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PATENTING HUMAN GENES THE ADVENT OF ETHICS IN THE POLITICAL ECONOMY OF PATENT LAW

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SUMMARY

During the 1990s, Craig Venter, a scientist at NIH, then at the private biotechnology company Celera, proposed to patent human genes wholesale, knowing only their express sequence tags (ESTs). His proposal stimulated broad-based opposition within the biotechnology community, many of whose members feared that allowing patents resting only on ESTs would permit company's like Venter's to lock up many human gene patents. Venter's proposal was rejected by the U.S. Patent Office as a violation of existing patent law, but it also elicited ethical opposition on grounds that the human genome was a universal birthright that belonged to everyone. In the United States, ethics was held to have no place in patent law. In Europe, in contrary, ethical considerations were written into the Biotechnology Directive enacted by the European Community in 1998. Covering the patenting of human genes as well as other forms of biotechnological inventions, the Directive may force American biotechnologists to take ethical matters into account if they want protection for their inventions in Europe

One of the most controversial issues in biotechnology in the United States and Europe has been the patenting of human DNA sequences –human genes. The medical, pharmaceutical and economic interests at stake are huge, making investments in biotechnology firms involved in gene patenting highly volatile. President Bill Clinton and Prime Minister Tony Blair recently applauded the commitment by scientists "to release raw funda-

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mental information about the human DNA sequence and its variants rapidly into the public domain"[1]. Investors, taking the communiqué as a declaration against gene patenting, sold off biotechnology shares as though they were post-Bolshevik Russian bonds.

The disputes surrounding gene patenting are partly familiar – contests of political economy among individuals, companies, and governments over what constitutes allowable intellectual property rights. But the contest has raised issues that have been, for the most part, historically unfamiliar in patent policy – ethics. The controversy over gene patenting has swirled most turbulently around the claim that granting private intellectual property rights in parts of the human genome violates a moral code because the genome, the common program for human life, belongs to us all.

I. Background: The Patenting of Life

The patenting of life was first formally contested in the United States when the case of *Diamond v. Chakrabarty*[2] made its way to the United States Supreme Court.[3] The case had been brought by Ananda Chakrabarty against the U.S. Patent Office after it denied him a patent on a bacterium that he had engineered to consume hydrocarbons[4]. The Patent Office argued that no patent could be issued on a living organism, not least because it was a product of nature[5]. But in 1980, the Court held, by the slim margin of 5 to 4, that whether the invention was alive or dead was irrelevant, that the bacterium was not a product of nature, that it was a product of Chakrabarty and hence deserved a patent[6].

After the *Chakrabarty* ruling, several critics insisted that the decision appeared to leave no legal obstacle to the patenting of higher forms of life — plants, animals, and possibly human beings — or, by implication, to the genetic engineering of such life forms[7]. In fact, although the Patent Office later held that human beings could not be patented[8], American patents were awarded during the 1980s on a plant and a mouse[9]. Patents were also allowed on human genes of known function – for example, the gene for insulin – in a form that did not occur naturally but that

had been derived from natural DNA by scientific manipulation[10]. Called "cDNA" – short for "copy DNA" – genes in such form were patentable because they are not products of nature. As a result, by the end of the 1980s, the new biotechnology industry was flourishing in the United States, energized by venture capital willing to invest heavily in firms that could patent genetically modified organisms and genes themselves. In contrast, the European Community provided no patent protection for living organisms or their genes[11]. Fearing for the competitiveness of the Community in the industrialization of molecular biology, the European Commission proposed a biotechnology directive in 1988 that would authorize the patenting of life, but the European Parliament was unwilling to concur in the initiative, partly on ethical grounds[12].

II. Patenting Expressed Sequence Tags

In the 1990s, J. Craig Venter, a biologist at the National Institutes of Health (NIH), in Bethesda, Maryland, suddenly raised the stakes in the patenting of life by proposing the wholesale patenting of human gene fragments. Venter's lab, using automated machines, had sequenced not whole genes but random fragments of cDNA derived from part of the brain[13]. Such a fragment was called an "expressed sequence tag," or EST[14]. Although just 150 to 400 base pairs long, each was unique and served to identify the gene of which it was a part[15]. In June 1991, Venter and NIH filed for patents on 315 ESTs and the human genes from which they came[16].

Venter's patent ambitions seemed boundless. His lab could churn out EST sequences so quickly that NIH planned to file patent applications for 1000 of them a month[17]. At that rate, it would not be too long before he had locked up a substantial fraction of the 100,000 genes then estimated to comprise the human genome[18]. Indeed, by 1994 the number of ESTs covered by the Venter/NIH application had multiplied to almost 7,000[19].

Venter attributed the idea for patenting the ESTs to Max Hensley, a patent attorney for Genentech, who apparently suggested the idea to Reid G. Adler, the director of NIH's Office of Technology Transfer, who in turn convinced Venter. Adler ap-

parently felt that if NIH could patent these DNA sequences, there would still be an incentive for companies to develop products using them because NIH could grant the companies exclusive or partly exclusive licenses under the Federal Technology Transfer Act of 1986[20]. If the sequences were published without being patented, they would be in the public domain, and companies would thus be without that incentive to develop products from the sequence information.

Others, however, argued that NIH patents on ESTs would inhibit industrial development of products from them[21]. Bernadine Healy, the director of the NIH, later testified: "NIH is amenable to not enforcing any patent rights that may issue to partial sequences of unknown function, except in the unusual situation where the licensing of such rights is necessary to provide for the development of a therapeutic agent that might not otherwise come to market"[22]. Healy also stated: "The NIH is doing this in a socially responsible way for the purposes of assuring that products that are life-saving remedies and therapies that are derived from this basic knowledge will be developed in the interest of our mission, which is science and the pursuit of health"[23]. She said that it was important for NIH to be at the table.

The debate that ensued turned in part on technical legal issues of patentability. Considerable emphasis went to the patentability of sequences that were merely fragments of genes of unknown function. Venter's approach raised questions about the "non-obviousness" and "utility" of the sequences that had not been raised by earlier gene patents. The international Human Genome Organization (HUGO) later argued:

> *Several uses have been suggested for genes and gene fragments to get past the utility requirement for patent protection. For any random gene, gene fragment, or collection of genes or gene fragments, it is easy to give a list of potential uses without knowledge of their true biological functions. . . . In all important cases the development of a truly useful tool for these purposes will require the investment of considerable further effort and creativity, far more than that invested in finding the initial fragment*[24].

A number of patent experts, however, insisted that ESTs were not patentable[25]. In the United States, an invention's eligibility

for a patent depends in part on its being "nonobvious" and possessing "utility" – that is, its being somehow useful. But the task of finding ESTs is obvious to practitioners in the field. Venter did claim that the ESTs would have utility as diagnostic probes for detecting gene expression in specific cell types and as markers for mapping the locations of genes on the chromosomes of human DNA[26]. However, his gene fragments revealed nothing about the utility of the full gene in the body – that is, its function or malfunction. He nevertheless seemed bent on using the fragments to gain control of the intellectual property in the entire gene that the EST identified. His patent strategy was comparable to claiming copyright ownership in an undescribed painting on the basis of having just a sliver of the canvas. A lawyer for the leading biotechnology firm Genentech noted, *"If these things are patentable, there's going to be an enormous cDNA arms race"*[27].

Venter's initiative also provoked denunciations from scientists anxious that his EST patents, if issued, would close off research by others on countless human genes. Academic biologists called EST patenting a terrible idea – *"like trying to patent the periodic table,"* one fumed[28]. A lawyer and medical ethicist at Boston University snapped, *"This is not science. This is like the gold rush"*[29]. James D. Watson, a Nobel laureate for his work on DNA and now head of NIH genome project, declared cDNA patenting "outrageous"[30] and *"sheer lunacy"*[31], adding that *"virtually any monkey"*[32] could perform this type of research. *"What is important is interpreting the sequence. . . . If these random bits of sequences can be patented, I am horrified"*[33]. In April 1992, Watson resigned as head of the genome project, explaining that he was unalterably opposed to the NIH attempts to patent ESTs[34].

Response in the Biotechnology Industry and Abroad

The prospect of EST patenting split the biotechnology industry. The Association of Biotechnology Companies in Washington, DC, which represented 280 companies and institutions, endorsed EST patenting by NIH so long as it did not favor any one company over another – say, by granting an exclusive license[35]. Still, many of the opponents of EST patenting were upset by the prospect that the government – through NIH – would own those

patents[36]. The Industrial Biotechnology Association (IBA), representing companies that accounted for eighty percent of U.S. investment in biotechnology, contended that it would be "unfair to permit the Government to exercise complete control over a product to whose development the Government contributed little"[37]. Richard Godown, president of the IBA, predicted that the commercial possibilities would be clouded

> *"if somebody spends a lot of time and money to discover the whole gene and its function, and then discovers they've got to deal with somebody who owns a patent to part of it"*[38].

The Pharmaceutical Manufacturers Association also opposed the NIH patent venture, declaring that

> *"a governmental policy of ownership and licensing of gene sequences would inevitably impede the research and development of new medicines in this country"*[39].

Abroad, France, Italy, and Japan announced their opposition to NIH's EST patents, fearing that they would competitively disadvantage their budding biotechnology enterprises[40]. Echoing Watson, the French Academy of Sciences condemned

> *"any measure which, answering purely to a logic of industrial competition, strove to obtain the legal property of genetic information data, without even having taken care to characterize the genes considered"*[41].

However, the British Minister of Science Alan Howarth chose to join the competition, announcing in March 1992 that the Medical Research Council would also seek cDNA patents[42]. Howarth explained that *"a decision . . . not to seek patents when researchers funded by public bodies in other countries have or may do so could place the UK at a relative disadvantage"*[43].

The mounting controversy was defused when in August 1992, the U.S. Patent Office rejected the Venter/NIH claims, calling them *"vague, indefinite, misdescriptive, inaccurate and incomprehensible"*[44]. In the agency's judgment, the patents failed to meet the standard for "non obviousness" and the related standard of

novelty[45]. NIH intended to appeal the rejection, but in February 1994, Harold Varmus, a Nobel laureate and the new director of NIH, announced that the agency was withdrawing its patent application on all ESTs, explaining that such patents were *"not in the best interests of the public or science"*[46]. In Britain, the Medical Research Council quickly followed suit[47].

Venter Raises the Stakes

The Venter/NIH application, however, had let the gene-patent genie out of the bottle, and Venter himself was of no mind to stuff it back inside. In July 1992, he had announced that he was leaving the NIH to head a new private, nonprofit research center called The Institute for Genomic Research (TIGR), to be located in Maryland near NIH[48]. TIGR received seventy million dollars as a ten-year grant from a New Jersey venture capital group called Healthcare Investment Corporation, which had already created several biotech companies[49]. The chair of Healthcare Investment Corporation, Wallace Steinberg, asserted that American scientists needed to patent genes before their European and Japanese competitors beat them to it[50]. While TIGR itself would be nonprofit, Steinberg established Human Genome Sciences Inc. (HGS) to develop and market products resulting from TIGR's research[51]. Venter took thirty NIH researchers with him and said TIGR would "do the genome project," beginning with a scaled-up continuation of his project to sequence random ESTs[52]. He predicted that TIGR would track down 1,000 genes daily and would identify the majority of human genes within three to five years.

Venter initially claimed that neither TIGR nor HGS would file patent applications for ESTs with unknown function[53]. He said he had supported the NIH patent application only because it stimulated debate and actually hoped that the patent would not be issued[54]. A prospectus for HGS, however, indicated that the company had filed patent applications for almost ten thousand ESTs. Several other companies had also submitted EST applications, including Incyte Pharmaceuticals, Inc., which filed for protection on more than forty thousand ESTs and said that it planned to file as many as one hundred thousand each year[55]. The EST arms race was on.

III. Ethical Objections to Gene Patenting

The door to ethical debates over gene patenting was opened in the Senate by Mark O. Hatfield, of Oregon, who had already introduced a bill to impose a 5-year moratorium on patenting animals. Although the bill did not refer to gene patenting, Hatfield argued in speeches that gene patenting raises the *"specter of removing the building blocks of life from the common possession of us all and shifting them to the private use and profit of researchers or corporations."* He also complained that biotechnology generally has reduced man to a *"biological machine"*[56]. Hatfield's bill, reconstituted as an amendment to the NIH reauthorization bill, providing a 3-year moratorium on patenting of both living organisms and "genetic matter," did not advance. Hatfield withdrew the amendment after reaching an agreement with Senator Dennis DeConcini and Senator Edward M. Kennedy, chair of the Senate Committee on Labor and Human Resources, that they would each schedule hearings on gene patenting. Hatfield, DeConcini, and Kennedy also requested a report from the Office of Technology Assessment (OTA) on legal, ethical, and economic issues raised by human gene patenting[57].

The ethical objections to gene patenting were rooted in the *Chakrabarty* case. During arguments in the case, vigorous objection to Chakrabarty's claim had come from the People's Business Commission (PBC), an activist group headed by Jeremy Rifkin.[58] Rifkin was a social agitator and sleepless critic of biotechnology. The PBC's dissent was partly economic – patents on living organisms would foster monopoly in vital areas such as the food industry. It was quasi-religious, too, holding that *"the essence of the matter"* was that to permit patents on life was to imply that *"life has no `vital' or sacred property," that it was only "an arrangement of chemicals, or mere `compositions of matter'"*[59]. In its ruling on the case, the Supreme Court majority took note of these and other apprehensions, observing that they *"present a gruesome parade of horribles"* and *"that, at times, human ingenuity seems unable to control fully the forces it creates."* The majority observed, however, that genetic research with its attendant risks would likely proceed with or without patent protection for its products and that neither legislative nor judicial fiat as to

patentability would *"deter the scientific mind from probing into the unknown any more than Canute could command the tides"*[60].

With the subsequent patenting of animals, the ethical objections to the patenting of life had grown more charged, enlisting animal rights activists, environmentalists, and clerics[61]. Once Venter put ESTs on the patent agenda, Rifkin and his allies contended that human genes, even those fully characterized as to composition and function, should not be patented at all[62]. At Senate hearings on ethical issues in gene patenting in 1992, Andrew Kimbrell, the policy director and attorney for Jeremy Rifkin's Foundation on Economic Trends, the successor to the PBC, argued in favor of a moratorium on gene patenting, saying, *"We are right in the middle of an ethical struggle on the ownership of the gene pool"*[63]. He held that Congress should *"intercede to decide where this ethical and legal free-fall ends"*[64].

Congress, its eye on the economic and medical potential of biotechnology, was unwilling to do anything of the sort. Patent attorneys, biotech representatives, and several congressmen warned that restrictions or a moratorium on the patenting of life or its parts would put the U.S. at a competitive disadvantage internationally and impede research on cures and therapies for disease[65]. Moreover, advocates of biotechnology insisted on distinguishing between issues of political economy and issues of ethics[66]. The former had a place in disputes over patent policy; the latter, at least in the United States, did not, even though they might be legitimate in principle. The appropriate venues for considering them were the legislative and regulatory arenas of government, not the Patent Office[67].

William D. Noonan, a physician and patent attorney who testified on behalf of the Oregon Biotechnology Association argued that because of advances in human genetics, *"we have to confront some of the darker questions about our human nature as we gain the power to practice eugenics on a scale and with a precision that was previously impossible"*[68]. In this context, however, the debate about patenting human ESTs was a red herring. Noonan elaborated:

> *[T]here is nothing inherently wrong or even ethically new about patenting DNA molecules. We have been patenting chemical components of the human body for years. Patents have been issued for decades on purified pro-*

teins, enzymes, neuropeptides, and many other gene products. There is no inherent ethical distinction between patenting these molecules and a purified molecule of DNA. Promoting the development of new medical treatments ethically justifies gene patents. Patent applications have been filed in recent years on genes involved in cystic fibrosis, neurofibromatosis, Fanconi's anemia, and other diseases. These filings did not provoke the ethical outcry. It was only when the NIH filed Dr. Venter's patent applications on cDNA's of unknown function that a sustained international debate arose about the ethics of gene patents. I think we run the risk of failing to address the real ethical concerns if we become too fixated on what is essentially a problem in international scientific politics and the uncertainty about the scope of patent law. What we should instead talk about is the social impact of human genome research. Do we want to practice molecular eugenics on humans and animals, and what is the acceptable scope of such eugenic efforts? These ethical questions have nothing to do with patent law and cannot be addressed by changing the scope of patentable subject matter. The Patent Office is, of course, the wrong place to conduct any ethical inquiry [69].

In support of biotechnology and in opposition to a moratorium, Senator Orrin Hatch (R-Utah) warned against any measure that jeopardized jobs in biotechnology. Such a measure would *"certainly undermine our world competitiveness,"* he warned, asking, *"Do any of my colleagues believe the Europeans and Japanese are going to slow down their efforts, let alone engage in a moratorium in this cutting edge industry? Of course not. They are going to take advantage of it"*[70]. Domenici chimed in that gene patenting would assist the search for cures and treatments for genetic disease[71].

Bernadine Healy also opposed a moratorium on gene patenting, saying it would be contrary to the Federal Technology Transfer Act of 1986 and would be the *"death knell for the patent system in the biotech field"*[72]. Healy argued that the attempt to patent human gene fragments did not raise ethical concerns as serious as the patenting of entire organisms, which she personally regarded as questionable, but which had already received the stamp of approval of the U.S. Supreme Court. She also pointed out that complete human gene sequences that code for proteins with known functions had been routinely patented without a fuss, and added:

"Some have said that we should not patent our universal heritage as a matter of ethics. But the same people who are saying that—the French Government has said this many times—. . . [also say that] if you know the function of the gene and it has commercial value, then you can patent it. That seems to be an ethical double standard"[73].

Rifkin nevertheless maintained an ethical enfilade against gene patenting, finding allies among clerics, feminists, and whoever else might feel threatened or offended by private ownership of the gene pool. In 1995, prompted by his Foundation on Economic Trends, several prominent clerics announced at a press conference in Washington, D. C. that a coalition of one hundred eighty religious leaders representing eighty denominations had joined Rifkin's group in signing a joint appeal opposing the patenting of human genes and genetically altered animals[74]. Richard Land, President of the Christian Life Commission of the Southern Baptist Convention, declared that *"[T]he patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves"*[75].

The next year, Rifkin mobilized women's rights leaders against attempts to patent genes implicated in breast cancer, claiming that such efforts represented an *"assault on women"* and *"denies them control over the most intimate aspect of their being, their bodies' genetic blueprint"*[76]. He said that a coalition would petition the Patent Office to challenge claims that had been filed on the breast cancer genes BRCA1 and BRCA2. Rifkin's statements were endorsed by members of women's health organizations in sixty-nine countries, including Betty Friedan, Gloria Steinem, and Bella Abzug, the former member of Congress and herself a breast-cancer survivor[77]. Abzug averred, *"Human genes are not for sale or profit. Any attempt to patent human genetic materials by individuals, scientific corporations, or other entities is unacceptable"*[78].

IV. European Commission Initiatives

All the while, the European Commission had continued its attempt to promulgate a biotechnology directive that the European Parliament would find acceptable. Resolution of their differences had to take ethics into account. According to article 53a

of the European patent convention, patents that violated "public order and morality" were inadmissible[79]. Thus in Europe, unlike in the United States, by law ethical issues enjoyed a seat at the table of patent policymaking. The Commission's effort had been repeatedly blocked by ethical opposition to patenting life from members of the Green Party and their sympathizers, among others, in the European Parliament[80].

In 1994, the Commission presented the Parliament with a new compromise draft directive that allowed the patenting of human genes, provided that *"they cannot be linked to a specific individual"*[81]. Willy Rothley, of Germany, the head of the effort to find suitable language for the directive in the Parliament, considered this provision an adequate constraint, declaring, *"The European Parliament has been able to impose an ethical dimension on patent rights and has been able to obtain most of the guarantees that it was asking for"*[82]. However, Linda Bullard of the European Green Party, countered:

> *"We feel that Parliament, having voted previously against patents on parts of the human body —including genes — under any circumstances, is morally obliged to reject this compromise. This is not a question of individual human dignity, but of collective human dignity"*[83].

The compromise directive died in March 1995, when the European Parliament voted 240 to 188 against approval, with twenty-three abstentions[84].

But the European biotechnology industry was growing, eager to prevent the kind of ethical issues raised by Rifkin, the European Greens, and their allies entirely to block the establishment of a patent policy for biotechnological inventions. Interpharma, an association representing Swiss pharmaceutical companies, supported patents on genes or gene fragments *"in a form that does not occur in nature,"* arguing that *"isolated genes do not occur naturally, nor do large quantities of purified proteins; they should, therefore, be patentable"*[85]. In Germany, biotechnology had been lagging. By 1996, the political winds had shifted and the federal government began offering financial incentives to encourage German biotechnology[86]. As Maria Leptin, head of the genetics faculty at the University of Cologne, put it:

> *"if there's anything that's more important [to Germans] than saving the environment, it's saving jobs. As soon as people saw the [pharmaceutical] industry possibly disappearing, morality went out the window"*[87].

In the summer of 1997, the European Parliament reconsidered the question of the patenting of biological inventions[88]. In the spring of 1998, it approved a wide-ranging directive on biotechnology designed to encourage patents while adopting explicit ethical restrictions – for the first time anywhere – on what can be patented[89]. Holding that biotechnology patents must safeguard the dignity and integrity of the person, the directive prohibits patents on human parts, human embryos, and the products of human cloning[90]. The directive also prohibits patents on animals if what they suffer by being modified exceeds the benefits that the modification would yield[91].

The ethical restrictions stopped short of limiting patents on genes and gene fragments. The directive passed by the Parliament, formally issued by the European Commission in July 1998, authorizes patents for partial DNA sequences that are isolated from the body and for which an *"industrial application"* – that is, a practical use — has been disclosed. Nevertheless – again, for the first time anywhere – the directive calls for ongoing oversight of *"all ethical aspects of biotechnology"* by the Commission's European Group on Ethics in Science and New Technologies[92].

V. Patents and the Human Genome

In the United States in December 1997, Jeremy Rifkin and a biologist announced that, as a provocation, they would seek a patent on methods to create a human/animal hybrid, a creature part animal and part person[93]. Bruce Lehman, the U.S. Commissioner of Patents, declared that the Patent and Trademark Office would in general reject patents that were *"injurious to the well-being, good policy or good morals of society"*[94]. Patent lawyers roundly attacked Lehman, contending that he had no authority in U.S. patent law, because it is literally amoral, to back such a prohibition[95]. Yet even if ethics has no rightful presence in American patent policy, an ethical principle – that the human genome must not be locked up — has been creeping in-

to it through the issue of gene patenting. And nothing has done more to introduce it than the robust ambitions of Craig Venter.

In May 1998, Venter announced that he would leave the nonprofit TIGR to move to a new, for-profit company, called Celera, that would be located next door, in Rockville, Maryland[96]. Celera would aim to sequence all the DNA in the human genome by 2001, using rapid new automated machines supplied by its principal owner, the Perkin-Elmer Corporation[97]. Venter declared that Celera would make all its sequence data publicly available while at the same time earn money from selling access to the information[98]. Venter's rapid-fire approach to the sequencing prompted scientific critics to predict that his company's data would contain numerous serious gaps in the DNA, perhaps 100,000 of them[99]. It was also unclear how the company could publish and profit from its sequence data. Early in 2000, strategies that Celera said it would follow to profit from its work appeared to threaten broad access to the sequence information[100]. Indeed, suspicion of Celera's intentions appeared to prompt Clinton and Blair's declaration that information about human DNA sequences should be released into the public domain.

But Venter has revived his original goal of wholesale gene patenting. Along with several other genomic companies, Celera has proposed to use ESTs to identify new genes and guess their function by finding genes of known function and similar structure through computerized searches of the genomic data base. The company would then seek utility patents covering these new genes, arguing that their functions were likely the same as those of the genes with similar structure[101]. That strategy stimulated a forceful statement in late March by Aaron Klug and Bruce Alberts, the presidents, respectively, of the Royal Society of London and the National Academy of Sciences in the United States[102]. They called guessing at gene function by computerized searches of genomic data bases *"a trivial matter"*[103]. Its outcome might satisfy *"current shareholders' interests,"* but it did *"not serve society well."* Holding that its results did not warrant patent protection, they stressed that *"the human genome itself must be freely available to all humankind"*[104].

Gene patenting has exposed a conflict and, possibly, an incompatability in patent policy between the United States and

the European community. Even though the former does not impose ethical constraints on the patentability of products, the latter does, with the consequence that what may be patentable in the U.S. may not be so in Europe. Paradoxically, while trade barriers have been steadily falling with globalization, at least in the commerce of living organisms and their parts, patent barriers may be arising to some degree. The transatlantic mismatch aside, within both the United States and Europe, gene patenting has prompted important challenges to the scope of intellectual property rights in genes. Given that the human genome is widely regarded as a common birthrate of people everywhere, governments may feel increasing pressure to limit the property rights sought in DNA sequences.

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Articoli/*Articles*

THE COMMERCIALIZATION OF HUMAN GENETICS: FUTURE POLICY CONCERNS

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SUMMARY

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

I. Introduction

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

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