# Is It Ethical To Patent Human Genes?

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Human gene patents are patents on human genes that have been removed from human bodies and scientifically isolated and manipulated in a laboratory. The U.S. Patent and Trademark Office (the USPTO) has issued thousands of patents on such genes, and patents have also been granted by the European Patent Office, (the EPO).[1] Legal and moral justification, however, are not identical, and it is possible for a legal decision to be immoral although consistent with legal precedent and procedure. So, it is surprising to learn that some people believe that the legal justification of human gene patents can remove the most serious moral objections to them.[2] Yet, those who are well-versed in patent law often believe that confusion over some quite basic legal and scientific facts accounts for moral objections to such patents[3] and, in particular, for the belief that they justify the ownership of one person by another.[4] Once these confusions are removed, they contend, we will see that there is nothing especially alarming about patents on human genes, and no reason to believe them immoral. [5]

Such claims seem especially surprising because the morality of an invention is generally supposed to have little role in decisions about whether or not an invention deserves a patent under U.S. law. Although the European Patent Convention's article 53 (a) prohibits patenting inventions, the publication or exploitation of which would be contrary to public order or morality, it turns out that this clause rarely justifies withholding a patent from an invention that otherwise meets legal criteria. Thus, although more than 320,000 patents have been granted by the EPO since its creation, this clause has never been used successfully to strike down a claim for a patent. Indeed, Ulrich Schatz explains, "Poisons, explosives, extremely dangerous chemical substances,

devices used in nuclear power stations, agro-chemicals, pesticides and many other things which can threaten human life or damage the environment have been patented, despite the existence of the public order and morality bar" in almost all European countries**.**

Indeed, this paper shows, while ethical objections to human gene patents are often controversial, they need not be unreasonable, nor need they depend on mistaken assumptions about patent law. Rather, they may reflect familiar ethical concerns about the dominance of commercial imperatives in modern societies; concerns about the disparities in power and wealth amongst individuals and countries; and concerns about the lack of public discussion, transparency and accountability surrounding significant changes in people's rights, status and opportunities. Hence, I conclude, ethical concerns cannot be easily dismissed and, indeed, point to the need to think harder about the nature and justification of patent law, itself.

**Legal Facts about Human Gene Patents**

Human genes can only be patented in the U.S. – or, indeed, anywhere – if they can be distinguished from genes as they naturally occur in human bodies. To be patentable in the U.S. an object or process must count as an invention, not a discovery, in addition to meeting further legal tests such as those for novelty, non-obviousness and usefulness. It is, therefore, a legal fact about patents that they do not apply to naturally occurring objects, unless these have been sufficiently altered by human effort so as to count as "made by man" for legal purposes. Thus, human genes can only pass the threshold test, which marks them as legally patentable, if they have been altered

sufficiently to be legally distinguishable from naturally occurring genes, which cannot be patented.

Though the genes in your body are not patentable, the degree of manipulation and alteration that is required to isolate and identify a human gene scientifically means that genes so altered and manipulated can merit a legal patent. This is hardly surprising for human genes that are patentable have scientific and commercial properties that distinguish them from naturally occurring genes. For example, while there are several methods of sequencing DNA, all of them require at least some of the following: isolating DNA, purifying DNA, removing a small segment of the DNA from its place in the genome and connecting it to bacterial DNA, chemically unwinding DNA, and constructing radioactive or florescent copies of the genomic DNA fragment.[6] As Ossorio explains, "When a patent claims a particular DNA sequence, it must teach others how to "make" that sequence – the patent must give enough information that another investigator can synthesize the sequence *de novo* or clone the sequence herself. [7]

In *Diamond v. Chakrabarty*,[8] the U.S. Supreme Court upheld a patent on oil-eating bacteria, arguing that such a patent was perfectly consistent with legal objections to patenting natural objects that have not been significantly altered by human endeavor. In *Parke –Davis and Co. v. H. K. Mulford and Co.*,[9] a lower Court held that purified human adrenaline was patentable because, through purification, it became "for every practical purpose a new thing commercially and therapeutically". Hence, given the work that goes into scientifically isolating and identifying a gene, and the changes in the

properties of the gene that this involves, treating human genes as patentable inventions does not, in and of itself, threaten the bodily integrity of human beings.

Moreover, critics claim, the difficulty with the main moral objections to human gene patents is not simply that they confuse legally patentable genes with naturally occurring genes. In addition, they confuse patenting with owning. Thus, they fail to see that whatever the complexity involved in legal ownership, a patent simply does not confer legal ownership of anything. One can have a legal patent on a bicycle without owning any bicycles. Indeed, one can have a legal patent on an invention, but lack any legal rights to use that invention, let alone to license others to use or manufacture it. This is because the only legal right conferred by a patent is the right to prevent others from using or possessing one's invention: "…patents do not grant rights of use or possession, only rights to exclude". [10] Hence, Ossorio concludes, a human gene patent cannot be identified with legal ownership of human bodies, not simply because human gene patents confer no rights over naturally occurring genes, but because patent rights confer none of the positive rights to possess and use in which ownership typically consists.

Attention to the legal facts about human gene patents, then, does remove some serious doubts about their morality. We may be sceptical that these patents are necessary to promote research and investment in biotechnology, or in the prevention and cure of human suffering.[11] Nevertheless, doubts on this score hardly imply that human gene patents are intrinsically immoral, as they would be if they prevented people from using their genes to live or to reproduce. Moreover, while these legal features of human gene

patents do not alleviate the concern that patenting may exacerbate existing inequalities between rich and poor countries, or between rich and poor people in the same country,[12] they suggest that there is nothing about a legal patent that precludes government regulation of licensing agreements with these worries in mind. For example, governments might require patent-holders to license the use and manufacture of human genes for medical purposes, (thereby implying that the right to exclude is not absolute),[13] prohibit their use for others, and limit how much they can charge for their use or manufacture by poor countries or poor people.[14] In these ways any morally objectionable consequences of human gene patents could be met, and even preempted, while acknowledging the legality of these patents. Yet this, too, would be impossible, were human gene patents the moral equivalent of slavery.

**Patenting v. Owning**

However, if we can put to rest the worry that human gene patents literally threaten our self-ownership, the moral significance of the legal distinction between patenting and owning is less conclusive than one might suppose. The right to exclude is, in itself, a very powerful property right, and the patent system typically implies that someone – if not the patent holder – is entitled to use, license or sell a patented invention.[15] Thus, the differences between patenting and owning are probably of much less significance to ethical controversy over gene patents than are the differences between absolute and non-absolute property rights, or between patent systems that allow compulsory licensing and those that forbid it.

For example, the difference between patenting and owning – conceptually, morally and politically - depends on the background assumptions about people's rights and powers that one uses to assess it. Hence, the right to exclude can be a very significant and controversial right, and may be sufficient to turn what, previously, would have been collective property into private property. Likewise, it might be sufficient to turn what had previously been unowned into the exclusive property of one person or corporation. So, if one assumed that human genes were unowned and unownable prior to patenting, one might rather be struck by the fact that patenting creates a right to prevent others from using or possessing a gene - as would private ownership - and less by the thought that it creates only one of the many rights in which private ownership consists. Hence, the ethical significance of the distinction between patenting and owning depends fundamentally on the background assumptions about people's rights and duties that we use to interpret it.

Moreover, some experts in patent law define patent rights so as to include the positive right to use associated with ownership. Thus, Gerrtrui Van Overwalle refers to a patent as a "legal title granting its holder the exclusive right to exploit" an invention. [16] This is understandable, because it is implicit in any patenting system that *someone*, if not the patent-holder, is usually entitled to exploit an invention for commercial purposes.[17] In fact, patents typically grant a limited monopoly to patent-holders in order to reward inventors for putting the details of their invention into the public domain. Even if the patent-holder does not own the patented invention, it is typically the case that someone else is entitled to do so; and is thus in a position to use, sell, profit from, and even give

away or destroy the patented invention. Consequently, patenting either presupposes that the necessary ownership rights are available already, or that they will be forthcoming, so that inventing will be profitable not simply for the inventor, but for other people as well.

In short, patents put quite significant powers in the hands of a patent-holder, and are designed to do so. Typically, they amount to a monopoly right to license, exploit and profit from an invention; less typically they simply grant a right to exclude others from using or profiting from it. Absent compulsory licensing schemes, and other limitations on the rights of patent-holders, then, patents can seriously constrain commercial and non-commercial uses of human genes. Indeed, the Nuffield Council on bioethics made its concerns in this area quite explicit, and highlighted the difficulty of "designing around" genes as a reason to suppose that compulsory licensing might be justified in the case of human gene patents, even if it were not in the case of other inventions.[18]

Human gene patents can threaten people's jobs and careers, as well as their health and wellbeing. They can bring research to a standstill and inhibit the development of medical tests and products.[19] Gene patents, therefore, raise concerns about the power that that they grant their holders over the lives, employment, hopes and prospects of large numbers of people. After all, the point about gene patents is that they promise to help us to understand and cure some particularly cruel and devastating diseases. Thus, it seems unlikely that ethical objections to human gene patents are going to be resolved by recognizing the differences between patenting and owning. Rather, what is most likely to matter are the constraints on patenting that governments feel entitled and able to make.

And here, it is the similarities, not the differences, between patenting and owning that are likely to prove decisive.

**Ethical Objections to Monopoly Powers and Rights**

Critics of human gene patents are often accused of being ungrateful, or of being unwilling to reward those who have advanced scientific and medical knowledge. Or they are thought to have overlooked the fact that patented inventions are not spontaneous natural occurrences, but require human effort and skill to produce. These seem to be standard responses to critics of gene patents.[20] However, it is not self-evident that people lack rights to use or to possess something, such as land or medicine, that they did not create, or that they cannot be harmed, or unjustly treated, if they are denied such rights by law. Indeed, the thought that this is a real possibility underpins objections to libertarian views about people's rights from a wide variety of philosophical perspectives.[21]

Perhaps one has no right to the creation of a gene that can be scientifically manipulated and commercially manufactured in ways that are useful and medically beneficial. However, it does not follow that one therefore lacks rights to those genes once they have been invented. Indeed, if patenting rights are assumed to be absolute (as they might be on libertarian views of rights), so that patent-holding can prevent the use or commercial development of inventions, however useful and desirable, there might be very strong moral objections to the idea that human genes are legally patentable.

Generally, one assumes, those who hold patents on human genes will try to avoid behaving in ways that generate negative publicity, and so will be careful about denying patents to people if this would prove embarrassing. The key point, however, is that if the rights created by a patent are understood to be monopoly rights, a patent holder might be legally entitled to behave in ways that would seem obnoxious or arbitrary to most people. Indeed, inventors might feel morally entitled to behave in such ways, whether or not they are legally entitled to do so. Thus, they may suppose that if they are legally entitled to keep an invention to themselves, rather than sharing it with others, they should have broad rights to do what they like with their invention, no matter what other people think. Likewise, they may reason, they should be legally entitled to refuse to license it, because they could have withheld their invention altogether. So, it is easy to see why inventors might resist compulsory licensing agreements, ceilings on licensing fees and efforts to exempt research from licensing requirements altogether.

Inventors have an interest in patenting not merely because it enables them to achieve publicity and glory from their inventions, as well as any commercial benefits, but because it protects them from the difficulties of trying to develop and profit from their ideas while keeping them secret.[22] We are accustomed to the idea that the public owes a debt of gratitude to inventors, which patenting reifies in the form of a temporary monopoly. But if debts of gratitude are not all one way, it is unclear that people must be ungrateful or mean-spirited in order to reject monopolies on patented genes; or, indeed, to assert that, like other property rights, it is unethical to treat patents as absolute. Such a response is reinforced when one considers that patents are often held by companies,

rather than by solitary inventors,[23] and that monopoly rights to exclude or exploit have no automatic relationship to gratitude. After all, discoveries get no patent protection however useful and beneficial they may be. So, while constraints on the monopoly created by patents will require justification, they need in no way imply ingratitude, an unwillingness to support inventions and inventors by other means, nor the belief that people are always entitled to share in the creative efforts of others.

**Patents and Human Dignity**

Ethical concerns with the patenting of genes, however, are not limited to worries that people may be unable to buy, lease or sell services that they ought to be able to buy, lease or sell. On the contrary: many people object to the patenting of genes because they deny that genes should be thought of as property at all. Some of these objections reflect explicitly religious premises and others appear to have an implicitly religious character, albeit with no definite theological content.[24] The belief that genes should never be treated as property certainly depends on a rather particular conception of moral value, and one that we might reasonably reject. Nonetheless, I will show, it need not be unreasonable, and need reflect no confusions about legal and scientific facts. In particular, it need not exaggerate the differences between humans and other animals, or the ethical significance of the human genome.

What might motivate objections to the commercialization of genes? Quite plausibly, it is the thought that human capacities for invention, and for reflective thought and action, cannot readily be separated from our genetic endowment. Those troubled by

the commercialization of human genes, for example, may believe that the reasons to condemn the ownership of one person by another tell against treating human genes as though they were cars, which are patentable, or as great pieces of art, which are not. They may be willing to say that some reasons for patenting genes are better than others. Nonetheless, they may think that all patents in human genes, and all efforts to turn human genes into property, confuse human beings and their potential with that of objects - however lovely, useful and valuable.

Such objections to patenting need not imply that all biotechnology research is immoral. Nor, importantly, need they depend on any confusion about scientific facts about genes. Those who believe that it is immoral to patent human genes may be well aware that the human genome is very like the genome of worms, not to mention that of animals with whom we identify more closely. Just because humans do not differ all that much from other animals, it does not follow that we should be indifferent to the moral significance of whatever differences that there are. Indeed, they might think, it would be as wrong to ignore the significance of these differences as to fixate on them at the cost of appreciating the moral significance of the similarities amongst living things.

An implication of this view might be that some patents on animal genes are immoral, just as some uses of animals are immoral. This, indeed, is Munzer's position: "…other things being equal", he concludes, "the arguments tend to justify genetically related property rights in bacteria more readily than in plants, in plants more readily than in animals, in animals more readily than in chimeras, and in chimeras more readily than

in humans".[25] But whether this type of objection to patenting human genes extends to other biotechnology patents – or, indeed, to other patents generally – it need no more exaggerate the genetic differences between humans and other animals than need objections to rape or justifications for marriage exaggerate those between one person and another.

Racist assumptions may underpin objections to rape or to marriage, but they need not.[26] Likewise, some arguments against patenting human genes may exaggerate the genetic and non-genetic differences between humans and other animals. But there is no compelling reason to suppose that this must be so.[27] Hence, one does not have to be a genetic fundamentalist in order to worry that human gene patents are immoral. Given the current state of our knowledge, one might simply suppose that our genetic endowment constitutes an important part of the reason why humans have the morally significant capacities that they have, including the capacity for conscious reflection on the moral significance of their genetic attributes.[28]

For people who think this way, and so suppose that there is something morally wrong with treating genes as property, their concerns about the way that people see and treat their genes may extend to the way that people treat their natural and social environment.[29] Some people tend to think that our genetic endowment is more closely connected to our sense of ourselves as moral agents than is our environment. Others do not. Rather, they think that our natural, political and social environment is at least as significant for our moral capacities, and our ability to recognize, develop, and exercise

these, as are our genes.[30] Consequently, their objections to patenting human genes may reflect their concerns about the destruction of some human habitats and ways of life, and to the ways that other human habitats and ways of life are fostered and insulated from criticism and change.

We can therefore object to patents on human genes without mistakenly supposing that commercial objects are incapable of having non-commercial meaning or value for people. Wedding rings, for instance, can be intimately bound up with our identities even though they are commercial objects, and their emotional value to us may not reflect their commercial value at all.[31] But this does not show that *genes* cannot be devalued by commercialization. The fact that wedding rings are expensive is, increasingly, a reason why they have the emotional value that they have. Even where this is not the case, rings have been commercial objects for so long that their commercial status does not generally constitute a threat to their emotional value. This is not so with genes which, until recently, were not commercial objects. Even now, they are rarely conceived of as industrial objects. So it is quite possible that genes can be devalued by being turned into property, even though we often value objects we buy and sell quite highly.

It would be a mistake, therefore, to suppose that objections to the commercialization of genes must imply an aristocratic distaste for commercial objects or society; or some particular animus against the modern world. Instead, those who object to the commercialization of genes may simply wish to draw the line between commercial and noncommercial values in one place rather than another, not because commerce itself

threatens human dignity, but because the commercialization of human *genes* would do so. Indeed Munzer claims that "it could offend human dignity to sell or license for cloning genes that relate to, say, the shape of one's face, key features of one's temperament, or salient aspects of one's intelligence", although he wants to leave open the possibility that some human gene patents might be ethically justified.[32]

Ossorio supposes that such are views absurd, because she can see no reason why we should be diminished "if one person can make, use, or sell copies of another's extracorporeal, non-particularized body parts". (p.414) However, the morality of copying human genes – with or without a patent - is likely to depend, in part, on what is done with those copies. Were genes used to make a new type of toy, for instance, or a new type of food, even Ossorio might feel less sanguine about the copying of human body parts.[33] It is true that people do not always pay much attention to the fate of their discarded body parts – be it hair, nails or organs. But that does not prevent them from being shocked or perturbed by the results of their carelessness.[34] Such reactions may be irrational. But before reaching such a conclusion, it seems desirable to investigate further how the commercialization of cloned genes might threaten respect for the human body, for human attributes, or for human feelings.

In short, I do not believe that one needs to draw untenable lines between nature and nurture, genes and environment, individual and society, or one species and another to believe that patenting human genes is immoral. Though one may have to make some controversial assumptions, or reach some controversial conclusions, if one believes that

human gene patents are intrinsically immoral, neither the assumptions, nor the conclusions need be unreasonable, even if they are not the only reasonable ones that one might make. So, while some ethical objections to the patenting of human genes collapse when confronted with legal facts, I do not see that they all must do so.

**The Justification for Patenting**

Indeed, it is not clear that objections to patenting, however interpreted, must be any less reasonable, or any more speculative, controversial, and sectarian than justifications for these particular patents, or for a patenting system in general. Once one considers that most justifications for patents on human genes depend heavily on the thought that patenting in general is justified, it becomes clear how speculative, controversial, and morally problematic are most arguments for these particular patents.[35]

The justification for a system of patent rights reflects a couple of rather different considerations. On the one hand, there is the thought that patents are a solution to the problem of motivating people to invest their time, energy, and money in the creation and development of socially useful knowledge and products. On the other, there is the thought that patents are a solution to the problem of rewarding people who successfully contribute to the public good, given that all of us have incentives to try to enjoy these benefits without acknowledging and rewarding those who made them. Neither reason by itself singles out patents, as opposed to other ways of rewarding and motivating people.[36] Taken together, however, patents appear to have attractive features that other ways of motivating and rewarding people lack. For example, patents ensure the publication of

useful knowledge, and not merely its creation. They establish rules that are relatively automatic, and capable of being fairly applied, to the problem of deciding what counts as knowledge deserving of recognition and reward. They tailor the size and costs of rewards to inventors based on the preferences, beliefs, and interests of people in the invention, and so on. In short, patents seem to combine concerns for efficiency, reciprocity, freedom, and equality in a rather attractive way.

But appearances are, to some extent, deceptive here, as in other matters. Like other private property rights, it is unclear that patent rights actually reward merit, and they certainly do not seem to reward effort, *per se*.[37] The relationship between benefit and reward, created by patent rights, may be very loose, as is the relationship to the common good or public interest.[38] Once we recognize this, it is hard to know how well patents motivate the creation or publication of knowledge that, otherwise, would not be produced, or publicized. And it is very hard to know how far the legal, economic, and political benefits conferred by patent rights tailor reward to merit, or proportion it to benefits conferred. In short, the justification for a system of patent rights rests largely on speculation about human motivations, needs and interests.

There is a further difficulty with patents, as compared to other ways of rewarding and motivating people, which moral objections to human gene patents highlight, even though they rarely raise them explicitly.[39] If patents look democratic when compared to the granting of titles of nobility, to inheritable personal powers to tax, and so on, they do not look especially democratic when contrasted with tax-breaks, election to public office,

or to public honors.[40] If, from a democratic perspective, patenting is attractive because it involves specifying public criteria for rights, and then providing a relatively automatic procedure through which people can determine whether they are entitled to those rights, it also has considerable disadvantages. For the public may have no idea about the significance of the inventions that provide the claim to a patent, or about the adequacy of the criteria used to distribute these rights.[41] This casts doubt on the idea that the benefits created by patentable inventions are sufficiently general or public to merit special reward. It also means that very significant changes in people's rights, expectations, and beliefs may occur without ever being publicly acknowledged, discussed or chosen. In a democracy, this should cause some concern.

Legislators can pay attention to the sorts of things are being patented and why.[42] Moreover, in any system that gives private individuals the power to alter their legal relationship to each other, as will bodies of private law, many changes in people's rights, powers and expectations, for good and bad, are likely to occur without public knowledge, representation, and control. Still, the moral objections to patenting point to the need to think more carefully about the place, content, and justification of a patenting system in a democratic society, and in particular, its implications for democratic forms of accountability, choice and participation. For some of the bitterness, mutual distrust, and incomprehension, evidenced by debates on genetic patenting, reflects the lack of open public debate on the issue, and the assumption that ordinary people have little knowledge about, or control over legal rights, public policies, and scientific developments that may fundamentally affect their lives.[43]

Thus, proponents of patenting suppose that the general public is unlikely to know even quite basic and straightforward facts about patent rights, such as their justification, the sorts of things to which they apply, the way that they differ from other rights. Likewise, critics of patenting, especially in the U.S., clearly suppose that most people do not know that plants, animals and human genes can all be patented. This contrasts with the situation in Europe where efforts by groups like the Greens and Greenpeace to publicize these issues mean that people have been subjected to questionnaires, as well as a great deal of publicity about recent developments in the law and biotechnology. Yet it is evident that in the U.S, too, there is a public interest in, and demand to know more about, recent advances in biotechnology and their legal, scientific, moral, and political implications for people's lives. Thus, one can find articles about genetic testing, and its moral and medical implications in local, as well as national, newspapers; public interest in, and public sources of information on, the science of the genome project, as well as more sensational developments like the cloning of sheep. By contrast, it is rare to find discussions of the ethics or the economics of patenting human genes outside of relatively specialized and obscure journals and book presses.

Of course, given what one might consider to be the disastrous consequences of the politicization of abortion in the U.S., it would be foolish to assume that democratic discussion of patents on human genes – whatever one thinks that might mean or involve – would preclude confusion, mutual suspicion or promote the speedy and principled resolution of complex questions of ethics and public policy. But it would, at least, give

people the chance to learn about, and to participate in, decisions that can fundamentally shape their life-prospects and those of future generations, even if it failed to promote other desirable things.

If, as seems likely, the patenting system has made such discussion and decision-making significantly less likely, despite considerable public interest in biotechnology and its consequences, there is reason to incorporate concerns for democratic participation and accountability into one's evaluation of human gene patents. This is partly because concerns about the justification for patents in general can, quite properly, affect our judgment about the merits of any particular patent. More fundamentally, though, it is likely that ethical objections to patenting human genes reflect doubts about the democratic credentials of the motivations, procedures, and criteria that have led to this development.

**Conclusion**

Ethical disputes about human gene patents are not over the meanings of words alone, but over the justification of public policies and legally binding rights, powers and obligations. They require us to consider not only the justification of past practices and institutions, and of present actions and decisions, but of the terms on which, in future, people will have access to the knowledge, powers, and liberties that they need to live and to flourish. What those terms will be is still largely open to influence, from a variety of quarters, but probably not for long. As we have seen, remarkably little is settled legally, morally, and politically, by treating human genes as legally patentable. However, what is

possible conceptually can become practically unthinkable. This essay highlights the costs of such a transformation for moral and political judgment.

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[1] For a useful discussion of the patent system, including the differences between US and European patent law, (The Nuffield Council on Bioethics, 2002 ch. 2) available from their website: http://www.nuffieldbioethics.org.

[2] For the main critical positions, see (Annas 1998 pp. 21 – 2) ; (Rifkin 1998 ch. 2) ; and the views of (Meister, Mertens, Emmot and Alexander 1997 pp. 185-201). The volume is based on the proceedings of the International Workshop on "Biotechnology, Patents and Morality: Towards a Consensus", held in January 1996, by the Department of Philosophy and Moral Science and the Centre for Environmental Philosophy and Bio-Ethics of the University of Ghent. It consists in a series of relatively short presentations, by legal experts, representatives of various environmental groups, and so on, and also provides a helpful introduction and concluding summary of the proceedings and debate.

[3] (Ossorio, 2002 pp. 408-419). Ossorio was the director for the genetics section of the American Medical Association's Institute for Ethics when she wrote this article.

[4] It is hard to find a published source for this belief, but it occurs frequently enough in oral arguments about patenting to merit attention by (Crespi, 1997, pp. 219-223). See, in particular, Crespi p. 225; also Ossorio, p. 411. However, Jeremy Rifkin claims that "genetically altered human embryos and fetuses as well as human genes, cell lines, tissues, and organs are potentially patentable, leaving open the possibility of patenting all of the separate parts, if not the whole, of a human being. (Rifkin, 1998, pp. 44 – 45).

[5] See (Schatz, 1997 pp. 159 – 160), and, more generally, pp. 160 – 166. Shatz is the Former Principal Director, International Affairs, of the EPO in Munich. Just to prove Shatz's point, the onco-mouse was originally refused a patent by the EPO, but this was reversed in 1992. "In the overall balance the Examining Division concludes that the present invention cannot be considered immoral", the EPO maintained. Quoted p.447 (Munzer 2002 p. 447). Munzer makes plain his disagreement with the EPO's conclusion at p. 452.

[6] Ossorio, p.412

[7] Ossorio, p. 412

[8] *Diamond v. Chakrabarty*, 447 U.S. (1980) For a more sceptical view of this decision see (Sagoff, 2002 pp. 420-437) , especially pp. 434-6.

[9] *Parke-Davis and Co. v. H.K. Mulford and C*o., 189 F. 95 (SDNY 1911), affd 196 F. 496 (Second Cir. 1912). P.102. Quoted In Ossorio, p. 413.

[10] Ossorio, p. 411

[11] Ossorio, p. 409. See also ( Heller and Eisenberg 1998, 5364). Available on the web at www.Sciencemag.org. Theirs is a response to an article by (Doll,1998), also available on the web. Doll maintains that "A strong U.S. patent system is critical for the continued development and dissemination to the public of information on DNA sequence elements", and that "It is only with the patenting of DNA technology that some companies, particularly small ones, can raise sufficient venture capital to bring beneficial products to the marketplace or fund further research".

[12] For such concerns see ( Krishna R. Dronamraju, 1998) especially chs. 13 and 15; and "The Consequences of Modern Genetic Engineering: Patents, 'Nomads' and the 'Bio-Industrial Complex" by (McNally and Wheale 1998), ch. 18. For a skeptical view, see Crespi, supra, pp. 229 – 235.

[13] However, as Seth Shulman notes, "Compulsory licensing is anathema to many participants in the U.S. patent system". See (Shulman, 1995, p. 7) available on the web at www.usis.usemb.se/sft

[14] See Ossorio, p. 418. The Nuffield Council's discussion paper notes that "in the case of patents that have been granted for diagnostic tests based on genes, compulsory licensing may be required to ensure reasonable licensing terms are available to enable alternative tests to be developed". See the Executive Summary, p. xi; and ch. 5, sections 5.25 – 5.29, pp. 54-56.

[15] As Ossorio says, "…patents are intended to encourage not just the pursuit of knowledge, but the practical application of that knowledge in marketable form". (416)

[16] (Van Overwalle, 1997 pp. 139-148). The quotation comes from p.139.

[17] Hence the significance of the denial of any positive rights by the EPO in the case of the onco-mouse. See Munzer, p. 447, who notes that the EPO stressed that all it was granting was the right to exclude others, rather than a "positive right to use the invention".

[18] Nuffield Council on Bioethics**,** discussion paper, ch. 5.12 – 5.13, p.50.

[19] The Nuffield Council discussion paper notes that "one study in the US indicates that research on genetic testing has been inhibited by patents on DNA sequences: almost half of the research laboratories which were surveyed have ceased to pursue such research because of existing patents. Another US study found that as many as 30% of laboratories have discontinued or not developed genetic testing for haemochromatosis because of exclusive licensing of patents…" 5.15, pp. 50-51. Dutfield and Suthersanen report David Porteous' complaint that patent-related legal problems have affected the ability of scientists in Scotland to conduct gene-based diagnostic tests for breast cancer, "despite the fact that geneticists do not even need to read Myriad's patent specifications since all the knowledge required to conduct the test is already in the public domain". (p.15) David Porteous is head of Medical Genetics at Edinburgh University. (Dutfield and Suthersanen, (2005, pp. 5 – 29). The article discusses the worry that companies are increasingly turning to copyright and trade secrets as ways to protect their investments, *in addition* to using patents.

[20] For example, Ossorio notes that critics of patenting "…must engage the question of why people who actually generate…knowledge do not deserve some compensation for their efforts and contribution; [and

why] having a common interest in the genome does not necessarily mean that we can appropriate the fruit of other people's labor"p. 418.

[21] For a helpful discussion see (Kymlicka 1990) , especially ch. 4.

[22] For the difficulties involved and, therefore, the significance of patent rights as opposed to trade secrets, see Munzer, p. 439. Importantly, patents are "usually a more robust set of property rights than a trade secret, for the patentee can exclude others from making or selling the patent invention or discovery, even if these others arrived at the invention or discovery independently". In the US, apparently, there is no federal provision for protecting trade secrets, so this is a matter for state law. See also Dutfield and Suthersanen, pp.16-19

[23] In fact, Dutfield and Suthersanen remark that patents have become "a form of currency in inter-firm transactions", and quote Fowler's observation that "For many companies, the patent becomes the product", with the result that research decisions in many companies now depend on the advice of patent lawyers at least as much, and possibly more than, the opinions of scientists. Dutfield and Suthersanen, p.13. The reference to Fowler is to (Fowler, 1994, p.173).

[24] (M. A. Warren, 2002 pp. 147 – 157), especially p. 152.

[25] Munzer, p. 452. He concludes: "There should be a limited public-interest exception to patent suppression. Very few expressed sequence tags should be patentable; for most ESTs a weaker form of intellectual property rights is in order. Some genetically engineered bacteria and plants should be patentable…The suffering of genetically engineered mice should case doubt on their patentability under the European Patent Convention…". Munzer, then, does not suppose that all human gene patents are unjustified; but it is clear that, even so, he supposes that there are a variety of ethical distinctions that need to be made. There is no reason to suppose that these are any more difficult to make if one believes that human gene patents are never justified than if one allows that some are.

[26] See *Loving v. Virginia*, 388 U. S. 1 (1967), in which the Supreme Court finally struck down antimiscegenation laws in the United States.

[27] ( T. Wilkie, 1998 p. 12)

[28] Apparently, "even the 'gene' is beginning to look like a rather fuzzy concept" as a result of recent advances in molecular biology, according to Dutfield and Suthersanen, p.11. "The sheer complexity, subtlety and context-dependence of DNA ….cast[s] a sceptical light on the view that genes should be treated as a text in four letters containing instructional information". Instead, genetic messages, apparently, seem more like poetry, in their complexity and ambiguity than like instruction manuals. (p.10). Dutfield and Suthersanen even quoted a Swedish scientists who apparently said that "we tend not to talk about 'genes' anymore; we just refer to any segment that is transcribed [to RNA] as a 'transcriptional unit'", (11). This suggests that references to "genes" might better be replaced with "genetic materials", in order to catch the increasing ambiguity of the concept.

[29]Mertens, p. 190 in ed. Sterckx implies that this is, indeed, the case for the Greens; and Meister implies that it is also true for Greenpeace. See ed. Sterckx, p. 185. Hence I do not see the clear differences that Ossorio appears to see amongst Ownership, Human Dignity and Commodification objections to human gene patenting, even though it can be helpful to distinguish amongst them.

[30] See, for example, (Dworkin 2002), especially ch. 6. on "Equality and the Good Life". Consequently, I think Mary Anne Warren overstates the objections to what she calls "the Sanctification of Genes" at pp. 153-5.

[31] The example comes from Ossorio, p. 415.

[32] Munzer, pp. 49 – 50

[33] Munzer pp. 49-50. In fact, Ventria Bioscience, a US company, is conducting field trials of rice that has been given human genes to make it produce beneficial human proteins, including lactoferrin, which is found in breast milk. The hope is that these antibacterial proteins might help to treat children with diarrhoea, which is a major killer in the developing world. But imagine that the point was simply to make food prettier, or cheaper to grow, rather than to produce medicine as cheaply and safely as possible. See (Adam, 2007 pp. 6-9, section G2).

[34] For an example of the problem, see *Moore v. Regents of the University of California* (793 P.2d 479 9cal.1990), concerning the fate of John Moore's spleen.

[35] See Ossorio, p. 409 "An underlying assumption of the patent system is that other, non-market incentives will not lead to as good or as much development of new and useful knowledge and products" and "The

assumption is that without patents the biotechnology industry could not compete effectively for private capital against other industries, such as the computer industry". (409) Neither of these assumptions, of course, is self-evidently correct. Moreover, as Ossorio notes, while "patent law can be described as serving a positivist, functionalist strategy: we choose the rule governing patentability to accomplish the goal of getting new and useful knowledge disseminated, and the rules are justified according to whether or not they accomplish this goal..", her conclusion is that "In practice, this is an empirical determination which is quite difficult to make with any confidence". (408)

[36] Hence, David Resnik is wrong to suppose that a purely utilitarian justification of patents is possible, even if we suppose that such a utilitarian justification would operate against a background of moral and legal rights precluding such things as theft and forced labour. See (Resnik, 1997 p. 4) online version.

[37] Concerning effort, see Ossorio, p.408, and Resnik p. 4: "the law seems to reward results, not contributions and efforts".

[38] See Ossorio, p. 409. concerning what may be a substantial difference between the socially optimal rate of invention and the maximal rate of invention.

[39] Some exceptions are (Mertens, 1997 pp. 189 – 90) , (Van Overwalle, 1997 p. 147) , and (Emmott, 1997 pp. 192 and 194).

[40] Grants are, here, understood as an alternative to patents, not as an addition to them. Hence, they do not raise the concerns about "doubledipping" usefully described by Ossorio, at p. 409.

[41] (Shulman, 1995). At p. 2 Shulman notes of the USPTO that "despite its size, age and pedigree, the agency must surely rank as one of the least-known agencies of the U.S. government", he also expresses widespread doubts about the ability of the USPTO to interpret its criteria for awarding patents, and gives the example of the patenting of Kirchoff's law, first expounded in 1845.

[42] Resnik notes, at p. 1, that "In 1996 the US Congress considered a measure, the Ganske-Wyden Bill 9Hr1137) that would have prevented the PTO from awarding patents that do not involve a new machine or compound". This, so it seems, would have met some of the concerns about patents raised by (Gleick, 2000 pp. 44-49) . However, this would have no obvious effect on the "capture" of the PTO by companies pursuing patents, on whom the Office frequently depends both for expertise and for revenues. Gleick notes at p. 41, "In 1991, the patent office was cut off from general tax revenues and required to subsist entirely on

fees from its operating budget. The political argument was that customers should pay for government services. Thus, officials think of their fee-paying applicants as their customers: *the more the better*". (Emphasis in the text). Gleick says, "It is virtually forgotten that government's customers also include the rest of the nation, the citizenry at large, whose fortunes depend on the agency's judgments and policies". [43] (Martens 1997 p p. 198 – 90).

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