

Ethics and the Patenting of 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 Office has issued thousands of patents on such genes and it is generally believed that their legality is well-established, although no court has yet ruled on the matter directly. The legality of such patents under the European Patent Convention [EPC] has yet to be determined. However, legal experts believe that there would be no legal objection to treating human genes as patentable inventions under the EPC either.

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. Thus, it is not surprising that the emerging legal consensus on human gene patents has not significantly allayed doubts about their morality.[1] If anything, it is surprising to learn that there are those who believe that attention to the legal justification for human gene patents could remove the most serious moral objections to them. Yet that, precisely, is Pilar Ossorio's claim, and she is not alone in making it.[2] Like Ossorio, those who are well-versed in patent law often believe that confusion over some quite basic legal and scientific facts can account for the belief that human gene patents are immoral and, in particular, for the belief that they justify the ownership of one person by another.[3] Once these confusions are removed, they contend, we will see that there is nothing especially alarming about these patents, and no reason to believe that they are immoral. [4]

Legal Facts about Human Gene Patents

The idea that patents on human genes is immoral, because indistinguishable from the claim to own other people, rests on two confusions about patent law, according to Ossorio. The first is confusion over what is patented by a human gene patent; the second, there is confusion over what a patent enables one legally to do. Because patents on human genes do not, and legally cannot, apply to genes as they naturally occur in our bodies, Ossorio maintains that human gene patents constitute no threat to the bodily integrity of individuals, or to their use of their own genes in living and reproducing. Because patent rights are different from ownership rights, and do not

confer ownership on anything, she believes that patenting must be distinguished from owning, whether we are talking about patents on bicycles or on human genes.

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.[5] 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 objects that occur naturally, unless these have been sufficiently altered by human effort as to count as “made by man” for legal purposes. Thus, human genes can only pass the threshold test that 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. Or so the U.S. Patent Office has held, when granting patents on human genes. As Ossorio describes it, this is hardly surprising for human genes that are patentable to have scientific and commercial properties that distinguish them from naturally occurring genes. For example, Ossorio explains that 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 (apparently doing this is called “cloning” DNA), chemically unwinding DNA, and constructing radioactive or florescent copies of the genomic DNA fragment.[6] She explains that “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. Cloning or synthesizing DNA according to information in a patent generally results in DNA that resides in a very different biochemical environment than that of a human cell.”[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., 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.”[9] 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.

As Ossorio believes, these considerations should allay at least some significant doubts about the morality of patenting human genes. Perhaps patentable genes do not differ as greatly from naturally-occurring human genes as do oil-eating bacteria from naturally occurring bacteria – though this is not self-evident. However, it is clear that, legally,

patents on human genes are on genes that are scientifically and legally distinguishable from the genes in our bodies, or from natural genes taken out of our bodies.

Moreover, Ossorio argues, 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.[10] Thus, they fail to see that whatever the complexity involved in legal ownership, a patent 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.[11] Because a patent does not confer the rights to use or possess, Ossorio maintains that patenting is quite distinct from owning. Hence, she concludes, a patent on a human gene does not confer ownership of that gene, let alone ownership of all genes made according to the patent.[12] A human gene patent, then, 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 that are typically associated with ownership.

So, Ossorio is right to claim that attention to the legal facts about human gene patents removes the most serious doubts about their moral justification. We may, with Ossorio, be skeptical that these patents are necessary to promote research and investment in biotechnology, or in the prevention and cure of human suffering.[13] 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,[14] 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 patentholders to license the use and manufacture of human genes for some purposes (thereby implying that the right to exclude is not absolute),[15] prohibit their use for others, and limit how much they can charge for their use or manufacture by poor countries or poor people.[16] 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.

Why Moral Concerns Remain

However, if reflection on Ossorio's claims indeed suggests that there is nothing inherently wrong with these patents, the moral significance of the legal facts she cites is

less conclusive than she thinks. Perhaps some confusion about what is patented by a human gene patent, or over the rights conferred by a patent, motivate the thought that these patents are intrinsically objectionable. Nonetheless, patents on human genes pose a greater threat to human freedom, equality and dignity than she acknowledges.[17] Indeed, I will argue that although ownership objections to human gene patents are not very helpful analytically, they need involve no confusion about relevant legal or scientific matters. On the contrary, they may simply reflect doubts about the moral justification of quite ordinary legal rights, and point to the conclusion that considerable moral, as well as legal, reflection may be necessary to resolve ethical controversy over gene patenting.[18]

For instance, take the claim that patenting is different from owning, because the patenting simply consists in the right to exclude, whereas the owning presupposes positive rights to use and possess.[19] How significant this difference is conceptually, morally and politically depends on the background assumptions about people's rights and powers that one uses to assess it. 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.

If, therefore, one supposes that, prior to patenting, human genes are collective property, one might be struck by the similarities between patent rights and other forms of private property, rather than by the differences between the right to exclude and the rights of exclusive use and possession that are distinctive of private ownership. Ossorio considers this possibility when assessing "common heritage" objections to patenting human genes.[20] She concludes that if one interprets people's rights to imply that the genome belongs equally to all, and that all should therefore have equal access to the derived knowledge or beneficial uses of research on the genome, then "it would be unjust to grant patents on the human genome." However, those who object to human gene patents on the grounds that they unjustifiably give one person property rights over may also believe that human genes are collective property, although people should have exclusive rights over the genes in their own bodies. Hence, Ossorio is wrong to suppose that ownership objections to patenting can be dismissed more easily than those based on the idea that genes are part of the common heritage of humankind. Similarly, if one assumed that human genes were unowned and unownable prior to patenting, one might be struck more 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 might consist.

Nor would such objections to patenting collapse in face of the thought that patentable genes are not spontaneous natural occurrences but the product of human effort and skill. After all, 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 (although these may not be rights of exclusive use and possession), 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.

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 patentholding 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.

These objections might be couched in the language of property rights and ownership, to highlight the idea that rights to use, possess, and exploit human genes are being wrongly denied to people, though these may no less merit the description "property rights" than the right to patent itself. But one need not couch the objection this way, even if one's objections to patenting human genes are based on concerns about private ownership.

For example, if one is worried about the consequences of patents for disparities in medical care, or in political and economic power between countries and individuals,[21] one might object to patents on human genes not because they prevent people from owning something that they ought to be able to own, or from buying, selling, or leasing services that they ought to be able to buy, sell or lease, but because one thinks that this is the wrong way to describe and think about people's rights to genes.[22] One might be perfectly open to the idea that people should pay for medical services in some form, and that reciprocity requires acknowledging and rewarding or compensating the efforts and skills of those who have benefited us. One would merely doubt that such recompense should take the form of exclusive rights to human genes, let alone absolute rights to prevent others from using or possessing them, even if only for a finite period of time.[23]

It is likely that people, who object morally to patents on human genes for reasons I have described, will find patents on other things objectionable too. Thus, they might suppose that medical or therapeutic inventions ought not to be patentable and that, therefore, there must be some other way to reward people who create and invest in medical research and technology. As I understand the matter, this is precisely the interpretation of patent law reflected in the European Patent Convention. Under that convention, medical and therapeutic devices and techniques are not patentable.[24] In this the EPC differs from U.S. law, where the patent right to exclude is thought to be consistent with the rights of researchers to use a patented invention for non-commercial purposes, and some use of a patented invention for personal, non-commercial enjoyment and entertainment by the general public.

If this distinction between U.S. and European law is as I've described it, this may, perhaps, reflect differences in the way that medical care and training are organized and funded in the U.S., as opposed to Europe. But I have some doubts on this score. If this were the case one would expect to see public and private doctors, hospitals, and

medical facilities treated differently for the purposes of patent law in the U.S. – and to see these differences reflected in public debate on the ethics of patenting human genes. But one does not. Instead, the U.S. supposes that scientific research, though not medical treatment, constitutes grounds for an exception to the rights created by a patent – quite possibly with the result that people will have access to drugs as part of an experiment that they will be unable to afford as part of their regular care.

Thus far I've focused on concerns about the implications of gene patents for medicine. But the objections to patenting human genes that I've described have broader implications that need to be examined. Indeed, they seem either to imply that there are no other purposes – or, at any rate, no legitimate purposes – that human gene patents could serve, or that human genes are special in some way that makes the very idea of patenting them shocking.

It is not clear how sharply one can distinguish these two lines of thought, or how far they support the view that what is bad about patenting is that it gives one person unjustified forms of power and control over another, as ownership objections to patenting imply. Still, I think these two lines of thought can be distinguished and that, in some circumstances, the differences between them may prove theoretically and practically important. For the first view implies that there might, conceivably, be some legitimate uses of human genes that would justify patenting them, something which the latter view denies. If both would likely object to patenting if the non-medical uses of human genes were, say, to produce new forms of food, or new toys, they might nonetheless differ in their approach to these patents as the source of genetic tests for non-medical purposes.

Even in the absence of a cure, or a treatment, people may want to take a test that tells them whether they have, or are likely to have, a serious disease. Indeed, they might simply want to take such a test because they are curious about their genetic makeup.[25] While the former objection to patenting would reject patents on medical resources, because they give some people unacceptable forms of power and control over others - given the importance of life and health to all people - they may find the promotion of a wide array of safe, relatively cheap and accessible genetic tests, in the long term, an adequate justification for some patents on human genes in the short-term. They might be moved by the thought that some people could benefit from genetic testing, even if it serves no special medical purpose, and that patents on human genes for these reasons would be ethical.

People troubled by the patenting of genes for medical purposes will, very likely, want to ensure that genetic testing not be mandatory, and that it not threaten people's jobs, healthcare, civil and political rights and so on.[26] They may also want to ensure, perhaps, that counseling is available for those who use the tests. But these problems with genetic testing will likely arise, and need to be dealt with, whether or not genes are patented. Patenting will likely exacerbate these problems, by creating more tests, and more opportunities for genetic testing, than there otherwise would be. However, excluding people who cannot afford such testing from satisfying their curiosity, or from more accurate estimates of their likely life-course, implies significantly less control over

people's lives, and over basic resources, than does the ability to deny people needed medical care, or to make this unaffordable. Hence one might well find the one acceptable, although believing the other immoral.

So, it may be possible for some people who object to the patenting of human genes to distinguish amongst the uses to which a patentable gene might be put theoretically, and in practice. Thus one could allow - as, it seems, the EPC will allow - for a person to have a patent on a human gene, but deny them the right to prevent people from using the gene for purposes a, b, and c; perhaps require them to use it for purposes d, e, and f; and give them considerable leeway thereafter. Notice, however, that one could still say that patents on particular human genes are immoral, and that patents on human genes for certain purposes are always immoral, while granting that other gene patents might be morally justified. However, on this interpretation of objections to patenting, the difference between patenting and owning, stressed by Ossorio, would be relatively insignificant. Instead, what is critical for this first version of the ownership objection is whether or not the patent rights should be treated as absolute, for moral and legal purposes.

By contrast, those who think that human genes should never be patented may be moved by two rather different concerns with slavery. The first would be the concern about the illegitimate power and control of one person by another made possible by the right to exclude people from some important or necessary human good. The second would be the concern with the attitude toward people's needs, aspirations, and capacities implicit in the right to own slaves. Someone concerned as much with the attitude toward people implied by slavery, as with the power and control it brings, and the misuse of people that it licenses, may simply believe that no one can have exclusive rights over human genes and that there is something morally objectionable in thinking of them as property at all. [27]

What might motivate such objections? One possibility is that they may believe that our genetic endowment cannot be separated from our capacities for invention and, more generally, from reflective thought and action. They may, therefore, believe that the reasons to reject slavery, based on the attitude to human capacities that it involves, 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, and that some of the potential consequences of patenting raise concerns about slavery more acutely than do 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.

Clearly, if considerations of this sort underpin "ownership" objections to patenting human genes, they do so in ways that are more radical and for reasons that are even more controversial than the reasons I have described. But just because they are controversial, and because their rejection of patents is so radical, it does not follow that they are confused about what is patented by a human gene patent, over the rights

conferred by a patent, or about what is and is not immoral. Such objections to patenting need not imply that all biotechnology research is immoral, or that debts of gratitude and justice are not owed to those who benefit humankind through their efforts and ingenuity. Nor, importantly, need they depend on any confusion about scientific facts about genes.

For example, those who believe that there is something about human genes that makes patenting them immoral may be well aware of the fact that the human genome is very like the genome of worms, not to mention that of animals with whom we may identify more closely.[28] 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 genetic or other 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 and condemned by reflection on the evils of slavery and its indifference to human suffering, human hopes and human capacities. 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 and justifications for marriage, but they need not. 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 the case, anymore than it is inevitable that ethical objections to patenting human genes should be racist just because they could, conceivably, be.[29] Hence, I am unpersuaded by Tom Wilkie's claim that gene patenting poses no necessary threat to the privacy of individuals because individuals' genes are so similar. Our diaries, as well as our genes, may be very similar to those of other people, yet our privacy, as well as our property rights, can be violated when someone sells or publishes our diary without our consent. So, while Wilkie may be right that the risks to privacy from gene patenting are contingent and avoidable, rather than inherent and unavoidable, it cannot be for the reasons that he gives.

If one accepts these points, it looks as though one can also dismiss the charge that those who believe patenting to be immoral must, therefore, be genetic fundamentalists, or identify being human with having some particular set of genes, in ways that are unreasonable or, even, unethical. 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. [30]

For people who think this way, and so suppose that there is something morally wrong with treating genes as property – whether they couch their concerns in the language of ownership, or on analogy to slavery – 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.[31] While some people tend to think that our genetic endowment is more closely connected to our sense of ourselves as moral agents than it is our environment, others do not. Rather, they think that our natural 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. 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.

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. Although one may have to make some controversial assumptions, or to reach some controversial conclusions if one believes that it is always wrong to patent human genes, neither the assumptions, nor the conclusions need be unreasonable, even if they are not the only reasonable ones that one might make. So, while it is possible that some ownership objections to the patenting of human genes may collapse when confronted with the legal facts to which Ossorio draws our attention, 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 given 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 most arguments are for these particular patents.[32] For that reason, I will suggest, it is erroneous to suppose that the burden of proof lies with those who would reject these patents as immoral, rather than with those who ask us to accept them, albeit provisionally, on the assumption that these patents are morally justified in and of themselves, or that they are a morally acceptable consequence of a practice (patenting) that is, itself, morally justified. Instead, the burden of proof rests equally on those who would deny, and those who would affirm the morality of patenting human genes.

As Ossorio explains, the justification for a system of patent rights reflects a couple of rather different considerations.[33] 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.[34] Taken together, however, patents appear to

have attractive features that other ways of motivating and rewarding people will probably 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.^[35] 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.^[36] Moreover, such rewards as patents generate, and such success as they are likely to have in motivating people, depends on us assuming what Ossorio ignores when distinguishing patenting and owning: namely, that patent rights typically enable their holder to benefit financially from a patent. Hence, they either presuppose the existence of rights to use and possess the invention (if not by the patent-holder, by other people), or motivate the creation of such rights. In short, while it may well be true that one can have a patent on a bicycle without owning any bicycles,^[37] it is typically the case that someone, if not the bicycle inventor, can legally own a bicycle. 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, as Ossorio concedes, the justification for a system of patent rights rests largely on speculation about human motivations, needs and interests.

Finally, 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.^[38] 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.^[39] 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.^[40] 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.^[41] And as Ossorio rightly stresses, patenting does not preclude considerable legislative

oversight and regulation of inventions. 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 – not just efficiency. For some of the bitterness, mutual distrust, and incomprehension, evidenced by debates on genetic patenting, reflect 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.[42]

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 democracy 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 that a patenting system creates. 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 event.

Conclusion

I conclude that Ossorio is right to believe that attention to legal facts and theory can illuminate the ethics of patenting human genes. However, she is wrong to assume that legal facts and theory are as morally conclusive as she thinks, when neither need reflect our considered judgments about morality. Moreover, I have argued that the rights that ownership consists in are hardly self-evident conceptually, morally, or legally. As Ossorio says, this tells against ownership objections to the patenting of human genes, and in favor of the effort to specify, as precisely as possible, what rights, values, powers, and liberties make the patenting of human genes unethical. But, I have argued, this objection tells as much against moral justifications of patenting that turn on sharp distinctions between patenting and owning, as it does against those who elide the two when opposing such patents. If patenting genes is ethical, therefore, we need to know what rights, values, powers and liberties justify these particular patents, or those legal, scientific, economic, and political practices that have made the patenting of human genes seem natural, justified, and inevitable. We do not yet have the answers to such questions.

Finally, I conclude that our conception of, and commitment to, democracy has a place in resolving ethical debate about human gene patents though, so far, this has been largely ignored. The point is not just that our conceptions of, and faith in, democratic forms of choice, deliberation, and accountability likely influence our perspectives on ethical questions, and so need to be factored into these explicitly. Rather, as long as one wants legally binding resolutions of ethical disputes to be made democratically, it is necessary, and urgent, to decide what this would imply for the procedures through which, and the evidence upon which, ethical disputes about human gene patents are to be settled. Those disputes, I have shown, 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. One of the merits of Ossorio's article is to highlight this fact, by stressing how little is settled, legally, morally, and politically, by treating human genes as legally patentable. However, the difficulties with her distinction between patenting and owning indicate how easily what is possible conceptually becomes practically unthinkable, and what that transformation may cost us in moral and political judgment.

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[1] For the main critical positions, see George J. Annas, "Life Forms, the Law and Profits", The Hastings Center Report, (Oct. 1998), pp. 21 – 2; Jeremy Rifkin, The Biotech Century: Harnessing the Gene and Remaking the World, (Putnam Books, New York, 1998) ch. 2; and the views of Isabell Meister, Jan Mertens, Steve Emmot and Daniel Alexander in Sigrid Sterckx, ed. Biotechnology, Patents and Morality, (Ashgate Publishing Ltd., Aldershot, England). The Sterckx 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.

[2] Pilar Ossorio, "Legal and Ethical Issues in Patenting Human DNA", forthcoming in A Companion to Genethics: Philosophy and the Genetic Revolution, eds. Justine Burley and John Harris, (Blackwell's, Oxford, Jan 2002). (ISBN 0631206981). Page numbers to Ossorio's article are to the unpublished manuscript. Ossorio is the Director for the genetics section of the American Medical Association's Institute for Ethics.

[3] 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, at p. 225, and for Ossorio to try to dismiss it as a red herring, at p.6. 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, *supra*, pp. 44 – 45.

[4] Such claims seem especially surprising because the morality of an invention is, generally, supposed to have little role in decisions about whether or not the invention deserves a patent under US law. Though, 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 320,000 patents have been granted by the EPO since its creation 18 years ago, this clause has never been used successfully to strike down a claim for a patent. Indeed, Ulrich Satz 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. See Schatz, pp. 159 – 160, and his interpretation of ART. 53 (a), at pp. 160 – 166.

[5] See Ossorio, pp. 6 – 9; and Schatz, p. 169

[6] Ossorio, p. 7. She notes, (footnote 1, p. 18) that molecular cloning should not be confused with the kind of cloning that produces genetically near-identical animals.

[7] Ossorio, p. 7

[8] Diamond v. Chakrabarty, 447 U.S. 303 (1980)

[9] Parke-Davis and Co. v. H.K. Mulford and Co., 189 F. 95, 102 (SDNY 1911), affd. 196 F. 496 (Second Cir. 1912). Quoted In Ossorio, p. 8

[10] Ossorio, pp. 5 - 6

[11] Hence, at p. 5, Ossorio states that "patents do not grant rights of use or possession, only rights to exclude". However, because people typically have rights to use, possess and exploit patentable inventions, it is common even for legal experts to define patents, as does Gerrtrui Van Overalle, as a "legal title granting its holder the exclusive right to exploit". See p. 139 ed. Stercx.

[12] Ossorio, p. 10: "a person who held a human gene patent, and obtained the further right to make, use or sell DNA constructed according to that patent, would be trafficking in copies or representations of the DNA inside of another person's body".

[13] Ossorio, p. 4. See also, Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" in Science, 280, (5364), 1998. Available on the web at www.Sciencemag.org. There is a response to an article by John J. Doll, "The Patenting of DNA", in the same issue of Science, 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". These debates have their counterpart in disputes about the necessity or, indeed, the desirability, of patents in computer science and business. See, for instance, "Patently Absurd" by James Gleick, in the New York Times Magazine, Sun. March 12, 2000, Section 6, pp. 44 – 49.

[14] For such concerns see Krishna R. Dronamraju, Biological and Social Issues in Biotechnology Sharing, (Ashgate Publishing Ltd. Aldershot, 1998), chs. 13 and 15; and "The Consequences of Modern Genetic Engineering: Patents, 'Nomads' and the 'Bio-Industrial Complex'" by Ruth McNally and Peter Wheale in The Social Management of Genetic Engineering, ed. Wheale, von Schomberg and Glasner, (Ashgate, Aldershot, 1998), ch. 18. For a skeptical view, see Crespi, in ed. Sterckx, pp. 229 – 235.

[15] However, as Seth Shulman notes, p.7, "Compulsory licensing is anathema to many participants in the U.S. patent system". See Seth Shulman, "Patent Medicine", a special feature of Technology Review, 1995, available on the web at www.usis.usemb.se/sft

[16] See Ossorio, p. 15.

[17] Ossorio, p. 10: "Making, using or selling the patented DNA would not interfere with the bodily integrity or functioning of the person from whom the patented sequence was derived. The 'ownership argument' against patenting would therefore rest on the claim that it would diminish us if one person can make, use, or sell copies of another's extracorporeal, nonparticularized body parts. Some may want to defend this claim; for me, it does not carry much persuasive force".

[18] For example, Jan Mertens, suggests that, for The Greens, patents on human and other life-forms are politically significant because this is something that the Greens believe they can alter, although their ethical objections to patents reflect a broader moral and political critique of the ways that people see and treat both human and non-human nature. See p. 190 in ed. Sterckx.

[19] Ossorio makes a similar use of the negative/positive distinction between rights to exclude and rights to use and possess at p. 12, when assessing the claim that patenting is immoral because it commodifies human genes. According to Ossorio, "Although patents may be integral to the process of creating commodities it is the affirmative rights, the actions of manufacturing and selling, which constitute commodification". However, as she recognizes, at p. 13, the point of a patenting system is, in part, to facilitate the commercial application and development of knowledge, and so patents typically presume that people – if not, necessarily the inventor – will have, or be likely to have, the legal rights of use, possession and so on that, as she sees it, make for commodification.

[20] Ossorio, p. 16

[21] Martens, p. 191, where he also notes the pressure placed on India to make its patent laws consistent with those in the U.S. and Europe.

[22] Ossorio recognizes this possibility at pp. 15 – 16 when discussing “common heritage” objections to patenting.

[23] See Heller and Eisenberg, *supra*, on the changing standards of rewards in academia.

[24] See Larissa Gruszow in ed. Sterckx, p. 153. Article 52 (4) of the EPC “excludes from patentability therapeutic, diagnostic and surgical methods applied to the human and animal body”. Quite what this means in practice, I must say, is unclear, if, as appears to be the case, the EPO initially granted a patent on a DNA fragment able to encode human relaxin, in April 1991, though it subsequently had to review the decision. See Gruszow, p. 154. Schatz discusses article 52(4) at p. 167. He claims that “The reason [for the exclusions it defines] is that the patent system is a regulation of competition in industry and trade, whereas the medical art has to abide by medical deontology rather than by the rule of commercial competition...” It is the profession that is exempted from the reign of patent law”. At p. 172 R. Schapira expresses some doubts about the efficacy of this clause.

[25] Additional uses might include the development of increasingly accurate and simple tests for the purposes of facilitating the identification and prosecution of those who are guilty of various crimes, and as tools for exonerating the innocent.

[26] See Philip Kitcher, The Lives to Come: The Genetic Revolution and Human Possibilities, (Touchstone, New York, 1996), ch. 6

[27] For example, Isabelle Meister, a spokesperson for Greenpeace, seems troubled by the patenting of human genes and, indeed, those of life –forms more generally, because, she claims, this inappropriately confuses living things with industrial products.

[28] Compare Ossorio, pp. 10-11: “Human-dignity arguments against patenting human DNA occasionally refer to the notion that our DNA is unique and uniquely involved in our identities. However, it is difficult to formulate a credible argument based on that premise...If we excluded from patentability only that part of the human genome which is unique to human beings, then only a tiny fraction would be unpatentable. If we excluded from patentability only gene sequences that were unique to a particular person, than any human gene or DNA would probably be patentable”. See also Tom Wilkie, “Lords of Creation”, in Prospect, no. 32, July 1998. Ossorio’s interpretation of human dignity arguments tends to suppose that the threat to identity presented by human gene patenting must be a threat to personal identity, rather than to our collective identity as humans. This highly individualistic interpretation of our personal identity and dignity then leads her to conclude that while a concern to protect personal identity tells against patenting the whole genome of a person, it does not ground a compelling objection to patenting in general. The key assumption here seems to be that only what differentiates