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Reclaiming the Human Genome: A Philosophical Perspective

The human genome sequence has become central to ethical and policy debates on the application of genetic research to biomedicine and biotechnology. It is also shaping contemporary ideas about our *humanness* with scholars using the powerful scriptural metaphor of the "Book of Man" to refer to the human genome and likening its decoding to the search for the "Holy Grail."

Considering the benefits to mankind that the Human Genome Project promised to all those who could exploit it, the race to grab our DNA through the patenting system was inevitable. But when the first patent was issued way back in 1449 by King Henry VI to John of Utynam for a method of making stained glass, with the proviso that the inventor must teach his art to others, the situation was very different from what it is today, where patents are being sought for human genes and academic research can be commercialized as a result of the *Bayh-Dole Act* of 1980.[1] Preoccupied that the patenting of human genes may lead to illegal profiteering from the human genome, several international bodies such as the United Nations Educational, Scientific, and Cultural Organization (UNESCO), the World Medical Association and the Human Genome Organization (HUGO) have all adopted specific statements about DNA patenting. While HUGO[2] declared that those who participate in genetic studies should receive some benefits from participation, both UNESCO and

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[1] Bayh-Dole Act: The Patent Trademark Law Amendments Act, enacted into law and passed by the U.S. Congress on December 12, 1980. Pub. L. No. 96-517.

[2] HUGO, "Hugho Ethics Committee Statement on Benefit Sharing, April 9, 2000," *Clinical Genetics* 58, no.5 (2000): 364-366.

the World Medical Association[3] have declared the human genome as common heritage of mankind, and condemned any commercial benefit from the human genome in its natural state.[4] The World Medical Association has even urged medical organizations around the world to lobby against gene patenting.[5]

Modern Science and the Human Genome

The problem is that today the patenting system which sees the human genome as public property rather than common resource is supported by several scientists who choose to look upon the individual human being as nothing more than a "combinatorial unit of reassorted molecules." Metaphysically this is analogous to saying we are only DNA making more DNA. And when you reduce the individual to a "combinatorial unit of reassorted molecules," you are in effect doing two things: on the one hand, reducing the individual to a complex entity made up of essentially non-living entities that have no moral value, and on the other hand, denying that the individual human being can be the subject of morality. The individual is divested of all moral value because morality only belongs to the living and when you consider the individual as a combination of non-living entities, there is no longer any place for moral conclusions. The problem with this position is that it tends to deny the need to adopt a metaphysical account of human nature which is essential for addressing fundamental bioethical issues. Some bioethicists, in the empiricist tradition of David Hume, go so far as to deny that metaphysics can have any relevance to biomedical issues. This position is strongly contested by other authors who believe that a metaphysical account of human nature is necessary to discuss ethical issues and therefore reject any form of reductionist thinking. It is unfortunate that there has not been a serious moral discussion between biologists, who deny the relevance of metaphysics to biomedical issues, and philosophers, who hold that it is impossible to discuss these issues without metaphysical considerations.

Unfortunately, modern scientific thought has been taken over by a predominantly mechanistic understanding of Darwinism which rejects any form of teleological theory about the moral significance of the individual human being. It is an established fact, that for many biologists today, the

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[3] World Medical Association, *WMA Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, Edinburgh*, *October 2000* (Guilford: Canary Publications, 2000).

[4] UNESCO, *Universal Declaration on the Human Genome and Human Rights, 1997* (Paris: UNESCO, 1997).

[5] World Medical Association, *Declaration of Helsinki 2000.*

chemical explanation of life and evolution has no need of resorting to the idea of purpose or to what Aristotle termed "final cause." Modern biology has no use for "teleological" explanations; physico-chemical explanations are sufficient! According to Daniel C. Dennett, Darwin effectively put an end to any form of teleological thinking about the purpose and meaning of human life, when he showed that the evolutionary process was the result of a mindless, algorithmic process, which he termed "natural selection."[6]

This position is very contrary to that of several contemporary philosophers who are beginning to think of the human genome as embodying our humanness, determining both our individuality and our species-identity. This genomic metaphysics sees the genome as being the true essence of human nature, with external influences considered as accidental events. This notion of the human genome is very similar to the Aristotelian notion of *eidos* which is the organizing principle inherent in every living thing. Aristotle and Aquinas saw *eidos* as closely connected to the notion of soul, which gave a living organism its distinguishing characteristics as well as the essence of the organism's species. For Aristotle, it was not only human beings who had a soul but so did plants and animals with a vegetative and sensitive soul respectively.

With the human embryo denied its moral status or *forma* as the embodiment of our species-identity and personal identity, and reduced to a "blob of cells" or a "conglomeration of re-assorted molecules," the slippery slope to the patenting and commercialization of the human genome was inevitable. Modern scientific thought believes that Darwin provides the only feasible solution to the deep problem of man's existence. It stands to reason that this position not only undermines the consideration that the human genome constitutes the distinctive element that is specific to each individual as a component of his or her uniqueness, but also undermines the consideration that the human genome should not be made the object of appropriation as it is a "common resource."

But the crux of the matter is that Darwin's theory of natural selection, and Aristotle's teleological approach to human nature, are not mutually exclusive. Darwin never meant to reject all teleological ideas about life and nature. Leon Kass has argued that Darwinism cannot be correctly understood without the notion of teleology.[7] The root of the problem lies with the tendency of the modern mind to appropriate science and the scientific method for its own anti-metaphysical ends, thus reducing rational analysis to reductionism with its

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[6] Daniel C. Dennett, *Darwin's Dangerous Idea: Evolution and the Meanings of Life* (New York: Simon & Schuster, 1996), 48-60.

[7] Leon Kass, *Toward a More Natural Science: Biology and Human Affairs* (New York: The Free Press, 1988), 249-75.

inherent scepticism. When one is able to go beyond the reductionist approach to natural science, it becomes evident, from an accurate reading of Darwin's *The Origin of the Species*, that in explaining natural selection, Darwin was in fact mainly concerned with explaining the teleological character of living organisms. In his introduction to *The Origin of the Species*, Darwin wrote:

> In considering the Origin of Species, it is quite conceivable that a naturalist, reflecting on the mutual affinities of organic beings, on their embryological relations, their geographical distribution, geological succession, and other such facts, might come to the conclusion that species had not been independently created, but had descended, like varieties, from other species. Nevertheless, such a conclusion, even if well founded, would be unsatisfactory, until it could be shown how the innumerable species inhabiting this world have been modified, so as to acquire that perfection of structure and coadaptation which justly excites our admiration.[8]

Darwin was therefore interested in explaining not only the internal purposiveness which was to be found in plants and animals, but also the underlying reason for the perfection which he could observe, not only in their structure but also in the ordered set of relations which governed their activity as members of the same kind. In fact, Darwin succeeds in giving a non-teleological account of the origin and basis for the teleological character of organisms by demonstrating that his non-teleological explanation of natural selection depends upon the immanent teleological character of organisms.

With his theory of natural selection Darwin explained the essential connection that exists between the desire to be found in living organisms to survive and propagate, and the teleological nature of these organisms. In other words, it is the teleological nature of life that provides the nexus between natural selection and the miracle of the continuity of life. At the heart of natural selection is the teleological nature of these organisms. These organisms survive because they are teleological! This is not to say that these organisms are teleological because they survived; this is the teleological interpretation of Darwin's thought that modern scientific thought never tires of attacking. In expounding his theory of natural selection, Darwin reaffirmed the teleological force of nature which is at the heart of the natural process of evolution.[9]

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[8] Charles Darwin, *The Origin of Species: by Means of Natural Selection* (Middlesex: Senate, 1998), 2.

[9] Kass, *Toward a More Natural Science,* 260-61.

As Professor Marjorie Greene[10] has pointed out to many philosophical biologists, especially those trained in the atmosphere of British science: only that which is non-living is real, because only what is non-living can be explained in terms of molecules. This mode of thinking is not concerned with Being, the autonomous, dynamic organization and potentiality of the living creature, because it cannot explain it!

A Teleological Approach to the Human Genome

Michael Polanyi remarks that while teleology has become a dirty word for us,[11] this was not always the case. Before modern science interpreted Darwin's evolutionary theory in a predominantly mechanistic way, there was no opposition to teleological thoughts about man and nature. Not only was man seen to have a special purpose or function, but even other living things, with their specific integrative structure of organs and tissues.

All this changed with modern science's mechanistic interpretation of Darwin's origin of the species and modern biology's attempts to explain life processes in terms of chemical and physical mechanisms. Polanyi believes that the major obstacle to the possibility of entertaining any sort of teleological views is the reduction of life processes to physical and chemical laws. Although in a given DNA molecule there is a finite number of physical and chemical mechanisms, still, argues Polanyi, we cannot explain and identify with accuracy these mechanisms, and therefore, the reduction of life processes into physical and chemical laws is, to say the least, premature. Completely chemical and physical explanations for certain crucial aspects of living things have not been found, in spite of the momentous discovery of DNA.[12] Although it has generally been assumed that since organisms are mechanisms, and since mechanisms work in accordance with physical and chemical laws, organisms must also work in the same way, biological mechanisms cannot be explained as the resultants of the operation of physical and chemical laws only. This is because there are two aspects of a biological mechanism that must be taken into account and these are (i) the factual aspect comprising the physical and chemical conditions which permit the physical and chemical reactions specific to the particular mechanism to take place and (ii) the boundary conditions or limits within which the particular physical and chemical

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[10] Marjorie Grene, "The Faith of Darwinism," in *The Knower and the Known*, (New York: Basic Books, 1966), 185.

[11] Michael Polanyi and Harry Prosch, *Meaning* (Chicago: University of Chicago Press,1975), 163.

[12] Ibid., 167.

reactions take place. These boundary conditions, for Polanyi, determine the pattern in which these physical and chemical interactions are put together rather than the way in which these physical and chemical parts interact with one another. For Polanyi, although all living organisms appear to function in a way that appears to be guided by meaningful boundary conditions, a mechanism acquires its organization by reference to some aim or goal or purpose that is to be achieved by it, and this purpose cannot be deduced from the physico-chemical aspect of the mechanism.[13]

In other words, the dynamics of a living cell cannot be explained by reduction to the laws governing DNA molecules because in the molecules of life there is a fantastic configuration of forms and activities which require being studied in yet another dimension. While the shaping of the boundaries which are represented by the physical-chemical forms establishes a "controlling principle," the system itself is put under the control of a non-physical-chemical principle by a "profoundly informative intervention."[14] Polanyi believes that life is characterized by a "striving forward" which can be explained as a "gradient" towards higher forms and self-consciousness. The high level of genetic possibilities in man, as compared with a lower animal, is a manifestation of this striving, and each individual, as it comes into being, is a fresh manifestation of the attempt by life to develop potentialities. As Polanyi points out, the apparent simplicity of the chemical composition of the DNA molecule masks the complexity of the process involved in the generation of new life, and the qualitative progression in the evolution of the species and the generation of life within the same species. In this regard, Charles Taylor, writing on the subject of Galilean principles, argues that to transpose these scientific principles from inanimate to animate behavior "is to make a speculative leap, not to enunciate a necessary condition." [15]

The Anti-Commons Effect: When the Juridical Clashes with the Ethical

These metaphysical reflections on the human genome can never be reconciled with the patenting of human genes which makes parts of the human genome subject to appropriation by individuals and groups through the granting of intellectual property rights. As has been demonstrated, the human genome

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[13] Michael Polanyi, "Life Transcending Physics and Chemistry," *Chemical and Engineering News* 45 (1967): 54-66.

[14] Ibid.

[15] Charles Taylor, *The Explanation of Behaviour* (London: Routledge & Kegan Paul, 1980), 25.

is not a collection of genes that can be explored and exploited but rather, the human genome is a metaphysical reality that defies the method of scientific control. For these reasons, the human genome has been at the centre of recent bioethical debates because many institutions, scientists and individuals are worried that the patenting of human genes is creating an *anti-commons* effect that impedes the progress of scientific research. As a result, there are long delays in the development of new medical treatments and therapies that can bring relief to thousands of individuals who are suffering from some serious illness. It has been estimated that in the United States alone, at least 20% of all human genes are already under patent.

Ironically, when the patent system was introduced, it was intended to encourage scientific progress and not impede it. It was meant to do this by providing inventors, investors and entrepreneurs with incentives to carry on doing biomedical research by granting them a right of ownership on their invention for a specified period of time. In exchange for this protection, the patentee was obliged to disclose information about his/her invention together with the patent application.

The problem with the patenting of human genes is that holders of gatekeeper patents exercise excessive control over the commercial fruits of genome research. Similarly, allowing multiple patents on different parts of the genomic sequence, such as a gene fragment, a gene or a protein, adds undue costs to a researcher who wants to examine the sequence. The researcher might need to pay royalties on hundreds of patents in order to be able to develop a new product.[16]

These are some of the factors that give rise to the *anti-commons effect* in the biotechnology industry, impeding researchers from making new discoveries and developing new products. Recently the Supreme Court in the United States has ruled that the patents claimed by Myriad Genetics on the BRCA1 and BRCA2 gene mutations were preventing vital research on breast, ovarian and other cancers. While the Supreme Court upheld the patent eligibility of cDNA since it is not naturally occurring, it ruled that that isolated DNA, or genes found in nature are not patentable subject matter.

Several patents on BRCA1 and BRCA2 were granted by the US Patent and Trademark Office between 1997 and 2000. In Europe, three patents on the BRCA1 were granted by the European Patent Office (EPO) in 2001 while two BRCA2 patents were granted in 2003 and 2004 respectively. In the meantime, several European laboratories were already offering diagnostic tests for BRCA1

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[16] David B. Resnik, "A Biotechnology Patent Pool: An Idea Whose Time Has Come?," The Journal of Philosophy, Science and Law, 3 (2003), http://www6.miami.edu/ethics/jpsl/archives/papers/biotechPatent.html

and BRCA2 using different methods for mutation detection. With the granting of the patents by the EPO, Myriad Genetics adopted a policy of not licensing the diagnostic test, or at least not at conditions that were acceptable to the laboratories. As a result, several groups of European geneticists appealed against the patents with the EPO.

Precisely in order to avoid a similar situation from happening again, several commentators have in recent years, been proposing to make the human genome a "common heritage of mankind" that puts the interests of mankind above both individual and community interests. With the "common heritage of mankind," an intellectual sanctuary would be created where intellectual property would not apply. A system of compulsory licensing would also be introduced so as to ensure that patentees would not be able to exclude other researchers from having access to knowledge related to their patent.

The political decision to declare the human genome a "common heritage of mankind" would carry with it five fundamental ethical implications, namely, that (i) the human genome must not be made subject to appropriation of any kind whether public or private; (ii) the management of the human genome must be carried out by and on behalf of all humanity by "trustee" representatives; (iii) any benefits derived from such management must be shared among all humanity; (iv) the use of the human genome must be limited to peaceful purposes; and finally, (v) scientific research on the human genome must be carried out freely so long as the human genome is not compromised in any way, and the results are openly published for the benefit of all humanity.[17]

While the application of the patent system in the field of biotechnology and biomedicine has seemed justified in the past as a way of ensuring a reasonable balance between the rights of inventors and the public interest, many commentators are beginning to question the ethical and legal legitimacy of granting exclusive proprietary rights on human genes. These concerns revolve mainly around the idea that as the human genome stands for both (i) the full set of genes of each individual and (ii) the full range of genes of the human species, it can never be made the object of exclusionary intellectual property rights for any reason whatsoever.

Building a Political Platform for the Human Genome

For these reasons, there have been, in the past years, several attempts to encourage the adoption of new legislation that would guarantee a more equitable

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[17] Arvid Pardo, *The Common Heritage of Mankind: Selected Papers on Oceans and World Order 1967-1974* (Msida: Malta University Press 1975), 1-41.

and sustainable use of biotechnology. These concerted efforts have produced a number of notable results, including the Council of Europe Convention on Biomedicine[18]with its related Protocols on Human Cloning[19] and the Transplantation of Organs and Tissues of Human Origin and Biomedical Research;[20] the UNESCO Universal Declaration on the Human Genome and Human Rights[21] and the related Declaration on Human Genetic Data;[22] the UN Declaration on Human Cloning[23] and, the EC Directive on Biotechnological Interventions.[24]

The Council of Europe's Committee on Legal and Human Rights has also called upon member states to change the basis of patent law with respect to rights of ownership over human tissue and genes into "law pertaining to the common heritage of mankind."[25] The Parliamentary Assembly of the European Union has found it expedient to recommend to member states that they should strive towards establishing a "suitable alternative system of protecting intellectual property in the field of biotechnology" which would replace the present patent system that is considered to be inadequate for dealing with the discovery of human genes in particular.[26] The Parliamentary Assembly recommended that this proposed new system should be founded on a principle of "common heritage of mankind" which should reflect the language of the Universal Declaration on the Human Genome and Human Rights. This Declaration was adopted by the

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[18] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Oviedo, 4 April 1997,* CETS, no.164 (Strasbourg: Council of Europe, 1998).

[19] Council of Europe, *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Paris, 12 January 1998,* CETS, no.168 (Strasbourg: Council of Europe, 1998).

[20] Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 Jan 2002*, CETS, no.186 (Strasbourg: Council of Europe, 2002).

[21] UNESCO, *Declaration on the Human Genome.*

[22] UNESCO, *International Declaration on Human Genetic Data Adopted by the General Conference of UNESCO at its 32nd Session on 16 October 2003* (Paris: UNESCO, 2004).

[23] Declaration on Human Cloning Adopted by the General Assembly of the United Nations at its 59th Session on 8 March 2005. UNGA Resolution 59/280.

[24] Directive 98/44/EC of the European Parliament and of the Council, of 6 July 1998 on the Legal Protection of Biotechnological Inventions, OJL 213, 30 July 1998, 13-21.

[25] Parliamentary Assembly of the Council of Europe Recommendation 1512 (2001) on the Protection of the Human Genome.

[26] Parlamentary Assembly of the Council of Europe Recommendation 1425 (1999) on Biotechnology and Intellectual Property, par. 13.

General Conference of UNESCO in 1997 as a result of the urgent need, felt by the international community, to provide itself with an international instrument more particularly focused on the human genome. Article 1 of the UNESCO Declaration states that: "The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity."[27]

It is precisely because the genes themselves are the place where genomic information is stored that the human genome can be called the "heritage of mankind." It follows that, as a common inheritance, the human genome can never be appropriated by anyone. In practical terms, a new governance of the human genome must strike a balance between rewarding and protecting an inventor for his/her research work and ensuring that the inventor's research is made freely and rapidly available to other researchers, in the interests of "mankind."

The Human Genome as the Embodiment of Our Humanity

The commercialization of the human genome has seemed justified until now on the grounds that the human genome is reducible to a collection of "genes" and "gene fragments" that, as "natural matter," can be made the object of exclusionary intellectual property rights. This reductionist view of the human genome devalues its true nature by obfuscating its ontological significance as the embodiment of our humanness, determining both our individual and species identity. These two different approaches represent the divide that exists between those who believe that there is no metaphysical reality that underlies the human genome, and those who believe that it is only by giving serious consideration to its metaphysical nature that we will be able to comprehend the human genome's true essential nature.

This divergence of opinions on the nature of the human genome is also reflected in the issues raised by a number of contemporary scientists and philosophers, on the kind of biotechnology that is being used by biotech companies to exploit the human genome. Jurgen Habermas argues that there are many applications of biotechnology that are violating our dignity as human persons, such as the use of biotechnology to selectively modify and/or engineer specific genetic traits for purely enhancement purposes.[28] Accordingly, he argues in favour of an unmanipulated genetic heritage because any such genetic manipulation would touch the core of our identity as human beings.[29] Habermas'

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[27] UNESCO, *Declaration on the Human Genome*.

[28] Jurgen Habermas, *The Future of Human Nature* (Cambridge: Polity Press, 2003), 16-74.

[29] Ibid.

criticism of biotechnology, like that of other philosophers who are critical of certain applications of modern biotechnology, is based on his concern that several applications of biotechnology during the last twenty years have ignored the metaphysical understanding of human nature that must be at the heart of all bioethical debates involving the human genome.

The concept of common heritage of mankind can constitute the nexus between biotechnology and the human genome. In this sense it is the concept of "common heritage of mankind" that can restore meaning and significance to the human genome as the embodiment of our humanity.

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