals and groups hold that patenting genes is immoral because it means that one individual has access to another physical being. From a legalist perspective this criticism does not apply since genes, as they naturally occur in our body, cannot be patented. Hence, there is no direct threat to the bodily integrity of the individual. Further, patent rights are different from ownership rights; the only legal right conferred by a patent is a right to prevent others from using or possessing one's invention. Patent rights are exclusive; they do not constitute a positive right.

The patent system has transformed as technologies evolved. For a genetic resource to be patented it must be considered novel, non-obvious, and useful. These conditions circumscribe the patentable subject matter. Questions still remain. Are these conditions sufficient in the case of genetic material? Is the ethical concern only a question of misconception regarding patents, or are there significant burdens attached to the patenting of human genetic material? The exploration of the history of patenting living organism will help us better understand the issues at stake.

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[46] Lever, A., "Ethics and the Patenting of Human Genes", *The Journal of Philosophy Science and Law,* vol. 1, November, 2001.

SECTION IV: A BRIEF HISTORY OF BIOTECHNOLOGY PATENTS

Biotechnologies have significantly evolved over the past 40 years. Scientific innovations are creating a number of new challenges. The patent tradition world-wide adapts and changes as new types of objects are presented to patent offices. In this section we will study a number of cases that appeared in this past century. These controversial cases have influenced jurisprudence on biotechnological issues. The patentability of living organisms and their components has been at the heart of this discussion. The distinction between discovery and inventiveness has been subject to extensive questioning through these cases. The weighing of burdens and benefits related to the allocation of patents on biotechnological products has also been a central question. This succinct historical study will permit us to better understand the ethical, legal and social issues at stake in this debate.

The *American Patent Act* does not contain specifications with regard to patents on living organisms. The "product of nature" doctrine has been established since 1889. The US commissioner of patents rejected an application which covered a useful fibre identified in the needles of a pine tree. He argued that it is unreasonable to allow patents on trees, plants, or animals. This discovery is not patentable for the same reason that a new gem in the earth cannot be patented. A gem is not an invention, rather it is a discovery. Finding a gem does not give you the right to claim ownership of all the existing gems of that given type. We would not have allowed the discoverer

to patent gems. Consequently, this fibre is not patentable.[47] Essentially, this judgement states that while processes devised to extract what is found in nature can be patented, objects discovered in nature are not patentable. These discoveries are not inventions and cannot be made one's exclusive property.

Plant breeders raised for the first time the issue of patents on living organism. In 1906, a bill was presented to Congress to extend patent protection to bred plants. That bill was denied because of numerous factors. First, the Mendelian heredity model was not yet a component of the breeding process. Hence, the production of new strains was a result of trial and error. The development and identification of new plants is not entirely intentional because of the lack of knowledge of plant reproduction. This breeding process, by its nature, is thus considered as a discovery more than an invention. In the traditional agricultural methods employed at that time, new varieties of plants were often discovered in the fields. These plants naturally emerge as a consequence of their adaptation to that given environment. In this context it would seem inappropriate to patent that plant, a product of nature, even if a certain few are produced with human intervention. In addition, at the time the idea of a monopoly on seeds seemed quite inappropriate. In a world of scarce food resources one does not want to hinder production improvements.[48]

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[47] Kelves, Daniel, *A History of Patenting Life in the United States with a Comparative Attention to Europe and Canada*, Office for Official Publication of the European Commission, 2002 available at http://europa.eu.int/comm/european_group_ethics/docs/study_kevles.pdf

[48] Ibid.

The Plant Patent Act finally appeared in 1930 after the intense work of men such as Paul Stark, the chairman of the American Association of Nurseryman. Even if the *Plant Patent Act* did not, in the end, make much pragmatic difference for plant breeders, the arguments that motivated Congress to approve the bill are certainly pertinent to our discussion. The congress first noted that plant-breeding research had considerable dependency on government money. The institution of legal rights on plants might significantly stimulate investment in this field. Further, this could lead to a higher production of plants of greater quality. From a different standpoint, it was argued that one has a right to intellectual property because one has the right to the fruits of his or her labour. Individuals who worked on the production of new products should be protected from the possibility of piracy. The element that distinguishes the patentable plant from those which should be considered as a product of nature is human intervention, human labour. To equilibrate the burdens and the benefits of such a policy, the act excluded a number of elements such as potatoes and seeds.

4.1 THE 1970s: A FIRST PATENT ON LIFE

The 1970s marked the beginning of what is now called the genetic revolution. During this decade, humans began to systematically control, manipulate and exploit DNA technologies. Scientists started using gene splicing and recombinant DNA technology. Important scientific findings were released such as the discovery of the first oncogene in 1970 by Duesberg and Vogt. Another important moment involved the successful transfer of DNA from one living being to another; this created the first

recombinant DNA organism in 1973.[49] The question regarding patents on life became a capital issue since many new biotechnologies were being developed. It is in this context that the Chakrabarty case becomes an important precedent.[50]

In June of 1972, Ananda Chakrabarty a biochemist at the General Electric Company, filed a patent for a bioengineered bacteria that consumes oil slicks. His application covered not only the process used to create this bacterium but also the product, a living genetically modified bacteria. The U.S. Patent Office denied, in 1973, the patent on the product stating that no patent could be issued on a living organism; neither legislative nor case law had made it possible for such a patent to be issued. MaLossi, Chakrabarty's lawyer, filed a protest brief in June 1974. The appeal board gave the same type of answer as did the commissioner. The board added to the previous justification that "to adopt a broad interpretation of phrases such as "new composition of matter", would open the flood gates to patentability for all newly produced micro-organisms as well as for newly developed multi-cellular animals such as...chicken and cattle."[51]

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[49] Fox Keller, E., *The Century of the Gene,* Harvard University Press, 2001.

[50] See also on this matter: Dorn, B., "Chakrabarty in the Era of Genomics", *Journal of Technology Law and Policy*, 6.1, 2000; and : Hefferson, T., "Patent law- Diamond v. Chakrabarty - the US Supreme Court Rules that Living Matter is Patentable", *North Carolina Law Review*, 1001, 1980.

[51] "Examiner's answer" Sept.23 1974", "Opinion and Decision of Boad of Appeals", May 20, 1976, in Transcript of Record, pp.86-89, 92-97 quoted in Kelves, Daniel, *A History of Patenting Life in the United States with a Comparative Attention to Europe and Canada*, Office for Official Publication of the European Commission, 2002, available at http://europa.eu.int/comm/european_group_ethics/docs/study_kevles.pdf

MaLossi built an interesting counter argument. It is understood that scientists conceived living matter, including bacteria, to be chemicals. Therefore, it can be said that the bug was manufactured in the same way as new chemical compounds made by a chemist. According to this argument, the modified organism is a new composition of matter, hence it is patentable. In December of 1977, the court ruled three-to-two in favour of Chakrabarty. Judge Rich, speaking for the majority, considered only the issue of the patentability of living matter.[52] According to his allocution, there was no congressional intent to limit patents to non-living organisms when the *Patent Act* was created. It is normal that innovations are not foreseen; it is precisely for this reason that the *Patent Act* must be interpreted broadly. It is interesting to remember the political and economic context at the time when this judgement was made. On the one hand, the commercial interest in molecular biology was rapidly increasing, while, at that same time, public and scientific concerns about these new technologies were also being raised.

Because of the tensions surrounding the issues of patenting life and new biotechnological innovations this case was brought to the Supreme Court. It was understood by the USPTO that, if patent application was refused, the issue could then be referred to congress. This important question required, according to them, that a legitimate political debate be engaged before proceeding regarding this matter. On June 16, 1979, the court held by a very thin majority of 5 to 4, that whether the

[52] Dorn, Brian, "Chakrabarty in the Era of Genomics", *Journal of Technology Law and Policy*, 6.1, 2000; Hefferson, T., "Patent law- Diamond v. Chakrabarty - the US supreme court rules that living matter is patentable", *North Carolina Law Review*, 1001, 1980.

invention was alive or not was irrelevant under the *Patent Act.*[53] This given bacteria was not a product of nature but rather the result of the inventiveness of Chakrabarty. Justice Warren Burger echoed the arguments of Judge Rich and added that the philosophy behind the *Patent Act* intended that ingenuity receive a liberal encouragement. Obviously, this ruling created an important precedent.

In Canada, patents on living organisms did not evolve in the same way as in the United States. In 1976, the Abitibi Company based in Toronto applied for a patent on a mixed fungal yeast culture system.[54] This yeast was developed so that it could absorb the spent-sulfite liquor that was generated by its paper mills. Scientists of the University of Ontario isolated fungi and subjected them to an increasing concentration of foaming sulfites. They eventually obtained five mutated fungi that consumed the effluent. Abitibi's patent application covered both the process of creating mixed fungal yeast and the product of the system. The patent examiner granted the process claim, but declined the claim on the microbial culture system. The decision was grounded on the fact that living matter was not a patentable subject matter under the *Canadian Patent Act.* It is interesting to note that this patent act resembles in its wording and intent the American Patent Law. Abitibi contested the decision and by that time the Chakrabarty case had been decided.

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[53] Ibid

[54] For further information on this issue see: Thomson, G., "Biotechnology: Legal and Ethical Issues", *Engineering Dimensions*, March-April, 1997, pp.33-36; Gillan, M., "Biotechnology Patent in Canada", *National Law Center for Inter-American Free Trade*, 1997; Kelves, Daniel, *A History of Patenting Life in the United States with a Comparative Attention to Europe and Canada*, Office for Official Publication of the European Commission 2002.

In 1982, the board recommended that the term "manufacture" and "composition of matter" include the subject matter of Abitibi's application. Responding to the changing legal and economic environment in the world, the first Canadian patent on a living organism was granted. Yet, the board was conscious that this decision opened the door to the contentious subject of patents on higher life forms. The board therefore modified the manual of *Patent Office Practices* to include the phrase: "plants and animals are not patentable subject matter. Seeds are also non-patentable, however, a coated seed may be patentable if the invention resides in the coating given to the seed provided that the life process of the seed has not been altered and there is no new living matter."[55]

4.2 THE 1980s: A BROAD PATENT ON THE "ONCOMOUSE"

Throughout the 1980s the genetic revolution continued. DNA was now used in courts in Great Britain to identify criminal suspects through genetic fingerprinting. More easily available enzymes combined with a computer revolution led to the creation of several new technologies like the polymerase chain reaction (PCR), thereby rendering the Human Genome Project possible. [56] This period was also one where the scientific and corporate sector began to realise the financial possibilities of

[55] Canadian Intellectual Property Office, "Chapter 16: Utility and non-statutory Subject Matter, section 16.04. Examples of non-statutory Subject matter" Manual of Patent Office Practice. http: strategis.ic.gc.ca/sc_mrksv/cipo/mopop_dnld-e.html, 1996.

[56] Fox Keller, E., *The Century of the Gene,* Harvard University Press, 2002.

biotechnologies. Another important legal case aroses; the development of the Harvard onco-mouse. This case significantly influenced the world of biotechnological patents.

In 1981, Philip Leder started conducting research at Harvard University. His research in biomedicine was supported by the Dupont Corporation. Philip Leder and his collaborator Tim Stewart developed the so-called "onco-mouse". In June of 1984, lawyer Paul Clark files an application for a patent.[57] His claim comprised not simply a transgenic mouse that had the property of developing cancer but rather any transgenic mammal that contains in all its cells an activated oncogene introduced at an embryonic stage. In April 1988, this broad patent was awarded to Harvard University.[58] The decision generated a flood of ethical objections.

Harvard later filed a patent in **Europe**. The evaluation of the application was facing a different challenge. The 1962 *European Patent Convention* differs from the *American Patent Act*. The European Patent Office must take in to consideration that Article 53(a) prohibits patents on any invention that is contrary to public order or morality and that Article 53(b) prohibits them on plants or animal varieties, or anything produced by a natural biological process, except for microbiological

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[57] Anderson A., "Oncomouse Released", Nature 1988 Nov 24;336 (6197):300; Orlan, B., "Patenting Animals: the Harvard Onco-mouse", in *The Human use of Animals: Case Studies in Ethical Choices*, New York, Oxford University press, 1998.Kelves, Daniel, *A History of Patenting Life in the United states with a Comparative Attention to Europe and Canada*, Office for Official Publication of the European Commission, 2002, available at http://europa.eu.int/comm/european_group_ethics/docs/study_kevles.pdf

products.[59] It was under the provision of article 53(b) that the ruling in June 1989 rejected Harvard's application.[60] According to the examiners, this oncomouse was not a new variety of animal. Rather, it was the product of a natural biological process. Consequently, the oncomouse could not be granted a patent. Harvard appealed the decision.

In 1990, the appeal board modified the decision of the patent officers. They agreed with Harvard that this patent could not be refused on the base of article 53(b). However, the examiners stated that they had to examine this claim against article 53(a). The appeal board studied the opposition filings that argued that this patent would lead to animal suffering and environmental dangers. They also considered the likely benefits to human beings that might arise from research on the oncomouse. The EPO issued a ruling indicating that a patent on the mouse could and would likely be granted. In the European context, even if the patent was granted on a higher life form, all new applications on living organisms will have to satisfy the requirement of Article 53(a).[61]

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[58] The claims in the Harvard 'oncomouse' **patent** issue on April 12, **1988** (USP **4736866**), http://www.uspto.gov/, Schneider K., "Mouse patent is issued to Harvard, world's first for higher life form". *NY Times,* Apr 13;A1, A22, 1988.

[59]Kelves, D., *A History of Patenting Life in the United States with a Comparative Attention to Europe and Canada*, Office for Official Publication of the European Commission, 2002, available at http://europa.eu.int/comm/european_group_ethics/docs/study_kevles.pdf

[60] EPO boards of appeal decisions, 03 October 1990, case T 0019/90-3.3.2, http://legal.european-patent-office.org/dg3/biblio/t900019ep1.htm

[61] Text of decision of Technical Board of Appeal 3.3.2, Lancon, Kinkeldy, Nuss, Persson, Schulte, EPO (Technical Bd App), 501 Harvard/Onco-Mouse, T19/90, 3 October 1990, available at http://usitweb.shef.ac.uk/~zzc01ss/mable/mable2001/v_bergner/Onco.htm. The patent # 0169672 was granted on May 13th 1992. EPO press release available at http://www.european-patent-office.org/news/pressrel/2001_11_05_e.htm

In 1985, Harvard filed a patent application in **Canada**.[62] Eight years later the patent officers granted a patent protection to the oncogenetic construct and to the process used to create the mouse, but they refused to allow a patent on the Mouse itself based on the CPO policy manual. Harvard requested a review. The commissioner reaffirmed the decision. "The commissioner argued that the transgenic mouse was not an invention because, once the oncogene was inserted into the newly fertilised egg, nature rather than the inventors controlled the creation of the whole animal."[63] Harvard appealed this matter to the Federal Court. In April of 1998 the trial court ruled against Harvard.[64] They held that controlling a gene does not imply that the being is also controlled. Also, the insertion of a gene did not constitute an invention. The judge also found that the reproduction of the gene from one generation to the next was the result of the laws of nature rather than the inventor's intervention. Further, the decision regarding the patentability of higher life forms should be left to the legislator to decide.

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[62] For further information on this issue: Check, "Canada Stops Harvard's Oncomouse in its Tracks."Nature. 2002 Dec. 12;420(6916):593.; Kondro W., "Canadian High Court Rejects OncoMouse", *Science.*; 298(5601):2112-3, Dec. 13, 2002; Kneen, B., "Oncomouse Verdict: Guilty Until Proven Innocent". *The Ram's Horn* (No. 183, August-September 2000), Deftos, "Patenting life: the Harvard Mouse that Has Not Roared", *The Scientist*, 14(23):6, nov.27, 2000; Kelves, D., *A History of Patenting Life in the United States with a Comparative Attention to Europe and Canada*, Office for Official Publication of the European Commission, 2002. Available at http://europa.eu.int/comm/european_group_ethics/docs/study_kevles.pdf, p.69

[63] Kelves, Daniel, *A History of Patenting Life in the United States with a Comparative Attention to Europe and Canada,* Office for Official Publication of the European Commission, 2002. Available at http://europa.eu.int/comm/european_group_ethics/docs/study_kevles.pdf,

Once in appeal, the Court judged that this was a patentable invention based on the arguments raised in the Chakrabarty case. Since the *Canadian Patent Act* was modelled on the US statute and used the same broad language, the same verdict allowing patents on living organisms was pronounced. The Court also held that the use of the laws of nature by inventors does not disqualify a product from being an invention, which replied to the judgement of the Federal Court. Moreover, allowing patents on higher life forms does not open the door to the patenting of human beings since that would be contrary the *Charter of Rights and Freedom.* Still, this matter was considered capital by the CPO and hence a matter to be addressed by the Supreme Court. In December 2002 the Supreme Court of Canada, refuse to grant a patent on the mouse, holding essentially that this was an issue to be discussed by parliament.[65]

4.3 THE 1990s: THE HUMAN GENOME PROJECT RACE

Another biotechnological project raised considerable controversy concerning the legitimacy of patents on life and its components. In 1998, the Human Genome Project, was officially launched.[66] The goal of this project was to decrypt the entire

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[64] Check, "Canada Stops Harvard's Oncomouse in its Tracks", *Nature,* 420(6916):593, Dec. 12 2002.; Kondro W.,"Patenting life: Canadian High Court Rejects OncoMouse" *Science*, 298(5601):2112-3. Dec. 13, 2002.

[65] The verdict pronounced by the Supreme Court of Canada regarding the Harvard Onco-Mouse is available at http://www.lexum.umontreal.ca/csc-scc/en/rec/html/harvard.en.html; also see: Check, "Canada Stops Harvard's Oncomouse in its Tracks." *Nature,* 420(6916):593, Dec. 12, 2002; Kondro, W.,"Patenting Life: Canadian High Court Rejects OncoMouse" *Science,* 298(5601):2112-3, Dec. 13, 2002.

[66] Palca J., "James Watson to Head NIH Human Genome Project", *Nature*, 335(6187), Sept. 15, 2002.

human genome. In 1991, Craig Venter pointed the way toward patenting anonymous gene fragments. Venter's lab, using automated machines, proposed to sequence not whole genes but random fragments of cDNA, Expressed sequence tags (EST).[67] Venter filed a patent application on 315 EST.[68] Much opposition arose. The attempt to patent EST raised an ethical struggle regarding the ownership of the gene pool. On its side, the industry held that patents on life and its parts are necessary if the US wished to be competitive on the international scene. They also argued that a restriction on such patents would impede research on cures and therapies for disease.[69] Venter's initiative failed essentially because he did not fully characterise the genes.

In May 1998, Venter announced that he would move from the National Institute of Health to a new, for-profit company called Celera. This company aimed at sequencing the active human genome by 2001. Venter declared that Celera would make all its sequence data publicly available while at the same time earning money by selling access to the information.[70] Essentially he proposed to give the data away free to the community by posting it on his company web page. Celera would not make money from the raw data but from the analysis that the company would perform and sell to subscribers. In the eyes of many observers, this was threatening

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[67] Venter, K., and al., "Complementary DNA Sequencing: Expressed Sequence Tag and the Human Genome Project", *Science*, 252, 1651-1656, June 21, 1991; Anderson, C., "US Patent Application Stirs up Gene Hunter", *Nature*, 353, pp.485-486, Oct. 10, 1991.

[68] Roberts, L., "Genome fight erupts", *Science*, 254, pp.184-186, 1991.

[69] Roberts, L., "Controversial from the Start", *Science*, 291, 5507: 1182a, 2001.

[70] Marshall, E.," Sequencing Hubris and the Human Genome", *Science,* 280: 994-995, May 1998.

the access to the sequenced information. Ignoring this view, Celera proposed to use EST to identify new genes and guess their function. They would attempt to find genes of known function and similar structure through computerised searches and establish their utility by comparing their findings to genes with similar structure. This announcement brought the Royal Society of London and the National Academy of Science in the United States to issue a forceful statement where they stressed that the human genome itself must be freely available to all humankind.[71]

This rendered the leader of the public project furious and perplexed. Could a private company suddenly start working on this project and finish decrypting the human genome before them? What would be the consequences of this outcome for the diffusion of this scientifically capital information. The leaders of the public program increased the pace of the decrypting program. They were aiming to finish first and informed the public of the new goals for the public project. By the Spring of 2001 a first draft covering 90% of the genome would be published.[72] This resolution was motivated in part by the fact they were concerned that the public funding could be withdrawn now that a similar project was being privately sponsored. This move also aimed at undercutting any potential patent claim on the human genome. The race lasted and generated considerable controversy until Collin, the leader of the public project, and Venter agreed to announce their draft at the same time. On July third

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[71] Roberts, L., "Controversial from the Start", *Science*, 291, 5507: 1182a, 2001.

[72] Marshall, E., "NIH to Produce a 'Working Draft' of the Genome by 2001", *Science,* 1774-1775, Sept. 18, 1998.

2000, they gave an interview to Time magazine which heralded: "The Race is Over".[73]

The notion of patent becomes broader and extends to new areas of living organisms as the biological and microbiological sciences quickly evolve. Patents on plants were allowed in the 1930s. That development was the first step toward the private appropriation of the sphere of the living beings. The Charkrabarty v. Diamond case set a legal precedent in 1973 when the US Supreme Court rules that whether an invention was alive or not was irrelevant under the *Patent Act*. This precedent allowed Dupont and Harvard to be granted a broad patent on the process to genetically modify an animal and on the genetically modified animal also. The patenting of human material is also a targeted objective. The human genome project raised an important controversy: can the human genome be subject to patent? In the following section a number of the consequences of this privatisation of the common goods will be exposed. The important question behind this remains the legitimacy of this application of private property.

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[73] Golden, F., Lemonick, D., "The Race Is Over" *Time Magazine*, vol. 156, no.1, July 3, 2000; Marshall, E., "Rival Genome Sequencers Celebrate a Milestone Together", *Science,* 2294-2295, Jun. 30, 2000.

SECTION V: SOME NEGATIVE CONSEQUENCES OF HUMAN GENETIC RESSOURCES

The commercial value of intellectual property rights (IPR) is so high and such an appealing tool to stimulate and develop markets that countries have been very liberal regarding the approval of patents. Western governments have interpreted the criterion of inventiveness & human intervention in a particularly broad way. Further, since the TRIPs agreement was reached in 1994, this type of extended interpretation can be imposed on developing countries.

In this section, impacts of patenting human genetic resources will be exposed. It seems that the patenting of human genes can affect in a negative way human rights, the scientific community, and efficiency of research. Further, this practice may hinder the quality of medical care. Many questions arise today when one observes the impacts of such a policy on the biotechnological realm. It is not obvious that the actual patent system allows widespread diffusion of the results and benefits of genetic research. If one concludes that the disadvantages outweigh the benefits, then this might invite us to reconsider the validity of this system in the present state.

5.1 THE RIGHTS OF HUMAN SUBJECTS

The rights of subjects are now an important element of biomedical practices and an essential consideration in occident culture. The notions of informed consent, privacy and autonomy, have been introduced in legislation and are actively promoted. It is

important to reflect on how patents on human genetic material might encroach these principles and examine how these difficulties can be addressed.

5.1.1 Informed consent and self determination

Individual autonomy and bodily integrity must be protected to conduct ethical research. For this reason, the investigator has the obligation of clearly informing the research subject of the nature of the research, and possible risks and benefits that could result from engaging in this trial.[74] In addition, regulatory standards demand that any financial interests or commercial potential of the researchers be disclosed to the participant.[75] The notion of informed consent is construed in such a way that it does not extend to include a right to receive direct benefit or compensations from the participation.

The *Moore v. Regents of the University of California*[76] case is an interesting example in the field of biotechnology. It illustrates how a physician may breach the fiduciary relation with his patient. Moore sued his doctor after he discovered the

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[74] Tigerstrom, B., *Human Rights Issues Related to the Patenting of Human Biological Material*, CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf

[75] The codes for research ethics are not standardised. International standards, such as the Helsinki declaration, are proposed by institutional bodies but are not necessarily enforced in every nation. Further, nation-states construct particular guidelines that they implement according to given conditions.

[76] Lagod, M, Martin, P., "Biotechnology and the Commercial Use of Human Cells: Toward an Organic View of Life and Technology", *Stanta Clara Computer and High Technology Law Journal*, 211, 1989; Prowda, J.B., "Moore v. the Regents of the University of California: an Ethical Debate on Informed Consent and Property Rights in a Patient's Cells", *Journal of Patent Trademark Office*

commercialisation of cell lines derived from his spleen removed in the context of a treatment for hairy-cell leukaemia in 1976. Moore's physician used Moore's spleen cells in order to develop, patent (1981-84), and commercialise a cell line without ever informing his patient. Moore argued that he had a property interest in his biological material. He pleaded that he should receive a share of the profit on the basis of his property interest. The court denied his claim. The judgement stated that this was a case of breach in the doctor's fiduciary duties. Moore should thus be compensated on that basis.[77] In this case, the court confirmed the importance of informed consent but denied the individual rights to the property interest on the substances derived from his body material.

The promotion of informed consent and self-determination is a greater challenge when genetic research is conducted on vulnerable populations. The international race for access to genes has brought this issue to prominence. For example, in 1993, the US government filed a patent on a virus derived from the cell line of a 26 year old Guaymi Indian woman from Panama.[78] A NIH researcher had taken a blood sample from this Guaymi women. These blood cells contained a particular virus that increased the production of anti-bodies so the researcher developed a cell line from it. The NIH was hoping to find in this cell line a potential cure for AIDS. Political pressures arose when the Rural Advancement Foundation International, an NGO, and

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Society, 77(8), 611-39, Aug 1995; Annas, G. "Whose waste is it anyway? The case of John Moore,"*Hastings Center Report*, 18(5):37-9, Oct-Nov 1988.

[77] Moore v. Regents of the University of California, 793 P.2d 479 (cal.1990)

[78] Pottage, "The Inscription of Life in Law, Genes Patent and Biopolitics", *Modern Law Review,* 740; Bright, Chris, "Who Owns Indigenous Peoples' DNA?", *Humanist*, January 1995.

other local associations found that this patent claim was filed without the consent of the Guaymi people. The Guaymi general congress publicly stated that they believe that owning life goes against their values. They argue that the human genome should be owned by all of humanity as a collective heritage. They were outraged to discover that NIH researchers could and would seek a patent on a genetic trait of Guaymi and profit from their biological inheritance in the global market place without ever advising the Guaymi of their intentions. The public protest that was waged finally brought the NIH to withdraw its application.

It is obvious that the financial appeal of patents can lead certain individual or groups to try to avoid ethical guidelines when research is conducted on groups that are less informed about their rights and poorly equipped to defend their legal and financial interests. The right to self-determination exists in international law and includes some rights to financial benefits, to health care benefits and services that result from their participation in research and other benefits.[79] Yet, the patent system does not, in its present form, encourage benefit sharing.

5.1.2 Privacy and discrimination

The collection and conservation of genetic information is especially problematic from a privacy perspective. DNA codes for genes occurring in the human body.

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[79] Anaya, "A Contemporary Definition of the International Norm of Self Determination", *Journal of Transnational Law and Contemporary Problems*, 131, 1993; Clark & Williamson, *Self Determination : International Perspective,* Houndmill, UK, Macmillan Press, 1996.

Genes contain private health information about individuals or groups of individuals that reveal characteristics about diseases and predisposition. Many illnesses including Huntington disease, cystic fibrosis and muscular dystrophy, result from an interaction of environmental factors and genetic predisposition. Certain genes are now known to play a part in cancer, heart disease, diabetes and other health disorders. Information regarding these traits may lead to discrimination.[80] If this information is not appropriately protected and managed it can lead to unjust treatments based on genetic discrimination. Employers, the medical and life insurance industry and even governments, may use this information to penalise individuals or groups based on this factor. [81]

Patents may play an indirect role in encouraging the development of technologies that increase the risk of genetic privacy violation. For example, genetic tests could lead to a misuse of information if private information was conveyed to insurers. Considering that these tests will become increasingly available, the amount of information will also multiply. It is likely that certain individuals will not be able to control when they are subjected to these tests and how the results are used. In such a context, genetic testing and screening could ultimately play an important role in the workplace if legislation is not implemented.

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[80] Privacy and Human Rights, *An International Survey of Privacy Laws and Development*, 2001, available at www.privacyinternational.org/survey/phr2001/phr2001.pdf

[81] Renzong, O., "Human Genome and Philosophy: What Ethical Challenge Will Human Genome Studies Bring to the Medical Practices in the 21st Century?" *C R Acad Sci III*, 324(12):1097-102, Dec. 2001;Tigerstrom, Barbara, *Human Rights Issues Related to the Patenting of Human Biological Material*, CBAC, 2001, available at

Certain legislation has been introduced to better protect privacy. For example, the *International Covenant on Civil and Political Rights* recognises the right of everyone to protection against arbitrary or unlawful interference with one's privacy which can be used to protect individuals from this type of discrimination.[82] National policies have also tackled the delicate issue of privacy. Yet, these policies were not built to directly protect against genetic discrimination. Because of the lack of legislation on this issue, biotechnological research done from a commercial perspective, motivated by the possibility of patenting, may infringe individual privacy.

5.1.3 Individual autonomy

Patenting the germ line, human body parts, and the issue of reproductive cloning, raise questions concerning individual autonomy. According to Beauchamp and Childress, an autonomous individual must have the possibility to act freely according to self-made decisions. "Personal autonomy is, at minimum, self-rule that is free from both controlling inferences by others and by limitations that prevent meaningful choice."[83] This principle is based on the acknowledgement of intrinsic human dignity, the recognition of our rights and the respect that we all deserve. By patenting

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http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf

[82] Ibid; International Covenant on Civil and Political Rights, G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 171, *entered into force* Mar. 23, 1976, Article 17.

[83] Beauchamp, Childress, *Principles of Biomedical Ethics*, fifth edition, Oxford University Press, 2001.

certain human biological material or human beings entirely we might be contravening this important principle.

The legal provisions regarding this issue are not yet explicit in every country. The EU has provided a specific directive stating that the human body and the processes for cloning human beings cannot be patentable.[84] Yet, in Canada and the US there is no statutory exclusion. In the thirteenth amendment of the US Constitution[85] slavery is prohibited. Property rights cannot, therefore, be applied to humans. Still, it could be argued that the patent holder does not own the individual but rather has an exclusive property right. The patent holder only has the exclusive right to make, use, and sell the invention.[86] It can be further argued that an attempt to enforce the right to exclude others from using the invention could interfere with the patented individual's right to use him or herself or associate with others. In Canada, our domestic law contains no specific prohibition on slavery. The patenting of humans would surely violate rights to liberty and security of the person and the equality rights that are protected in the charter.[87] Many unresolved legal questions remain regarding the potential patenting of eventual human clones.

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[84]Tigerstrom, B., *Human Rights Issues related to the Patenting of Human Biological*, CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf

[85] The Constitution of the United States of America, http://www.law.cornell.edu/constitution/constitution.table.html

[86] Andrews, Lori, "Genes and Patent Policy: Rethinking Intellectual Property Rights", *Nature Review Genetics*, vol.3, 803, 2002.

5.2 BIOTECHNOLOGICAL PATENTS & THE SCIENTIFIC COMMUNITY

Traditionally, academic scientific research had the ideal of being disinterested in personal profits. The sole aim of research was pure knowledge of the surrounding world. Discoveries, consequent to such investigations, are seen as a source of collective progress. This is capital to the advancement of the community.[88] In past decades, profound changes have occurred in the way researchers are likely to advance their science. Important research discoveries in the biotechnological sciences are increasingly likely to be patented, which attracts the private sector and its particular scientific procedures. The interests of the private sector and the collaboration between basic researchers and the industry have altered scientific practices. Scientists are now often attracted by personal and financial gains when developing research projects.

"To what extent the traditional research norm- the slow but methodical collection of data, the prompt and wide dissemination of findings, and the sharing of insights-will be displaced by commercial norms- that is, finely targeted research, secrecy, and protection of ideas- will in large measure depend on the nature of intellectual property rights and how they are protected."[89] Presently, it is in the nature of the quest for property rights to induce research secrecy; this consequently reduces

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[87] Tigerstrom, B., *Human Rights Issues related to the Patenting of Human Biological Material*, CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf

[88] Korn, D., "Patent and Trade Secret Protection in University-Industry Research Relationship in Biotechnology", *Harvard Journal on Legislation*, 191, 1987.

sharing of information. Secrecy is particularly damaging for the progress of science when the product or process patented is useful or necessary for upcoming research, when up stream research results, such as cDNA, are patented.

In some cases patents may encourage research in such a way that the investigator is greatly motivated to do research for his profit rather than for the benefit of society. "Financial interest engenders new and potentially large conflicts of interests for these scientists, from their ability to review peer work in their field, through their ability to impartially assess raw data, to their choice of research goals."[90] This type of conflict of interest also affects the relation that unites the members of the community. Increases in trade secrets, in publication delays and decreases in information and data sharing, have been observed in the area of biotechnology. Profits are privileged rather than scientific progress and the common good.

Trade secrets have increased in the biotechnological sciences community where patenting is an increasingly frequent outcome of research. One of the fundamental ideals of university research is its openness. Scientists communicate freely among themselves with students, and with other researchers to gain valuable collegial input.[91] On the other hand, private industry usually maintains a secretive environment in order to secure a competitive edge. The possibility of patenting

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[89] Gold, R., *Body Parts: Property Rights and the Ownership of the Body*, Georgetown University Press, Washington, 1996.

[90] Kelves, D., "Principles, Property Rights, and Profits: Historical Reflections on University/Industry Relations", *Account Res.*, 8(4):293-307, 2001.

discoveries attracts the private industry which chooses to financially support such research. In return, the industry will likely demand secrecy to protect potential patent rights.[92] In a study released in 1996, David Blumenthal and his colleagues found that academic researchers with industrial funds were four times as likely as those without such funds to report that a trade secret had resulted from their research. Moreover, the rates of publication declined as the proportion of the research funds provided by the industry increased.[93] Trade secrets are more likely when private sponsors are part of the research process. The possibility of patenting scientific findings is modifying the behaviour of scientists. Because of the researcher's interests in potential financial benefit, scientists will have a tendency to protect most of the pertinent information and material. This practice leads to a decrease in the sharing of information with the scientific community.

Patent laws in this area are still emerging and adapting to the rapid technological changes. In its present form patent laws are engendering an increase in scientific secrets. The novelty clause requires that the patent application be filed before any other individual has publicly presented that innovation; this condition intrinsically provokes secrecy. This unfortunate consequence of the legal structure is also noticed in extensive sociological studies examining research practices within the scientific

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[91] Research finding are often not shared until it's publication or the establishment of authorship/priority.

[92] Cardinal, G., "Commercialization of Genetic Research and its Impact on the Communication of Results", *Health Law Journal,*7:35-48, 33, 1999; Korn, D., "Patent and Trade Secret Protection in University-Industry Research Relationship in Biotechnology", *Harvard Journal on Legislation*, 191, 1987; Concar, D., "Corporate Science v the Right to Know: is the Rise of the Private Sector Bringing Down a Cloak of Secrecy?", *New Sci.*, 16;173(2334):14-6, Mar., 2002.

community. Again, according to another study effectuated by Blumenthal, Campbell and al., from 1849 respondents, among which 1240 identified themselves as geneticists, 10% of all post-publication requests for additional information were denied. "Data withholding occurs in academic genetics and it affects essential scientific activities such as the ability to confirm published results."[94] The authors state that both lack of resources and the issue of scientific priority may play an important role in the withholding of data, materials and information. In one reported example, the search for a gene that is related to autism was impeded because researchers from several prominent universities would not share DNA samples from affected children and their families. Each university wanted to capitalise on being the one to discover and patent the gene that is related to that disease.[95] Obviously, secrecy and refusal to share findings with the scientific community converts the relations within the community, the quality and efficiency of research, and ultimately it affects the public by slowing the creation of new treatments.

The appeal of patenting human genes can also significantly increase **publication delays**. Publications are very important for the scientific community since particular information can influence the outcome of a given research project. In certain cases

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[93] Campbell, E., Blumenthal, D., and al., "Looking a Gift Horse in the Mouth", *Journal of American Medical Association*, vol.279, no.13, April 1, 1998.

[94] Campbell, E., Blumenthal, D., and al., "Data Withholding in Academic Genetics", *Journal of American Medical Association*, vol. 287, no.4, January 23/30, 2002.

[95] Bekerman, J.E., Li, Y., Gross, C.P.,"Scope and Impact of Financial Conflicts of interest in Biomedical Research: a Systematic Review", *Journal of American Medical Association*, 289(4):454-65, Jan 22-292003; Marshall, E., "Data Sharing: a Declining Ethic?", *Science*, 248(4958):952-7, May 25, 1990.

the results of other studies may even lead to faster direct results for other scientists. The possibility of patenting genetic discoveries has influenced the publication practices of the academics.[96] "Scientists directly engaged in commercial ventures were three times more likely to delay publication and twice as likely to refuse to share information than scientists doing basic work."[97] As well, it is shown in this study that when gifts and/or funds are provided by industry, scientists are, or feel, obliged to offer the possibility of reviewing the article of the report before publication. It has been found that 32 % of scientists affirm that private sponsors expected pre-publication review of articles or reports.[98] Also, since financial interests are in play, patent filings are replacing journal articles. The place for public disclosure is being transformed. This shift reduces the body of knowledge in the scientific literature.

Further, the patent system may **affect the communication of research results to the public**, which can be vital for the public's interests. "A 1998 analysis of 70 scientific articles on new drugs for treating cardiovascular disorders confirmed that scientists with links to industry researchers whose studies found the drug beneficial had financial agreements with the manufacturer, compared to 60% of those who were

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[96] Cardinal, G., "Commercialization of Genetic Research and its Impact on the Communication of Results", *Health Law Journal,*7:35-48, 33, 1999; Korn, D., "Patent and Trade Secret Protection in University-Industry Research Relationship in Biotechnology", *Harvard Journal on Legislation*, 191, 1987; Concar, D., "Corporate Science v the Right to Know: is the Rise of the Private Sector Bringing Down a Cloak of Secrecy?", *New Sci.*, 16;173(2334):14-6, Mar. 2002.

[97] Campbell, E, Blumenthal, D, and al., "Looking a Gift Horse in the Mouth", *Journal of American Medical Association*, vol.279, no.13, April 1, 1998.

[98] Ibid.

neutral and 37 % who were critical."[99] It is very problematic that studies do not reveal the conflicts of interest that scientists may have, though this problem is not exclusively related to the issues of biotechnological patenting, this financial incentives does encourage conflicts of interest. This affects not only members of the scientific community, but can also impact public health and affect the trust relation that unites industry, physicians and the public.

These problematic realities stem directly from the intrinsically paradoxical nature of the patent system. To stimulate research and increase access to scientific innovation, a legal structure assures the exclusivity to an individual or a group in exchange for the disclosure of all the information related to the given innovation. This framework should assure the delivery of innovation and information to the public. It is argued that knowledge could and would be monopolised by particular individuals or groups if this structure was not present. Therefore, it is held that the patent system promotes the progress of science and useful arts.[100] Once this knowledge is available to the public, anyone can access this information. Yet, this same system that aims at rendering public the scientific data and technologies encourages secrecy and decreases information sharing during the research process. This tension could possibly be addressed by a reform of patent laws.

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[99] Stelfox, H.T., Chua, K., O'Rourke, and Detsky, "Conflict of Interest in the Debate Over Calcium Channel Antagonists", *New England Journal of Medicine*, 338: 101-106.

[100] Canadian Patent Act, available at http://laws.justice.gc.ca/en/P-4/; US constitution, Art I, para. 8.8, http://www.law.cornell.edu/constitution/constitution.table.html

5.3 PATENTS AND THE EFFICIENCY OF RESEARCH

Patents are justified on the assumption that the advantages conferred by economical exclusivity outweigh the disadvantages of such a monopoly. Yet, many informed observers have found that patents in the biotechnological sector are affecting the advancement of research. In the preceding section I argued that patents affect the scientific community and consequently the effectiveness of research. In this section, direct undesirable impacts of patents on the development of new biotechnological inventions will be exposed.

The commercial interests that are present in biomedical research **affect the type of research** that scientists choose to explore, and thus, the sole intentions behind a research project are changing. The importance of the health impacts of a piece of biomedical research is not the principal motivation. Rather, the commercial value and viability of the consequent products are sought as a condition of the outcome of the project. Academics are increasingly directing research priorities towards certain types of investigations that are likely to be patentable and commercially lucrative.[101] This leaves gaps in certain areas of research. These gaps may be of great importance to the general population or to disadvantaged groups within a national or international community.[102] Researchers target their work toward the discovery of

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[101] Bekerman, JE., Li, Y., Gross, C.P.,"Scope and Impact of Financial Conflicts of Interest in Biomedical Research: a Systematic Review", *Journal of American Medical Association*, 289(4):454-65, Jan 22-29, 2003.

genetic flaws, for which companies can develop therapeutic products, and away from the investigation of the social and environmental causes of diseases, for which only social remedies exists. This is problematic since it might disfavour the interest of the public and casts doubts on the validity of scientific enquiry.

Some of the negative impacts of the patenting system are more specific to genetic research. In the actual form, it is possible to apply quite **broad patents** on genetic material. It is feared, consequently, that the privatisation of this information will result in the under utilisation of knowledge, increased costs to scientists and patients, and restricted use of the scientific data.[103] The patenting of "up stream" discoveries such as genetic sequences and process reduces the possibility of creating "down stream" applications because of the inaccessible patenting information.[104] "The patenting of partial or uncharacterised cDNA sequences will reward those who make routine discoveries but penalise those who determine the biological function or application."[105]

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[102] Tigerstrom, B., *Human Rights Issues Related to the Patenting of Human Biological Material*, CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf

[103] Eisenberg, R., "Patent and the Progress of Science: Exclusive Rights and Experimental Use", *University of Chicago Law Review*, 1017, 1989.

[104] Eisenberg, R., "Genomic Patents and Product Development Incentives", in *Human DNA: Law and Policy,* Kluwer Law International, 1997.

[105] Willison, Macleod, "Patenting of Genetic Material: are the Benefits to Society Being Realised", *Canadian Medical Association Journal*, 167 (3), August, 2002.

Patents rights may hamper research that could lead to beneficial discoveries because scientists may not be able to conduct research without the **risk of infringement** on others patent rights or the cost of obtaining rights under a licence. Eisenberg, a legal scholar specialised in this matter, writes that "important research discoveries in biomedical sciences are increasingly likely to be patented, and the use of these discoveries in subsequent research is increasingly likely to threaten the commercial interest of the patent holder."[106] This will, as a result, generate obstacles in this field of research.[107] It will also reduce diagnosis and therapy because of the cost of using patent research data. [108] Obviously, the high cost invested in the licensing of patents will be passed to consumers when diagnosis and therapies are created. Further, to the extent that the patent holder can refuse to provide licenses to competitors, patents may also dramatically impede creativity in subsequent research.

The presence of patents on genes and genetic sequences will generate significant **transaction and legal costs**. Research groups will require legal and administrative support to determine what patent applies to the research project they are building and

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[106] Eisenberg, R., "Patent and the Progress of Science: Exclusive Rights and Experimental Use", *University of Chicago Law Review*, 1017, 1989.

[107] See: Tigerstrom, B., *Human Rights Issues Related to the Patenting of Human Biological Material*, CBAC, 2001, available at http://www.cbac-cccb.ca/documents/en/HumanRights_Tigerstrom.pdf; Eisenberg, R., "Patent and the Progress of Science: Exclusive Rights and Experimental Use", *University of Chicago Law Review*, 1017, 1989; Schrecker, T., Wellington, A., *Patenting of Higher Life Forms and Human Biological Materials: An Introduction to the Issues*, revised in 2001, CBAC; Nelkin, D., "Patenting Genes and the Public Interest", *American Journal of Bioethics*, 2.3 13-15, 2002.

[108] Nelkin, D., "Patenting Genes and the Public Interest", *American Journal Of Bioethics*, 2.3 13-15, 2002.

who has the right to down steam products.[109] This may be a very long and costly process that discourages research. After the identification process is terminated, the license will have to be granted by the patent owner. This step may again require a very significant investment that will affect the development of the research. Again, this cost will be passed to consumers. Also, it is capital to consider that the patent holder has the right to refuse licensing without any justification, which will alter the project and the potential beneficial outcome of the given investigation. Finally, if the patent is licensed this whole legalistic operation will have reduced considerably the amount of money available for research and development.

Eisenberg in a very pertinent article, *Can patents deter innovation? The anti-commons in biomedical research,* applies the theory of the **Tragedy of the anti-common** to the current state of the biotechnological sector. In 1968, Hardin developed the metaphor of the common to explain the destruction of the common goods.[110] It essentially illustrates that individuals tend to overuse common resources because they have no incentive to conserve them when they are in the public domain. This metaphor is often used to justify the privatisation of the public good. The tragedy of the anti-common exposes the problematic elements of over privatisation. In the anti-common, a resource is prone to underuse when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege

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[109] Scherer, J.E., "The Economics of Human Gene Patents", *Academic Med.*, 77(12 Pt 2):1348-67, Dec. 2002; Eisenberg, R., "Technology Transfer and the Genome Project: Problems with Patenting Research Tools", *Risk*, 163, 1994.

[110] Eisenberg, R., Heller, M., "Can Patent Deter Innovation? The Anticommons in Biomedical Research", *Science*, vol.280, Mai 1998.

of use. By conferring monopolies on discoveries, patents increase prices and reduce uses. This is a cost society chooses to pay in order to motivate inventions and disclosure. Yet, when a user needs access to multiple patents to create a single useful product this framework may retard and even halt innovation.

According, to Eisenberg there are two causes for the biomedical anti-common. First, there is a proliferation of patents on individual fragments. Different owners hold these exclusivity rights. Hence, before a firm can have an effective right to develop these products, it must encounter costly transactions to bundle the necessary licenses together. Furthermore, long delays between the filing and the issue of the patent aggravate the problem. Secondly, stacking licenses are also engendering anti-common. **RTLA** (Research Through License Agreement) gives the owner of a patented invention, used in upstream stages of research, rights in subsequent downstream discoveries. This permits the researcher to not pay the permit fees untill he makes a lucrative discovery or obtains valuable results.

Researchers will face increasing difficulties conveying clear title to firms that might develop future discoveries. If a particularly valuable commercial product is in view, downstream product developers might be motivated to reach an agreements. But if the prospect for success is more uncertain or the expected commercial value is small, the parties may fail to bargain past the anti-commons. In this case, the anti-common is hampering scientific advancement. Eisenberg recognises that it is possible that the anti-common is only a transitional phase in this particular sector.

5.5 THE IMPACTS ON MEDICAL CARE

Patent practices may ultimately **compromise medical care.** Patents might decrease innovation that could lead to new genetic treatment. They may prevent the introduction of inexpensive genetic testing for common diseases, for example from undertaking genetic research on certain diseases. With the actual system of restriction on research access deriving from ample patent protection, we might not even know what scientific breakthroughs we are missing because of a lack of available informational tools. To the extent that DNA sequence prevents an individual from gaining access to the information coded in his or her genes, the patent system threatens not only an individual's health but also his access to medical care. [111]

Access to new genetic therapies and tests might be inequitable due to costs imposed by the patent holder. [112] As noticed in the preceding section, many costs such as legal fees and transaction costs related to patent licensing would be passed to consumers. Exclusive rights held by patent owners might result in prohibitive cost for therapeutic applications of research, and thus lead to serious inequalities in access to the benefit of research. The exclusivity conferred by the patent will allow the patentee to impose

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[111] Quigley, R., "Waiting on Science: the Stake of Present and Future Patients", *American Journal of Bioethics*, 2.3, 17-18, 2002.

[112] Andrews, Lori, "Genes and Patent Policy: Rethinking Intellectual Property Rights", *Nature Review Genetics*, vol.3, 803, 2002.

whatever costs and practical conditions that he judges appropriate. The patent holder can foreclose testing for a genetic disease or charge licensing fees that raise the costs beyond the affordable range for ordinary people.[113]

We are observing that patenting practices can result in narrowed access to genetic tests.[114] Private biotechnological firms who own certain patents on genes can monopolise the entire gene test markets. Because one of the first steps in a genetic test is the isolation and copying of the target DNA sequence, the provision of these tests constitutes an infringement of the patent over that sequence. This monopoly allows the firm to impose not only unlimited fees to the patent holder; the patent holder can establish the condition under which the tests are provided. [115] The patent holder can go as far as requiring that the patient use a test that is less sure or more expensive than other existing tests.[116] There is also some evidence, yet to be confirmed, that those gene patents decrease test quality because competitors cannot create a test without infringing the gene patent.

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[113] Nelkin, D., "Patenting Genes and the Public Interest", *American Journal of Bioethics*, 2.3 13-15, 2002.

[114] Andrews, Lori, "Genes and Patent Policy: Rethinking Intellectual Property Rights", *Nature Review Genetics*, vol.3, 803, 2002.

[115] Gold, R., *Body Parts: Property Rights and the Ownership of the Body*, Georgetown University Press, Washington, 1996.

[116] Nelkin, D., "Patenting Genes and the Public Interest", *American Journal of Bioethics*, 2.3 13-15, 2002.

The case of Myriad Genetic's[117] patent on breast cancer illustrated some of the problems encountered when a gene and the associated gene test are patented.[118] In 1994, the discovery of BRCA1, a gene that is associated with the development of breast cancer, was reported by the University of Utah & Myriad Genetics. In 1995, a patent was filed. The application asserts rights over the normal BRCA 1 and the method for screening samples from tumours. The same year Myriad and other academic institutions file a patent on a number of mutations. In 1996, Oncormed filed a patent on a "consensus sequence". The patent asserted rights on a method of identifying an individual with the normal gene and seven of the mutations. In 1998, after complaints of infringement, Myriad Genetic acquired Oncormed's property rights to the test and all the business associated with it. In January 2001, generating much social controversy, Myriad was granted a European patent over the diagnostic use of the BRCA 1 gene. This patent gives Myriad the monopoly for the testing of this gene in many European countries.

In October 2001, a coalition of three French organisations including the Marie Curie Foundation filed an opposition procedure against the patent that was awarded to Myriad Genetics on BRCA1.[119] Other groups also filed opposition such as the Belgian Society of Human Genetics and the Danish Society for Medical Genetics.

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[117] Myriad Genetic's web page available at : http://www.myriad.com/

[118] Nuffield Council on Bioethics, *The Ethics of Patenting DNA*, http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf

[119] Henley, J., "Cancer Unit Fights US Gene Patent", *The Guardian*, September 8, 2001; "La main mise d'une société américaine sur le dépistage génétique du cancer du sein contestée", *Le Monde*, 07 Sept., 2001; "Swiss Seek to Block Us Patenting of Cancer Gene", *BBC Monitoring*, 7 august, 2002.

They opposed the patent on numerous grounds. They argued that Myriad Genetics patent does not sufficiently describe the invention and that it was excessively broad in its reach. They argue that many negative consequences follow from this, such as the slowing of research and the creation of new tests and diagnosis methods. This will significantly influence how hundreds of thousands of women are treated for breast cancer. This may also lead to inequitable access to testing. Further, it can be wondered if it is in the interest of the public to only have one test available for a particular genetic disease?

In Canada, opposition has also been raised against Myriad's patent. The Ontario provincial government decided to challenge Myriad Genetics restriction on genetic testing and continue testing women at risk of breast cancer. Myriad had threatened to engage in legal actions against Ontario's hospitals unless all samples are sent to Myriad genetic for testing.[120] The company wants 3,800US$ per test while it cost between 800$ and 1 100$ in Ontario's hospitals. About five to ten percent of breast cancer is hereditary which implies that more than a thousand Ontario women require genetic testing each year.[121] The confirmation of the presence of this gene allows for earlier diagnosis and preventive therapy. Under the same circumstances British Columbia's government stopped doing tests involving BRCA1 and BRCA2. The B.C. government intends to have the tests conducted in Ontario. In January 2002,

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[120] Honourable Tony Clement, Ontario Minister of Health and Long-Term Care, Speech Re: Myriad Gene Patent Issue, Wednesday, September 19, 2001, available at http://www.gov.on.ca/health/english/news/speech/sp_091901_tc.html, "Ontario Defies Order by U.S. Genetic Company", *CBC Ottawa*, Sept. 19, 2001.

[121] "Ontario to Begin Using New Breast Cancer Test", *Canadian Press*, Jan.6, 2003.

the Ontario government released recommendations on this that suggested, among other things, that health care providers be protected from infringement liability.[122] All the Canadian provinces supported this stance. In January 2003 the Ontario government announced it would spend 1,2 million on a screening test which is about 10% more efficient than existing tests.[123]

Other examples of the preceding concerns can be given by Athena Diagnostics[124], which holds the patent on a gene that is associated with Alzheimer disease, the apolipoprotein E (APOE) gene (US patent No.5,508,167). Athena will not allow any laboratory except its own to screen for mutation in that gene.[125] Doctors and laboratories across the country face a lawsuit if they try to determine whether one of their patients carries this genetic predisposition to Alzheimer disease. This threat of a lawsuit exists, even though testing can easily be done by anyone who knows the sequence of the gene, without using any product or device made by the patent holder.[126]

Finally, patent law risks undermining trust in the medical profession. Patent practices are leading to multiple financial conflicts of interests, which are undermining the

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[122] Ontario Government, *Genetic Testing & Gene Patenting: Charting New territory in Health Care*, Jan. 2002, available at http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf

[123] "Ontario to Begin Using New Breast Cancer Test", *Canadian Press,* Jan.6, 2003.

[124] Athena Neurosciences main webpage: http://www.athenadiagnostics.com/site/content/index.asp

[125] Merz, J.F., Cho, M.K., "Testing for Alzheimer's", Science, (5381):1288-9, 281, Aug 28, 1998; Borger, J., "Rush to Patent genes Stalls Cure for Disease", *Guardian*, London, 15 Dec., 1999.

[126] Andrews, L., "Genes and Patent Policy: Rethinking Intellectual Property Rights", *Nature Review Genetics,* vol.3, 803, 2002.

fiduciary relationship between physician and patients.[127] This is seriously placing clinical research subjects at risk. A very troublesome example happened in 1998 when professors of the University of California at Irvine were caught in a scandal.[128] The professors were part owners of a company, Meyer Pharmaceuticals, created solely to facilitate the commercialisation of the discoveries they made. The company financially supported experiments to evaluate the efficacy of the experimental treatment. The professors were to gain if the results of this investigation were positive. Those same professors failed to report adverse reactions and did not receive proper approval for experiments effectuated on their subjects.

Do these facts demand a reform of the present regime as the condition for admissibility of these objects? It has been demonstrated, in this section, that patenting human genes may affect an individuals' rights. Relations within the scientific community have also deviated from previous norms due to this practice. Because of the potential lucrative appropriation of biotechnological inventions there is more trade secrecy, researchers tend to hesitate when they ought to share information, and the communication of results is restrained. This reality hinders the efficiency of research by influencing research in lucrative areas, reducing the access

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[127] Krimsky, "The Profit of Scientific Discoveries and its Normative Implications", *Chicago Kent Law Review*, 75, 15-39, 1999; Bekerman, JE., Li, Y., Gross, C.P.,"Scope and Impact of Financial Conflicts of Interest in Biomedical Research: a Systematic Review", *Journal of American Medical Association*, 289(4):454-65, Jan 22-29, 2003.

[128] Blumenstyk, 1999, "U of California at Irvine is Under Fire Again Over Research Ethics." *The Chronical of Higher Education,* January, a52, 1999; Gottlieb, J., "UCI Case Raises Issues of Schools' Ties to Business", *Los Angeles Times,* A1, Dec. 27, 1998. Referred to in Nelkin, D., "Patenting Genes and the Public Interest", *American Journal of Bioethics*, 2.3 13-15, 2002.

to basic information, and raising the cost of research on patented fragments. Further, this practice may hinder the quality of medical care by reducing access to genetic tests and therapies and by undermining trust in the medical professions. It is not obvious that the actual patent system really allows the widespread diffusion of the results and benefits of genetic research that it apparently promises. If one concludes that the disadvantages outweigh the benefits, then this might invite us to reconsider the validity of this system in its present state.

SECTION VI: DISCUSSION

The question that must be asked at this point is one of great importance. Are the philosophical justifications of intellectual property rights sufficiently satisfactory to ensure that the adverse effects of such rights, as just observed, do not warrant the dismissal of patent law in this area? First, we will further examine the Lockean theory in order to find if the new inventions as developed by biotechnologies are suitable as an abstract object subject to property rights. Also, we will refer to utilitarianism to investigate whether the burdens of patent rights on genetic material outweigh the benefits in the present case. We will argue that a broad interpretation of IPR is philosophically justified and thus that human genetic material is patentable. Still, because of political elements that affect the calculation of benefits and burdens in the utilitarian framework we must set forward a number of legal limits to frame legitimate patents on such objects.

6.1 THE LIMITS OF THE LOCKEAN JUSTIFICATION

The Lockean justification of intellectual property is founded on two major terms. First, everyone has a property right in the labour of his own body. Second, the appropriation of an unowned object is based on the application of human labour to that given object. Two provisos limit the appropriation of the common goods. Enough and as good of that product must remain available. Also, there shall be no spoiling of the appropriated object. Can such a theory justify the patenting of human genetic resources?

At first sight one could argue that this framework justifies the patenting of genes and other products derived from human genes. Under this definition the extension of patentability is very broad and infinite in time. Anything that is mixed with human labour can be appropriated as it respects the two provisos. An intellectual object can be patented if it is not spoiled and is as available as before for others. Yet, this approach, notwithstanding the provisos, allows appropriations that could be considered morally non-acceptable.[129] For example, imagine that an individual creates a new genetic treatment that could relieve thousands of individuals. That person can monopolise that good and, more dramatically, decides to not make it available on the market. The provisos as construed by Locke do not oblige a creator to make the object upon which he has rights available to the community. It could be said that an inventor's appropriation does not deprive others from an object that would not have been discovered if not for the inventor's contribution, so the situation of others is not worsened. However, a response to this claim could be that in the absence of the original inventor sometime later someone else would have created the same thing.[130] This brings a solid argument to set time limits, at minimum, to the private appropriation of a good generated from an individual's labour. Other restrictions seem necessary to make this policy acceptable and ensure that public goods are protected.

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[129] This problem has been identified in the actual patent regime and that is why the *Canadian Patent Act* specifies that health care and food product should not be patent subject. This was narrowed in 1991.

[130] Nozick, R., *Anarchy, State and Utopia*, Blackwell, Oxford, p.181, 1974.

It can be argued that the Lockean thesis does not offer plausible justification of such an extended property regime. If an individual employs labour to generate a given product, this mixing of one's ability with the common good does not justify the appropriation of the total value of a commodity. Rather, it legitimately explains only the appropriation of the added value. For example, if an individual uses his ingenuity to create a new genetic test that identifies a cancer causing genetic mutation, the Lockean theory justifies ownership only on the added value not over the whole gene. That individual could have property rights on the test but not on the gene it self. Hence, we can say that this specification shows that Locke's theory does not justify the broad appropriation of human genetic material. One can only have right to the added value, not to the entire good. This argument can also be put in parallel with the procedures in place when one improves a patented product. A patent applicant can only make claims on new elements rather than the entire product. In the same way, only patents on unprecedented elements are merited. Entire goods, in cases where they remain part of the common, can not be legitimately appropriated.

The problem of proportionality can also be presented as a criticism of the Lockean approach. If I pour my can of tomato juice into the ocean do I own the ocean?[131] The answer to this question is obvious. The mixing must thus be limited in some way. The case of the Human Genome Project is a good example of this problem of proportionality of labour and rights. Can a systematic identification of genetic sequence deserve a 20 years monopoly for each compound identified? Is the amount

[131] Ibid.

of work performed sufficiently in proportion to the property rights received on the object ? Locke's theory does not help us answer this difficult question. How far does the right of the creator go? How much work or modification is necessary for a property right to be legitimate? These questions are not answered in Locke's theory. Hence, the Lockean justification of intellectual property can not be a solid foundation to the appropriation of genes, cDNA or even of genetically modified animals.

One last issue must be identified in order to illustrate the difficulties this theory of property raises. Humans are labourers and they are also creative beings. Creativity allows humans to develop new objects that are essential for the progress of the species. Creativity's essence lies in the act of cross fertilisation or recombination of different frames of reference, ideas and theory.[132] A strong link exists between scientific creativity and institutional structures that promote the communication of scientific ideas. Access to the common affects creativity. If the appropriation of common goods is too great this will reduce the production of new goods. This applies particularly to intellectual objects when the history of science is observed. It is found that the evolution of scientific theories is heavily affected by social and cultural factors. Theories, such as Kuhn's vision of scientific revolutions, illustrate this phenomenon perfectly. The limited access to the intellectual common implies limited creativity. Because intellectual objects are unusual resources that grow in

[132] The ontology of creativity is a vast subject that can lead to individualist views of this process or a vision where the individual is dependent upon various upon impersonal forces. Both factor combined are considered in the present context.

strength through use and exploitation, the theory of property as construed by Locke may not apply adequately to this particular type of object.

This discussion brings us to conclude that the mixing of labour theory combined with the two provisos does not justify in a convincing manner the appropriation of human genetic material. This theory can be interpreted as promoting a very inclusive notion of property right. Yet, this interpretation is not acceptable. This view can allow the appropriation of goods in a situation that seems morally reprehensible. In fact, the extensive interpretation is fallacious since only the value added by labour should be appropriated not the entire product. This can be a convincing argument in favour of limiting the patenting human genetic material. Further, the Lockean theory does not consider the necessary balancing between the amount of work provided and the extent of the property right. The strength of Locke's justification, once applied to IPR, is thus significantly weakened. A last issue illustrates how this theory may not be satisfactory when applied to intellectual objects. Since intellectual objects are necessary in order to allow creativity and thus scientific progress, the withdrawal of such goods from the commons seems less justifiable. This final argument can also be considered from a utilitarian perspective.

6.2 BALANCING OF BURDEN AND BENEFITS

Under a utilitarian view, a given action is acceptable when it produces the greatest good for the greatest number. In the case of intellectual property, the utilitarian justification demands that this system advance the progress of science and useful arts.[133] Patents are seen as an incentive for researchers and investors to create valuable intellectual work. They motivate individuals to invest time and money toward the construction of new goods that will then be socially diffused. The investment made by intellectual labourers requires that they be granted property rights in their work. Property rights protect investors and researchers against free riders that would copy their inventions. If no preventive system were in place the problem of free riders would halt individuals from pursuing innovation. This justification of intellectual property regimes demands that the maximum total value of production be generated. In an attempt to reach the optimal level in production of goods, benefits and burdens should be balanced in order to optimise the outcome.

Economical theories are often used as a source of utilitarian arguments for property rights. To evaluate the creation of goods you can classify economic activities, as proposed by Lehman,[134] on three levels, namely, consumption, production and

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[133] Hettinger, E., "Justifying Intellectual Property", in *Intellectual Property: Moral, Legal and International Dilemmas,* Rowman and Littlefield, 1997; Spector, H., "An Outline of a Theory Justifying Intellectual and Industrial Property Rights", *Intellectual Property: Moral, Legal and International Dilemmas,* Rowman and Littlefield, 1997.

[134] Lehman, M., "The Theory of Property Right and the Protection of Intellectual and Industrial Property", 1985; referred to in Spector, H., "An Outline of a Theory Justifying Intellectual and

innovation. Ownership of goods may be described as a restriction on competition at the level of consumption; yet, it will be in favour of competition at the level of production. Intellectual and industrial property can be viewed as a restriction of competition at the level of production in favour of competition at the level of innovation. The availability of property rights at one level ensures that the market and competition develop at that next higher level. It must be added that it is desirable to restrict competition at the level of production only during the period of time needed to develop a healthy level of innovation. Beyond such a period the implementation of the idea of abstract property would conspire against its own ultimate purpose.

There is a controversy over gene patenting among those who welcome the commercial development of biotechnology products by private firms.[135] It has been expressed by proponents of biotechnology patents that sometimes patents are unnecessary or evencounter productive while they endorse patents in some circumstances. Are gene patents good or bad for business? The answer to this question will vary depending on the type of product at issue and the type of firm whose incentives are under consideration. Obviously, firms are more likely to view patent rights as essential to their incentives when they cover the technology they sell to their own customers than when they cover technology that they need to acquire from other corporations. In biotechnology, R&D is a complex stream of successive

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Industrial Property Rights", *Intellectual Property: Moral, Legal and International Dilemmas,* Rowman and Littlefield, 1997.

[135] Eisenberg, R., "Genomic Patents and Product Development Incentives" in *Human DNA: Law and Policy,* Kluwer Law International, 1997.

innovations, in which firms use the discoveries of others in the course of making their own discoveries. In this context, it is easy to see how firms might disagree about the impact of patents depending on their situation in the stream of innovation and their own R&D incentives. The firms that specialise in identifying novel DNA sequences are motivated by patents on such sequences, while firms that use DNA in their research as a target for drugs are more likely to be hostile to such patents. Patents on DNA have, because of such considerations, different impacts on firms that occupy different niches in the biotechnology industry. Patents are thus not as beneficial for the advancement of sciences as patents in other areas of research.

The argument holding that patents serve as a positive incentive for innovation is further impaired by the fact that the issuing of patents results in the closure of communication. By introducing secrecy in biotechnological science IPRs, and the commercialisation and privatisation of knowledge associated with them, decreases the scientific potential for creativity. Further, since issuing patents on DNA prevents others from using that information during the life of the patent, the advantages of releasing useful information into the public domain are less than under the classical scientific model. Communication of knowledge is also limited in this context when a strong IPR system results in price discrimination and many market distorting practices like patent pooling, tied-up sales, cross licensing and refusal to licence. This leads to a concentration of resources rather than motivating competition between companies. Patents are legitimised on the ground that they permit the diffusion of knowledge that would otherwise stay secret without patents; yet, in fact,

in the absence of patents, genetic information & assorted knowledge is more widely available.

A number of other elements can be made to mitigate the utilitarian argument that patents do create incentive to innovate and to increase investment in R&D. It can be argued that there is no uniform cross sectoral link between IPR and innovations. Stronger patent protection does not lead necessarily to higher innovation or more investment in R&D. For example, the length of a patent has an impact on the resultant benefits. If a patent right is for a longer period this will increase the number of new products created, but the price paid by society will also be higher if the monopoly is longer. If the monopoly is too long it reduces the accessibility of that product and thus it may be that the burden, of reduced accessibility, outweigh the benefits, of more new products. In certain situations, patent rights do not generate more innovation in that given sector. Other elements can serve as incentives. Social needs, political pressure, and peer recognition have all been incentives for the production of innovation and are an influential factor. This brings us to question the power and the extent of patent benefits. If other less burdensome approaches can lead to the same result it might demand that this approach be revised.

Because of the underlying paradoxical structure, there can be no such thing as an ideally beneficial patent system, and it is bound to produce negative results in particular instances, impeding progress unnecessarily even if its general effect is favourable on balance. This theory has distorting effects on property rights, which is typical of every consequentialist justification. This type of theory can prove that

enforcement of a right will have a valuable result in the generality of cases, but it will never be able to guarantee that this will be so in all cases. For this reason it is important that we periodically evaluate this type of policy. The negative impacts observed in the patenting of human genetic material, such as communication problems in the scientific community, reduced research efficiency and diminished accessibility of new genetic therapies, demand that we amend the patenting structure when it comes to the patenting of human genetic material. Again the aim is to reduce the burdens while optimising the benefits.

6.3 SUGGESTIONS & RECOMMENDATIONS

This final section sketches a selection of ways to address the ethical issues of patenting genetic material. Because it has been argued that a modification of the regime is required on philosophical grounds, the status quo, which would let the CIPO and the courts establish the distribution of patents, cannot be defended. As the Supreme Court has noted in the case of Harvard's onco-mouse it is Parliament that should be determining Canada's policy regarding patenting genetic material. Would specific legislation be more effective than the *Patent Act* at deterring undesirable activities? Many diverge on whether ethical concerns should be addressed within the patent law or through specific laws and regulations outside the patent regime. While it is argued that the *Patent Act* should not be used as a tool to implement social changes and introduce ethical policies, many countries choose to include in their patent law clauses that assure the ethical acceptability of patents.

The European notion of withholding patents for breach of ethical standards is a way of assuring that the interest of the public is preserved. The actual patent regimes could be amended in order to involve the use of an ***ordre public*** **or morality clause.**[136] Such a provision prohibits patents over inventions whose commercialisation would offend society's fundamental and shared moral standards. Pragmatically this could require that a separate **ethics review panel** be set in place in the national patent office. Patent applicants might be required to submit for ethics approvals before receiving patents on certain subject matter. This could function in a way similar to the practice of university based researchers, who must receive approval from their institution's Research Ethic Board (REB), before Canada's federal granting councils will support research involving human subjects. This demands that the enforcement of patents be suspended until ethical concerns are adequately addressed. **An efficient opposition procedure** is another means of ensuring that patents are legitimate and that they are acceptable with respect to the morality clause.[137] This procedure is a way of articulating the ethical concerns in a transparent manner, it allows and encourages the deliberation of such concerns. The introduction of an opposition procedure for commercial reasons with a six to nine

[136] Ontario Government, *Genetic Testing & Gene Patenting: Charting New territory in Health Care*, Jan. 2002, available at http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf,
[137] Canadian Bioethics Advisory Commission, *Patenting Higher life forms and Related Issues,* June 2002, available at http://cbac-cccb.ca/documents/en/E980_IC_IntelProp.pdf; Ontario Government, *Genetic Testing & Gene Patenting: Charting New Territory in Health Care*, Jan. 2002, available at http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf, Nuffield Council on Bioethics, The Ethics of Patenting DNA, available at http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf

month time limit would provide a way to challenge the acceptance of excessively broad patents.[138]

It is also a decisive issue that we **narrow the scope of what can legitimately be claimed** by inventors with respect to DNA sequences. The tendency has been to be generous when granting patents on genetic sequences. The concession of patent rights on genes should be the exception rather than the norm. Exclusivity rights should not be asserted over DNA sequences that have been identified and characterised only by comparison with other identified sequences on the ground of lack of inventiveness. Also, the norm of utility should be set higher than the mere theoretical possibility of utility. All the criteria for granting patents must be applied stringently when DNA sequences are used for diagnosis. In this context it is appropriate to patent the test rather than the gene sequence. Because DNA of one gene will often generate more than one product, the patent on DNA can be too extensive and circumscribes elements that are not asserted by the inventor. Since novel findings on the same genetic sequence will be frequent, the scope of the patent must be limited. This recommendation requires that the genes patented in the past be accordingly submitted to an analysis of their patentability.

In order to reduce the negative impacts of the actual patent regimes, **exemptions for experimental research and non-commercial clinical use** of patent invention

[138] National Biotechnology Advisory Committee, sixth report, *Leading the next Millennium,* 1998; Canadian Bioethics Advisory Commission, *Patenting HigherLife Forms and Related Issues,* June 2002 available at http://cbac-cccb.ca/documents/en/E980_IC_IntelProp.pdf.

should be dispensed. Access to the basic platform or technology such as DNA sequences, cell lines, plants and animals at reasonable cost is crucial to research. Many subsequent inventions can be made only after further research or experimentation is done using the patented invention. If this access is denied, this can lead to a chilling effect in research. Under-investment in basic research may be observed. Also, researchers will tend to withhold experimental results from fear of drawing the attention of the patent holder on this given research. These activities would infringe the patent holder's rights.

It might still be possible to reconcile a system of exclusive rights in prior discoveries with the interest of the scientific community. To do so subsequent researchers should enjoy free access to such discoveries by exempting the use of patent inventions in research from infringement liability. Exceptions to the exclusive rights are permissible only if they do not unreasonably prejudice the legitimate interests of the patent owner, while also taking into account the legitimate interests of the third party. The CBAC notes that Patent legislation in many countries is articulated in such a way that research using a patented invention is not an infringement of the patent holder's right. [139] The present recommendation permits the balancing of the interest of the patent holder and the need to encourage and allow further research.

[139] Canadian Bioethics Advisory Commission, *Patenting Higher Life Forms and Related Issues,* June 2002, available at http://cbac-cccb.ca/documents/en/E980_IC_IntelProp.pdf.

Compulsory licensing[140] should also be permitted in circumstances where protection of public health is at issue. It might be useful to allow the commissioner, if required, to grant a compulsory license, and to set an appropriate royalty rate after engaging with the appropriate industry and health sector expertise, but without prior negotiation with the patentee. While a government may never need to actually use this power, its existence not only disciplines the market, but also provides encouragement to industry to create patent pools or to establish a patent collective society. This provision should be revised so that it covers genetic diagnosis and screening test in the public health care system

Where the research depends on access to a population or a sub-population in the search for a genetic disease, a mechanism of **benefit sharing** should be implemented. As noted above medical researchers are interested in identifying genetic causes of certain diseases. To identify the cause it may be necessary to study groups of people. Yet, in some cases, the very people who made this discovery possible are unable to afford this new drug or treatment. Based on the principle of justice, the benefits of medical and pharmaceutical research based on human genetic material should be shared with the groups or communities who provided the material.[141] The Human Genome Organisation[142] proposes that the fruit of genetic research should be accessible to all since the human genome is part of the common

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[140] Ontario Government, *Genetic Testing & Gene Patenting: Charting New territory in Health Care*, Jan. 2002, available at http://www.gov.on.ca/health/english/pub/ministry/geneticsrep02/report_e.pdf,

[141] Canadian Bioethics Advisory Commission, *Patenting Higher life forms and Related Issues,* June 2002, available at http://cbac-cccb.ca/documents/en/E980_IC_IntelProp.pdf

[142] Human Genome Organisation, statement on benefit sharing, available at http://www.gene.ucl.ac.uk/hugo/pubrep.html

heritage of all humanity. Their recommendation state that the benefits should not be limited to individuals who participate in research but more available to all those in need.

SECTION VII: CONCLUSION

The traditional philosophical justifications behind property rights allow us to justify that we remodel the patent system in order to diminish the negative impacts that result from patents on human genetic material. It has been argued that the appropriation of genetic material has led to a number of unfortunate social effects. Human rights are challenged because of these new privatisation trends. The scientific community is also subject to the pressures of patents. It has reduced its information sharing and the attribution of broad patents on genes has increased the risk of infringement when research is conducted. These temporary monopolies granted on genetic material also affect the quality of medical care. The philosophical justifications of property rights are not sufficiently strong to warrant such consequences.

The Lockean theory of private property is a stepping stone for the justification of intellectual property rights. According to this theory, an individual can possess a thing when he mixes his labour with that good. The additional value that derives from labour belongs to the individual who generated it. This concept can be applied to abstract objects such as ideas and inventions. Yet, Lockean justification is not sufficient to sanction the present patent practices. The strength of argument stating that labour entails property rights must be re-evaluated in this context. It has been argued that this theory is weak in that it does not address the moral issue that may emanate from issuing property rights. Further, this argument justifies only the appropriation of the value added to the object due to labour, not the appropriation of

the entire object. In this sense the Lockean theory does not justify patents applied directly on genetic material. Further, in such a view property rights must be balanced proportionally to work contributed; this consideration forces us to ask if the patenting of genes identified in a process of decrypting the genome can rightfully entail property rights.

On the other, hand the utilitarian framework argues that intellectual property rights should be granted to innovators to promote the progress of science and useful arts. Utilitarianism also brings us to question the actual application of patents on genes. Utilitarianism demands that the patent system be beneficial for society by increasing the production of useful arts and sciences. Yet, gene patents are not producing the benefits expected in the patent bargain. Patents on genetic material is not necessarily good for business; a number of firms use DNA in their research and are discouraged by licenses fees. Further, these patents reduce the amount of information available in the public domain. There can be no such thing as an ideally beneficial patent system. Still, in order to justify patents the benefits must outweigh the burdens. For this reason, it is necessary that we amend present patent practices on human genetic material.

In order to be coherent with their founding justification, the patent regimes must adapt to the present challenges. The introduction of the morality clause supported by an ethics review board, could be an assurance of the acceptability of the patenting of human genetic resources. Further, an efficient opposition procedure will allow the public to participate in the evaluation of ethical concerns. Also, the scope of the

patent claims on genes should be narrowed. To balance the benefits and the burdens, exemptions for experimental research and compulsory licensing for public health purposes should be adopted. Finally, the principle of justice demands that benefit sharing be implemented.

GLOSSARY

Abstract objects: Abstract objects are non-tangible goods such as ideas and information. These objects can be at many places at the same time and are thus, by nature, non-exclusive.

Autonomy: Being free from both controlling interference from others and from limitations that prevent meaningful choice.

Biotechnology: The art of the use of the biological process to manufacture products.

Cell lines: Cell lines are distinct families of cells grown in culture. Different cell lines have different features that are useful in molecular biological.

Claims: The definition of the monopoly rights that a patent applicant is trying to obtain for the invention.

Compulsory licensing: Legal mechanism that allows a third party to apply for a product license without the consent of the patentee.

DNA (deoxyribonucleic acid): DNA is the biochemical substance that makes up genetic material.

Down stream inventions: Inventions that are created following a number of other inventions, they depend on up stream inventions.

Expressed sequence tags (EST): A short section of complementary DNA sequence, where location and nucleotide sequences are known. EST has applications in the discovery of new human genes, mapping of the human genome, and identification of coding regions in genomic sequences.

Gene: A gene is an ordered sequence of nucleotides located in a particular position on a particular chromosome that encodes a specific functional product.

Genetic discrimination: Discrimination of individuals or groups based on the presence of a given genotype in their DNA.

Genetic engineering: The technology used to genetically manipulate living cells to produce new chemicals or perform new functions.

Genetic resources: This term is usually understood as defined in the biodiversity convention. Genetic resources are the genetic materials of actual potential value, containing functional units of heredity, and of microbial, plant, animal or other origin.

Genetic testing: Analysing DNA to look for a genetic alteration that may indicate an increased risk for developing a specific disease or disorder, or for the purpose of diagnosis.

Genetic therapy: Treating disease by replacing, manipulating, or supplementing a specific gene that is not working properly.

Human genetic resources: Genetic resources of actual potential value that are of human provenance.

Human Genome Project: An international collaborative project which determined the sequence of the entire three billion nucleotides of the human genome.

Informed consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure.

Infringement: Using or selling a patented item or process within the country covered by the patent with out permission or licence from the patent holder.

Intellectual property rights: A right granted by state authority for certain products of intellectual ingenuity. These rights are subject to specific laws enacted by parliament or other state authorities and are generally consistent with international standards.

Non-obviousness: A criterion used in the US for assessing patent eligibility. It requires that an invention be not obvious to a person skilled in the art of the relevant subject.

Patent: A legal document providing an exclusive right for the invention claimed in the patent application.

Privacy: A person's right to keep information about himself from being disclosed to other.

Prior Art: Technology previously used or published that may be referred in a patent application.

Trade secrets: Information, maintained confidential, and having commercial value.

Utility: One of the three legal criterion by which patent applications are assessed, it requires that an invention must serve a specific function or purpose.

ACRONYMS

APOE	Apolipoprotein
BRCA	Breast Cancer Gene
CBAC	Canadian Biotechnology Advisory Commission
CIPO	Canadian Intellectual Property Office
CDNA	Complementary Deoxyribonucleic Acid
DNA	Deoxyribonucleic Acid
EPC	European Patent Convention
EPO	European Patent Office
EST	Expressed Sequence Tags
EU	European Union
HUGO	Human Genome Organisation
IP	Intellectual Property
IPR	Intellectual Property Rights
NAFTA	North American Free Trade Agreement
NIH	National Institutes of Health
NGO	Non Governmental Organisation
PCR	Polymerase Chain Reaction
R&D	Research and Development
RNA	Ribonucleic Acid
SNP	Single Nucleotide Polymorphism
TRIPS	Trade Related aspects of Intellectual Property Rights
USPTO	United State Patent and Trade mark Office
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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