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Meeting Transcript
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Friday, June 21, 2002

COUNCIL MEMBERS PRESENT

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Michael J. Sandel, D.Phil.
CHAIRMAN KASS: Would the Council Members please join the table and take their seats. Good morning. This morning will be devoted to two sessions on the patentability of human organisms; the first session on history and current law; and the second session on ethics and public policy.

The topic of the patenting of life, with special attention to the patenting of human organisms, is a topic that we selected here for a number of reasons. First of all, as part of a larger interest in the interaction between biotechnology and society, the question of patenting policy is relevant.

Second, a number of the members of the council, going back to the very first meeting, expressed an interest in the significance of the commercial aspects of the new biomedical technology, and wondered about those special ethical and policy questions that arise from commercialization.

Third, patent protection, though not primarily an instrument for regulation, is nevertheless one area where this question of commercialization can be explored. And though it does not serve as a regulator, it does work as an accelerator, and therefore does have some considerable impact on what happens.

Fourth, as the staff has looked at documents and read case law, it seems as if patenting of human organisms and their parts may at least, and following the existing statute as the Supreme Court cases have interpreted them, be at least silent on, and perhaps even allow for the patenting of human life and human parts.

And one wonders whether there is an existing either ambiguity or lacuna in the current law as interpreted on this question that would allow the patenting of human organisms from embryos on up or the parts.

And we thought that we would investigate the question as to first of all is there such a lacuna, and we are not experts in this matter. And second is that lacuna a problem, and if so, why.

And if it does would that difficulty be sufficient to warrant a legislative remedy, and I think those are the larger questions that we would to at least think about with the help of our invited guests.

This morning, in considering the history and current law, we are very fortunate to have two guests seated to my right. First, Daniel Kevles, who is the Woodward Professor of History at Yale University; and a scholar of the history of science and its interactions with society.

And second, Karen Hauda, who is a patent attorney in the Office of Legislative and International Affairs at the United States Patent and Trademark Office, and was for a while the patent examiner, or one of the patent examiners, in gene therapy and transgenic animal art.

And we have asked Professor Kevles to talk about the history of patenting life as it leads up to the question of human organisms. And Ms. Hauda will speak about the existing state of the patent law, and try to educate us about what goes on over there, and how it affects these questions.

The larger biographies of our guests are in the briefing book, and I won’t say any more about it. Professor Kevles has provided a wonderfully rich and long paper, which I hope everybody has had a chance to read, and he, I think, is going to begin here by summarizing, embellishing, or adding to that, and let me without further ado please turn it over to Professor Kevles.
Thank you very much, Dr. Kass, and a thank you to the Members of the President's Council for this opportunity to tell you a bit about this issue of patentability. I should say that I first got interested in it in the late 1980s when the patent office announced that you could get a patent on a mouse, an animal, and I just thought that it was intriguing, and I began to wonder how in the world did this come about.

Obviously, there was a lot of controversy that surrounded it and so on, and so I began looking into the issue, and since then have embarked on writing a book about it, but got interrupted with a couple of other books in the interim, and going back to writing a book about it now. So it is particularly timely for me.

Very few people were interested in it in the late 1980s, but as is evidenced by the invitation to me to appear before the President's Council, has become a much more charged and important issue, not only in the United States, but also in Europe.

What I am going to do is provide a summary of highlights of what I know about this issue of this patenting of living organisms from the late 19th century, and then provide some reflections on closing.

I have been asked to speak for about 20 minutes, and so I will arrange my remarks to at least attempt to fall within that purview, and if I am going on too long, Dr. Kass, would you please just give me a high sign and I will finish.

Okay. First, with regard to patentability. The key issues or the key points to make here as to what is patentable historically are that, first — and this phrase was coined by Thomas Jefferson in the patent law of 1793, that it must be, among other things, that the invention can be a new composition of matter.

Second, however, what is relevant to our concern is that in 1889 the Commissioner of Patents ruled that you could not get a patent on a so-called product of nature, something that you found in the fields, for example.

That doctrine had come and since then had played a role in limiting patentability to non-living organisms. However, beginning in the early 20th century after the rediscovery of Mendel's laws of genetics, and plant and animal breeders begin to think that they might be able to acquire some sort of patent protection for the products of their labors.

Their efforts, which produced in 1930 the Plant Patent Act. They argued, that is, the plant breeders, and horticulturists, and so on, that they had a right to be protected in the fruits of their labors just as did physical inventors, like Thomas Edison.

The Congress agreed with them and passed the Plant Patent Act in 1930. However, the coverage, or the scope of what was patentable under the Plant Patent Act was limited for interesting reasons.

It is limited to asexually reproducing plants. For example, plants that you can reproduce by cuttings, or vines, that tend to reproduce themselves asexually. If you walk into your local nursery, for example, you often find roses that say patented with a number.

And that is because a rose as you know can be reproduced by a cutting. The reason for this limitation were that, first, in order to have a patent it was assumed that you have to be able to control the product to produce it identically at will; and secondly, that it must be highly specifiable.

The problem with sexually reproducing plants is that you cannot control, or at least you could not control at that time what the offspring would be like because of the mixing of genes from the two parents, and the changes would arise over various generations.

And, secondly, it was very difficult to specify, partly because you can't control it, but partly because it is a living organism, exactly what the product is.
So on the assumption that no property right is worth anything if you can't enforce it, and you can't enforce it if you can't specify the property, the Congress decided to limit the coverage to asexually reproducing plants.

The next landmark in our story is a ruling by the United States Supreme Court in 1980 in the case of Diamond versus Chakrabarty. Chakrabarty was a biochemist at General Electric, and he devised a bacterium in the early 1970s that was genetically modified so that it would consume oil.

His claim for the patentability of this product rested in part on the fact that the product was highly specific because it was genetically modified, and by that time it was well established that genes are chemicals, and therefore you could specify it as a composition of matter.

And furthermore, it could be controlled because of the constancy of the genetic material. The Patent and Trademark Office, however, objected to and rejected Chakrabarty's claim on the grounds of invoking the product of nature doctrine from 1889, and it was a product of nature, and a living organism, and then rejected it also on the grounds that it was alive.

And it cited the Plant Patent Act, reasoning that when Congress had passed the Plant Patent Act, and it implicitly declared to extend the scope of patentability to anything alive would require an act of Congress, and of course here there had been no act of Congress.

Chakrabarty appealed the rejection, or to say that G.E. did on his behalf through the courts, and hence the case reached the Supreme Court in late 1979, and the ruling came in 1980.

The ruling granted Chakrabarty his patent, but it was only by 5-to-4. The Court said in response to the arguments made by Chakrabarty's lawyers and also a number of friends of the court briefs, that the product, the bacterium in question, was not a product of nature. It was a product of Chakrabarty, and that it was in short man-made.

Furthermore, it was a new composition of matter because it had to do with changing the chemical DNA in the product. And thirdly, and perhaps most important, it ruled that whether an invention is alive or not is irrelevant to its patentability.

The dissenters in the case, the four, held that this really was a charged social issue. It arose at the time of the recombinant DNA wars in the United States, and in Europe, and which opened up the prospect of the engineering of all of life.

And given the charged nature of the case and its implications, the dissenters held that really this should come before the Congress. However, the majority disagreed and went on to rule as I have said.

During the arguments on the case, and as I said, a number of amicus briefs were filed, and among them was one from the People's Business Commission as was then called, which was the non-profit organization headed by Jeremy Rifkin, who had already established himself as a staunch opponent of genetic engineering.

Among the numerous arguments raised in the PBC's brief was that there were profound implications here that if you were to say that an organism is patentable, and its being alive is irrelevant, and that anything that is a new composition of matter could be patented, then that would leave no logical space, or no logical obstacle, to the patenting of higher life forms, including possibly human beings.

Observers in the wake of the court's ruling agreed with this reasoning and warned of that possibility. The court at the time ruled or held in its ruling that whether these implications might or might not be true, but it could only decide the case before it which concerned the bacterium and had been devised by Chakrabarty, and hence the ruling that I have described.

But the implications that were drawn were I think quite substantive and material. As a result, in 1985, the patent office awarded a patent on a plant, which meant that any plant could then be patented so long as it qualified or met the criteria for patentability, including new composition of matter, et cetera.

Then in 1987 the Board of Patent Appeals and Interferences in the Patent Office ruled in a case, Extra Parte Allen, allowing in the case of Ex Parte Allen, allowed the patenting of higher organisms, including animals.
The case involved an oyster that had been chromosomally altered by a laboratory at the University of Washington so that it would be sterile. It is always amusing to me why they wanted to do this, and it turns out that this oyster naturally spends three months of its life each year reproducing, and at that time the flesh of the oyster is much less eatable.

So if you could force the oyster not to reproduce ever, then you could have an increase in the eatability of these oysters by 33 percent over time, and that would be a great boon to the oyster industry in Washington.

Well, the Patent Office, the examiners, initially ruled against the claim on the grounds that the oyster was a product of nature and furthermore that the modification that had been engineered into the oyster was obvious to anyone schooled in the art of oyster breeding, and something that as obvious as by patent practice not testable.

The Board of Patent Appeals and Interferences agreed with the reasoning that it was obvious, but it held that a higher organism could be patented. It cited Diamond v. Chakrabarty, and the doctrine of whether an invention is alive or not is irrelevant and cited the point that new compositions of matter were patentable.

At the same time, the Board revealed its sensitivity to the apprehensions that emerged in the wake of Diamond v. Chakrabarty, namely the apprehensions about the potential patentability of human beings. So it declared that human beings are not patentable by reason of the 13th Amendment to the United States Constitution.

The 13th Amendment, of course, overturned the Dred Scott case, in which the Court in the 1850s did hold that one human being could hold a property right in another. The 13th Amendment basically said by implication that a human being cannot hold a property right in another, and a patent is a form of intellectual property right.

So for one human being to hold an intellectual property right in another human being is a violation of the 13th Amendment to the Constitution. The next landmark and the final one for our purposes here is that in 1988 the court, basing its decision on Ex Parte Allen, or I mean the Patent Office, basing its decision on Ex Parte Allen, issued a patent without any objection whatsoever in the Patent Office, to Harvard University for a mouse that had been genetically engineered in its laboratories, to be supersusceptible to cancer.

Now, the reason that it was a new composition of matter is that it had introduced into it at the stage of being a newly fertilized egg an oncogene, and therefore, the oncogene being DNA, made the mouse a new composition of matter and therefore under these accumulating precedents of Diamond v. Chakrabarty, Hibberd, and Ex Parte Allen, and the mouse was patented.

Now, what I want to conclude with is a set of observations concerning the ethical issues as they arose either implicitly or explicitly in the course of this history.

First, with regard to the patent system and the rights of inventors. One reason for the patent system in the United States and in other countries is of course for the practical purpose, the consequential purpose of encouraging innovation, by securing to inventors the fruits of their labors.

But secondly there is an ethical premise it seems to me in that doctrine, or in that policy, namely that inventors have a moral right to the fruits of their labors. One can see this moral right invoked in the attempts by breeders, for example, starting early in the 20th century to obtain intellectual property protection in the plants that they would devise.

The moral right was expressed in a Congressional hearing in 1906, and it certainly suffused the discussion and debates that preceded the Plant Patent Act in 1930, without intellectual property protection, and without the patent for the fruits of their labors in the case of plants, and it was claimed that in fact that others would just simply steal from inventors, and leave — that is, plant breeders, and leave them no recourse.

Secondly, since Diamond v. Chakrabarty, and the debates starting actually in the ’70s when the case was beginning to work its way through the courts, but certainly since Diamond v. Chakrabarty in 1980, and especially since the award of the patent to the Harvard mouse, opening the door to animal patents, the ethical objections to patents have arisen.
The one class of these objections is to the patenting of life per se as such, without regard to whether it is a plant, an animal, a human being, or whatever.

This objection is to be found vigorously advocated in the brief of the People’s Business Commission, and before the Court in Diamond v. Chakrabarty, but it has also found expression since then from clerics, from animal rights activists, once Ex Parte Allen allowed the patentability of animals, and so on, and also from certain groups of environmentalists.

The basic argument advanced in this ethical regard is that to patent life is to hold that it has no vital or sacred character. That it is commodifiable in ways that are no different from, say, tennis balls.

A second particular ethical objection, which is sort of a subset, but important for our purposes, is that to allow the patenting of life, especially animals, implies the potential patenting of human beings.

This possibility was disparaged in the amicus briefs on behalf of the biotech industry, the American Pharmaceutical Manufacturers, and so on, and Genentech, then a new company, in the debates over Diamond v. Chakrabarty before the court.

And saying that this is just carrying the doctrine of patentability of living forms beyond reason. And that potential of patenting human beings would seem to have been blocked entirely by Ex Parte Allen, which says explicitly that you cannot get such a patent.

However, in the wake of the ruling of Ex Parte Allen allowing animal patents, and then Harvard’s mouse patent, there was sufficient controversy that arose to prompt Congressman Robert Kastenmeier, who was then head of the appropriate subcommittee of the House Judiciary Committee, to hold hearings on the patenting of animals.

The ethical objections were raised but there were also other objections raised to the patenting of animals, especially by farm groups, agricultural groups, on the grounds that this was going to be disruptive to the agricultural economy and work adversely against the interests of small farmers.

In a sense, it would be another case of how the advent of technology, which may involve higher capital costs, tends to work or to favor better capitalized or agricultural groups, and to disfavor those that are less capitalized.

So there was a melange in the hearings of these ethical objections, plus consequentialist objections, and one of the major consequentialist objections for everybody in the agricultural community, agribusiness and small farmers, was who owns the progeny in impacted animals.

This was an issue that had never arisen before in the system because no invention had ever been capable of reproducing itself. But now with living organisms, you did have such capability.

In the end, Kastenmeier and his subcommittee concluded that the ethical objections had no place in the considerations of American patent law; that U.S. patent law is literally amoral. All it does is to grant an exclusive right to make, use, or sell an invention, or to exclude others from making, using, or selling it.

But with regard to the ethical objections that the subcommittee held, that Kastenmeier did, were excluded from American patent law, but did have a place in public policy because even though a patent really grants the exclusive right, it does not give you the right actually to make, use, or sell an invention.

For example, just to take an extreme example, if you were to invent a new nuclear weapon in your basement, you could get a patent on it. But that wouldn’t give you the right actually to make the weapon, or to sell it, et cetera, et cetera.

That would obviously come under rules of national security, public health and safety, and so on. And so Kastenmeier held, as did his subcommittee, that the literal amoral nature of American patent law relegated to all the regulatory safety agencies of the government, and to Congressional action, the implicit ethical issues concerning these matters.

However, Congressman Kastenmeier did attempt, and did think it important to deal with the consequentialist issues arising from the patentability of animals, namely as they might affect
farmers. And he constructed a bill that in part held that the patent holders would not have rights in the progeny of patented animals, simplifying the system, et cetera, and assuming that therefore the price, the lack of property control over progeny would be reflected in the initial price.

Secondly, however, he also included in his bill a provision by statute that would prohibit the patenting of human beings. He was not satisfied with the reliability of Ex Parte Allen, and so he incorporated that provision into the bill.

This bill passed the House of Representatives in 1989, but it died in the Senate, and since then there has been no action in the Congress. Then finally what is the current state of affairs with regard to human beings.

Well, Ex Parte Allen still prevails, but it is still possibly — I am not enough of a lawyer or patent policy expert to say, but possibly it is vulnerable. It seems to me though to have a pretty solid foundation, because it is not just a casual regulation. It is a legal ruling by the Patent Office itself.

But even if Ex Parte Allen should remain a solid fixture of American patent law, it omits consideration of what constitutes a human being. Is it a human being in its totality only, or does it also its parts — the organs of the human being, the liver, kidney, or whatever.

We do know that with regard to the patentability of those things that there is precedent in the patentability of human genes. Human genes have been patentable without objection initially since Genentec I think took out the first human gene patents in the late 1970s.

The ethical objections have been raised to the patentability of human genes, per se, but it seems to me that we have at least equal concerns, or we should have equal concerns of a consequentialist nature.

Gene patents are treated as absolute property rights, and we can see already that the way that private companies are dealing with their property rights in human genes is creating problems for medical research, and already even in the diagnostic area.

The medical research is problematic, and problems are arising in medical research arise from the fact that expensive licensing fees are being charged by some companies for people just to do research on these genes.

And it seems sort of paradoxical and bizarre to a number of observers that if you wanted to take a gene from your own body and do research on it that you can't do it without paying a license fee possibly to whoever owns the patent.

Secondly, these genes are important, and a growing number of them are in medical diagnostics because they can tell you, for example, which oncogene has gone wrong in your body, et cetera, and give a much more specific diagnosis of, say, cancer, and then you multiply those examples over a number of diseases.

It seems to me that quite possibly the notion of gene patents at least in human beings, and possibly other forms of possible patents in human beings, ought to be explored as whether this should be an absolute property right.

My own view personally is that it ought not to be. One can make analogies because it is a very limited resource. I mean, we have lots of genes, but we only have a finite number of them, some thousands, 30 to 40,000 at current estimates, and obviously they are all very important to us, especially with regard to biomedical research.

And one can analogize this limited resource to, for example, by riparian rights, and there are other analogies that you could make in the history of property law in the United States, possibly the electromagnetic spectrum.

But in the case of riparian rights, for example, we do not allow I think in most States people through whose property water rivers run to treat their property in an absolute way, because it is a public resource.

Downstream has interests in what is upstream, et cetera, and so all of us have interests in what happens to human genes, and how they can be used in biomedical research, and in diagnostics.
The bottom line for all of this in sort of summary it seems to me is that there has been no adequate, despite the valiant efforts of Congressman Kastenmeier, no adequate effort on the part of the Congress to explore in a thoughtful way the — and in a sufficiently serious way, the sense of being high enough on the public agenda to do something, adequate consideration of the myriad issues arising from the patentability of living organisms, but particularly in the human area.

I think that Ex Parte Allen is okay, and I don't think that anybody would object to disallowing patents on human beings as a statutory matter. But we have these other sort of infrastructural issues in human beings, which are now increasingly on the front stage center of intellectual property, biotechnology, biomedicine, and so on.

And it seems to me that there is more than a compelling reason for the Congress, and possibly prompted by the deliberations of this council, to examine in an serious way what these intellectual property rights might be, and what their scope might be, and what their limitations might be.

CHAIRMAN KASS: Thank you very much. I think in the interest of making sure that we have got full time for discussion that we should have the second presentation, and then discuss the two together if that is all right with everybody, unless there is something burning that anyone wants to ask Mr. Kevles. Please, Ms. Hauda. Thank you.

MS. HAUDA: Good morning. I would like to thank Dr. Leon Kass, Chairman of the President's Council on Bioethics, for inviting me here today on behalf of the United States Patent and Trademark Office. I will refer to this as the USPTO.

In my testimony, I will briefly outline the present state of the law and current policy of the USPTO regarding the patenting of life forms. I then will discuss recent technological developments that have raised new questions concerning patent eligible subject matter.

We welcome the advice and guidance of the President's Council on Bioethics as we consider these important issues. The President's Council on Bioethics may also want to consider recommending that Congress clarify its intent regarding patent-eligible subject matter.

The basis for the U.S. patent system is found in Article I, Section 8, of the Constitution, which provides that Congress should have the power to promote the progress of science and useful arts by securing for limited times to inventors the exclusive right to their discoveries.

In response to this Constitutional authorization our founding fathers designed an extremely flexible patent system based on principles that have proven remarkably suitable to 210 years of unceasing technological advancement.

Basically, in exchange for the full disclosure of an invention meeting the criteria of the patent law, the government grants the inventor of a patent, that is, the right to exclude others from practicing the invention for a limited time, now 20 years, from the filing date of the application.

Indeed, one of the key tenants of our patent system is that it is technologically neutral. For example, from gear shifts to genomics, it applies the same standards to all inventions in all technologies.

While some are critical of this aspect of the patent system, the uniformity and applicability of the patenting standards of novelty, of obviousness and utility, coupled with the incentives patents provide to invent, invest in, and disclose new technology, have allowed millions of new inventions to be developed and commercialized.

This has enhanced the quality of life for all Americans and helped fuel our country's transformation from a small struggling nation to the most powerful nation in the world.

In administering the patent system, USPTO takes its direction on what subject matter is patentable from Congress and our review in Courts. The current Act details the standards of patentability, and the Patent Act of 1952 specifies four basic statutory requirements that must be met to obtain a patent.

First, the claimed invention must be eligible subject matter and have utility. Second, it must be novel. Third, it must not have been obvious to a person having ordinary skill in the art at the time that the invention was made; and, fourth, it must be fully disclosed in the text of the patent application and enable a skilled practitioner to practice the invention without undue
experimentation.

Prior to granting a patent, the USPTO examines each patent application to determine whether it meets these four criteria as set out in Title 35 of the United States Code. The pertinent statutory provisions defining the subject matter that is eligible for patenting is 35 U.S.C. Section 101, titled, “Inventions Patentable.”

This section reads whoever invents or discovers any new and useful process, machine, manufacturer, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore subject to the conditions and requirements of this title.

Congress deliberately used expansive terms in describing the categories of inventions so that unforeseen technologies wouldn’t be included without the need for constantly updating the patent law.

The scope of patent eligible subject matter, however, is limited in part by the product of nature judicial doctrine, which provides that naturally occurring products are not patentable.

Under this doctrine, the mere discovery of a previously unknown naturally occurring product is not patentable. The courts, however, have long held that a purified composition of matter, such as a chemical compound isolated from nature, is a human made invention eligible for patenting, rather than an ineligible product of nature.

For example, purified prostaglandins isolated from human prostate glands are not naturally occurring and are therefore patent eligible subject matter because the pure form does not exist in nature.

Nevertheless, for many years the USPTO used the products of nature doctrine as a bar to patent living subject matter. In 1980, the Supreme Court decided the landmark case of Diamond v. Chakrabarty, addressing the patentability of living subject matter, and specifically of genetically altered bacterium capable of breaking down crude oil.

After a careful consideration of the history of Section 101, the Supreme Court reversed the USPTO’s position that microorganisms, even genetically altered ones, were products of nature as living things, and were per se, non-patentable.

The Supreme Court held that the statutory language of Section 101 was intended by Congress to be broad enough to include anything under the sun that is made by man.

Under this analysis the Supreme Court held that a living man-made microorganism qualifies as a manufacture or a composition of matter under the statute. The court explained that the relevant distinction for the purposes of patent eligibility was not between living and inanimate things, but between products of nature, whether living or not, and human made inventions.

Consistent with the Chakrabarty decision, Federal Courts have routinely upheld the patentability of products that have been modified or purified from nature. In the wake of the Chakrabarty decision, the USPTO has issued thousands of patents to living material, where the products are the result of human intervention and do not exist naturally in that form, provided that all other criteria of patentability are satisfied.

The USPTO issued the world’s first transgenic animal patent in 1988 to the now famous Harvard Onco-mouse, a mouse genetically engineered to be more susceptible to tumor growth. Patents have since issued on numerous other genetically altered plants and animals.

It should be noted, however, that in holding the microorganisms for patent eligible subject matter, the Supreme Court was aware of the lower court’s view that we are not dealing with patent eligibility of all living things, including man.

The USPTO concluded that inventions covering human beings are not within the scope of Section 101, and in 1987, published a notice in the USPTO’s official gazette advising the public of its conclusions.

The USPTO concluded that Congress never intended for a human being to be considered a manufacturer or a composition of matter under the patent law.
More recently, an immediate advisory issued in 1998, the USPTO reiterated its policy that an invention, including within its scope a human being, could not be considered to be patentable subject matter under 35 U.S.C. Section 101 because it would be against public policy to do so.

Shortly after the USPTO published its notice of intent not to patent human beings, it informed Congress of the decision by direct testimony in a 1987 hearing before a subcommittee of the Committee on Judiciary, House of Representatives, on the patents on the Constitution of Transgenic Animals.

On June 11th, 1987 the USPTO's Assistant Commissioner testified that a claim, including a human being within its scope, will not be considered to be patentable subject matter.

In the 15 years since it was notified of the USPTO's interpretations, Congress has apparently acquiesced to the USPTO interpretation. Further, the Federal Circuit held in 1991 that the USPTO has the authority to establish its policy through interpretative authority.

Guidance on the topic of patentability of living subject matter is provided to the USPTO patent examiners and to the public in Section 2105 of the USPTO Manual of Patenting Examining Procedure, otherwise known as the MPEP.

Generally speaking, living things are patent eligible. Let me briefly outline per USPTO policy regarding the patent eligibility of various forms of living subject matter.

First, animal or plant cells, or human stem cells. In view of Chakrabarty, the USPTO has applied the same reasoning applied to purified and/or isolated products of nature to animal and plant cells, including human stem cells.

A naturally occurring animal or plant cell is a composition of matter and may be eligible for patenting when the inventor describes and claims it in a purified form. For example, in the form of a cell line or a cell culture.

The purification process is human intervention in nature, and maintaining the cells in a non-naturally occurring state if a cell culture distinguishes the cells from the mere product of nature.

Of course, any such claim is subject to other requirements of Title 35, such as novelty, non-obviousness, and adequate disclosure. For example, a cell culture of human skin cells said to be useful for skin grafting may be a manufacturer or a composition of matter eligible for patenting.

However, such an invention must also pass the test for novelty, non-obviousness, and adequate disclosure. Additionally, if human cells are maintained in cultured, non-natural state, the cultured cell line would be eligible for patenting.

Genetically engineered animal and plant cells are made by human intervention, as was Chakrabarty's bacterium. While these kinds of inventions might be expected to routinely pass the non-naturally occurring test, there must be evidence that the invented cell is different from nature's handiwork in some measurable and useful way.

If not the claim is usually rejected and directed to non-statutory subject matter, as well as for lack of novelty. With respect to animals, plants, and non-human embryos, for the reasons discussed above, the USPTO issues patents on non-human animals and plants.

When the invention is the result of human intervention and nature, and the conditions of Title 35 are met, non-human, animal, and plant embryos — and for plants an embryo is typically a seed — are eligible for patenting when the embryo is different from the nature's embryos.

The invented, non-human animal, plant, or embryo, must be distinguishable from its naturally occurring counterpart.

Human beings and human embryos. MPEP, Section 2105, concludes with this instruction. If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to non-statutory subject matter.

When a patent claim includes or covers a human being, the USPTO rejects the claim on the grounds
that it is directed to non-statutory subject matter. When examining a patent application, a patent examiner must construe the claim presented as broadly as is reasonable in light of the application's specification.

If the examiner determines that a claim is directed to a human being at any stage of development as a product, the examiner rejects the claims on the grounds that it includes non-statutory subject matter and provides the applicant with an explanation.

The examiner will typically advise the applicant that a claim amendment adding the qualifier, non-human, is needed, pursuant to the instructions of MPEP 2105.

The MPEP does not expressly address claims directed to a human embryo. In practice, examiners treat such claims as directed to a human being and reject the claims as directed to non-statutory subject matter.

The rejection is withdrawn if the inventor amends the claim with the term non-human to exclude human being. Processes of preparing cell lines and methods of culturing cells are eligible for patenting because laboratory processes are not natural phenomena, and involve human intervention in nature.

This also means that laboratory processes or methods for making human cells and culturing human cells are eligible for patenting. Similarly, methods of manipulating non-human animal or plant cells to form embryos are patent eligible.

Cell cultures are used in a variety of ways, including immediately practical procedures such as surgical intervention. For example, using cultured cells to treat burn victims.

Methods of using the cells are also eligible for patenting as process interventions when they provide any practical utility. Thus, cloning procedures fit in the process invention category, and cloning is eligible for patenting subject to the conditions of Title 35.

Surgical procedures on human patients are eligible for patenting and can be directed towards techniques or use of materials such as implants. As applied to whole animals, the term cloning has several different meanings.

Cloning can occur naturally, such as in identical twins or triplets. Additionally, there are two quite different artificial laboratory procedures aimed at duplicating embryos that have been termed cloning.

Blastomere separation and nuclear transplantation. Also known as embryo splitting, blastomere separation is an artificial cloning procedure that involves isolating individual cells of very early embryos, and growing them into separate embryos.

Blastomere separation has been used successfully to increase the pregnancy rate in cattle. Nuclear transplantation is an artificial cloning technique that involves removing the nucleus from a cell and inserting the nucleus into an unfertilized egg from which the nucleus has been removed, an enucleated cell.

The clone cell is then implanted into a surrogate mother and allowed to grow to term. Somatic nuclear transplantation involves moving the nucleus from a somatic or adult cell into an unfertilized egg, as opposed to embryonic cell nuclear transplantation, in which the nucleus is transferred from an embryonic cell.

Somatic cell cloning is the process that lay persons typically refer to as cloning, in which an existing animal, adult animal, is cloned. Scientists in the United Kingdom were the first to report a cloned animal by somatic cell nuclear transportation.

The resulting lamb, named Dolly, is genetically identical to the sheep from whose cells the donor nucleus was taken. Following the successful cloning of Dolly the Sheep, many other animal species have been cloned using nuclear transfer techniques.

These include mice, pigs, cows, monkeys, cats and rabbits. There have been press reports that some researchers are pursuing human cloning using similar techniques.
Before closing, let me address the possible need for legislation. The current policy of the USPTO is to consider any claim encompassing a human being at any stage of development, and not to be patent eligible subject matter under 35 U.S.C. 101.

Several legal arguments may be used to exclude the patentability of claims directed to human beings. To date, the court's have not addressed this question. Legislation may be necessary to ensure that this subject matter is excluded from patentability.

As was noted earlier, Section 101 of the patent law contains the requirements that a patentable invention be new and useful, and fall within one of the statutory categories of process, machine, manufacture, or composition of matter.

Canons of statutory construction favor the ordinary meaning of the terms, and the ordinary meaning for the terms manufacture and composition of matter does not include a human being. Conferring exclusive rights over a human being would also raise constitutional questions, and canons of statutory construction counsel the interpretation that avoids constitutional issues.

In addition, the courts have interpreted the utility requirement to exclude inventions deemed to be injurious to the well-being, good public policy, or good morals of society.

In light of the above statutory and judicial constraints, the USPTO has for 15 years taken the position that it will not issue a claim directed to a human being or a claim that could be interpreted as being directed to a human being.

Any actions taken by the USPTO must have legal basis under Title 35 of the United States Code, as interpreted by the Federal Courts of the United States. The USPTO also lacks substantive rule making authority.

Legal challenges will therefore likely be raised to the USPTO's interpretation of statutory subject matter under Section 101. A challenge to the non-patentability of human beings would be a case of first impression to the court.

The resulting outcome, especially on public policy grounds, is uncertain. In the Juicy Whip case, the Federal Circuit questioned the continued viability of the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes, noting that this reasoning has not been applied broadly in recent years.

In addition to the role of the USPTO as a gatekeeper for the public, it is recognized that strong patent protection has been vital to the development and commercialization of innovations in biotechnology.

The U.S. biotechnology industry has more than doubled in size since 1993, with revenues increasing from $8 billion in 1993, to $22.3 billion in 2000. Experience in the biotechnology industry has been that patents in this area are widely licensed, and are considered to be some of the most profitable patents.

The profitability is largely due to their widespread use and advancement of biological research. These advances would not have been possible without broad patent eligibility and the balanced patent system strikes between generating intellectual property and distributing those ideas.

Despite the benefits afforded by the technological advancements, however, some technologies are raising profound legal and ethical issues. Until recently, scientific research had not reached a level that would require the USPTO to confront claims directed to a human being or methods of making a human being.

As I discussed that has now changed. Given the uncertain outcome of legal challenges to the exclusion of humans from patent-eligible subject matter, legislation may be required to ensure their exclusion.

However, any restrictions that would limit the patent eligibility of biotechnology inventions must be carefully crafted to avoid unintended consequences, such as general negative effect on the investment in the biotechnology sector.

Too much restriction could result in the loss of highly respected and prominent researchers from the
U.S. to countries that may provide greater protection or stronger research advantages.

The USPTO therefore welcomes the guidance and analysis of the President's Council on bioethics as we attempt to address these issues. I would be happy to answer any questions that you may have, and would like to assist the council in answering these questions.

My testimony today has been approved through all appropriate channels. Please understand, however, that my answers to questions are my own, and do not necessarily reflect the views of the USPTO or the Administration. Thank you.

CHAIRMAN KASS: Thank you. Thank you both for very lucid and helpful presentations. Before I throw the floor open, I would like just to clarify for myself that I have understood certain matters.

From Professor Kevles, I take it that you would agree that in terms of the gradual expansion of the terms of patent statutes to allow increasingly for the patent of living things that as you read the development, you don't at the moment see any obvious obstacle to the further expansion of these things to include human materials, even though that has not yet been granted.

And particularly that there is a kind of ambiguity about what you mean by human things.

PROF. KEVLES: That's right. First, it seems to me that the ruling in Ex Parte Allen still holds, and by the argument of Karen Hauda here, it has been tacitly accepted by the Congress, because the Congress has not done anything to contravene it.

Secondly, that applies, and which I think is the understanding, to whole human beings like us sitting around the table.

Secondly though, it leaves open the question of what is a human being, and does a human being extend to its parts. We do know, however, that human genes are patentable, and we have many patents on human genes.

And so it is not the case that all parts of human beings are automatically excluded, and that is just a fact. It does raise the question therefore with all due respect as to what the courts might do, no matter what the patent office policy is, with regard to applications on other parts of human beings.

And we do have historical precedent to strongly indicating that the policy of the patent office has not always prevailed in the patentability of living subject matter.

The patent office as I have said adamantly resisted the claims of Chakrabarty. It resisted the claims of Standish Allen, the claims of Hibberd and so on, and those claims were overturned in the first instance by the Supreme Court of the United States, and in further instances by the Patent Office’s own legal appeals board.

So how this will all work out is not altogether a matter of statutory — has not been altogether a matter of statutory law, and what is non-statutory has changed over time. So that is why I conclude that some, I think, clear clarification of this comparable to the overall of U.S. patent law in 1952 might be in order given the increasing possibilities of engineering different things that you might call human, or at least parts of human.

CHAIRMAN KASS: Thank you. And for Ms. Hauda, you say that at least the official policy of the patent office having to do with human things is answered in terms of the language that this is not statutory subject matter.

The patent office doesn’t speak about the 13th Amendment, and that is not part of the official language. It is the 13th Amendment, for example, that is the grounds of your restriction.

I mean, the patent claim comes in — the official answer is as you indicated this is the patent office's interpretation of the statute, and the patent office has the authority to interpret the statute, and therefore — am I understanding that correctly?

MS. HAUDA: Yes. Our policy is that we will not issue a claim that includes within its scope, or is directed to a human being in any stage of development.

That policy is based on statutory interpretation of the Constitution have been interpreted by the
Federal Circuit Courts and the Supreme Court of the United States.

So in interpreting those, there are for bases for which the USPTO relies on with respect to that. And why human beings are not patentable, and that would include the patenting of a human being does raise Constitutional questions.

It also includes that the terms or the composition of matter and manufacturer do not in their ordinary meaning and parlance include a human being, and that the utility requirement of Section 101 does raise public policy issue, and that it cannot be injurious to the well-being and good public policy of the statute.

And fourthly that for 15 years we have been telling Congress that we will not patent human beings, and Congress appears to acquiesce to that also. So we interpret that as part of their interpretation of the statute.

CHAIRMAN KASS: Thank you. The floor is open for general discussion. Rebecca Dresser.

PROF. DRESSER: Thank you very much for your testimony. It seems to me that there is a contradiction. I mean, this general view that the Patent Office decisions are amoral is contradicted by at least the partial invocation of the 13th Amendment as the basis for not granting a patent on a human being.

So certainly in interpreting what constitutes a human being, and not just whether a part constitutes a human being, but what is a genetic human being. So when is a transgenic creature a hybrid, and how many genes does it have to have to be a human.

And to me that really requires ethical analysis, and policy analysis, and sort of substantive analysis, that at least the general view is that the patent office should not engage in.

On the other hand, I am not that thrilled about having — and I don't mean any disrespect, but technicians at the patent office making these kinds of moral decisions. So I guess I don't have a particular view.

But it does seem to me that in this area that there are ethical judgments being made. So it is touch to square with this amoral label on patent law.

MS. HAUĐA: When an examiner interprets a claim, what they do is the examiners are instructed to consider what is encompassed within the claimed invention as broadly as is reasonable in light of what is disclosed in the application.

So when a claim comes in, when read in light of the application disclosure could read on a human being at any stage of development, the examiner will make a prima facie case of non-statutory subject matter.

And that is a rebuttable presumption. The applicant can then come in and argue that its not, and based on the prosecution and the disclosure, and what the evidence the applicant can provide, is how that examiner makes that decision.

So the analysis that the examiner undergoes is very technical based on what is disclosed in the application and what the scope of the claims as interpreted under the statute reads on, and it creates a prosecution history within that case as to what the final interpretation of the claims are.

And anything the applicant admits to on the record becomes prosecution estoppel when a court is interpreting the scope of the claims at a future time.

CHAIRMAN KASS: Professor Kevles.

PROF. KEVLES: First, it was Congressman Kastenmeier who basically argued that the patent law is amoral and may be implicit in what the patent office does. But it is my terminology, and so I wouldn't blame it on that.

Secondly though, the phrase, non-statutory subject matter, I think is problematic. That is exactly how the patent office responded to Chakrabarty's claim, and we know what happened with that.
Ms. Hauda will correct me if I am mistaken, but I know of no statute ever passed by the Congress of the United States which says that human beings are not patentable subject matter or their parts. That’s why Congressman Kastenmeier thought it necessary to enact such a statute in 1989, even though he failed.

So I think that the foundation here, while it is substantial in terms of precedent probably, is not statutory in any explicit way. Am I mistaken about that?

**MS. HAUDA:** No, I agree with your statement that there is no statute that says human beings are not patentable. However, the USPTO bases its interpretation of the statute on the case law and the history of what the courts have said.

And the fact that we were overturned in Chakrabarty indicates that living matter is patent eligible, but it is our interpretation of the statute, and based on the 15 years of acquiescence by Congress, and our direct testimony to Congress, that Congress did not intend the terms of the statute, manufacture and composition of matter, to include a human being.

**PROF. KEVLES:** But it is inferential?

**MS. HAUDA:** It is interpretative.

**CHAIRMAN KASS:** Frank Fukuyama and then Mike Gazzaniga.

**PROF. FUKUYAMA:** Yes. I have a question about Professor Kevles assertion about the amorality of the statute, because my understanding was that there actually was language in the statute which I believe Ms. Hauda quoted that said that the patent office can exclude inventions that are injurious to the morals of society.

But that as a matter of practice, since the 19th century had actually not ever tried to exclude anything on that basis. But there is actually statutory language that would permit that to happen if someone in the patent office decided to go down that path. That is the first question.

The second question is what would happen

— what would be the U.S. policy if, let’s say, a human embryo or some complete human being, something that is currently not permitted in U.S. practice was patented in a foreign country, and then that foreign country, through WIPO or TRIPS, would then try to get that property right recognized by the United States.

What would be the U.S. policy in a case like that?

**PROF. KEVLES:** I may be mistaken about that point that Ms. Hauda just testified to, as to the excludability of patents on inventions that may be injurious to society is new to me. It is certainly — I was basing my view on the considerable body of testimony that came out in the Kastenmeier hearings, and the fact that Congressman Kastenmeier never alluded to this.

I don’t know when that phrasing came into the U.S. patent code, and I am eager to see or to find out more about that. Now, I also recall that when Jeremy Rifkin, a scientist, proposed to patent a human animal hybrid, then Commissioner Lehman said that this might be unpatentable on moral grounds, and then he was widely attacked from the entire patent law community, saying that there is no statutory grounding for this view.

So I would say that the issue is at the least ambiguous certainly if you want to pay attention to precedent and the understanding of the larger body of, or larger community of patent lawyers.

With regard to the — and I am sure that Ms. Hauda will have more to say about this than I do, but I would just like to observe that the European patent convention does explicitly include an Article 53A which says that you cannot get a patent on anything contrary to public or morality, it has historically not been invoked until recent years, first with the Harvard mouse.

And there Harvard University had to jump through a number of hoops to demonstrate that this Onco-mouse was not contrary to public order or morality. I would say that the expectation in Europe is that the ethical requirements of patent law might be imposed through WIPO or TRIPS, rather than our imposing amorality on the Europeans.
But it is a very interesting issue it seems to me given of course the globalization of high technology.

**CHAIRMAN KASS:** Ms. Hauda, did you want to comment in response?

**MS. HAUDA:** Sure. With respect to your first question, I will just quickly go through some of the cases that have supported a public policy interpretation of the statute.

The United States Supreme Court in *Morton Salt Company versus G.S. Suppiger Company*, which is 314 U.S. 488, a 1942 case, stated that the grant to the inventor of a special privilege of a patent monopoly carries out a public policy adoption by the Constitution and laws of the United States to promote the progress of science and useful arts by securing for limited times for inventors the exclusive right to their new and useful inventions.

Furthermore, *Tol-O-Matic, Inc., v. Proma Product Marketing Gesellschaft*, I think you say, 945 F. 2d 1546, quoted from *Lowell v. Lewis*, which is an 1817 case written by Justice Story, stating that the term useful in Section 101, as used in the patent context, has been construed to include the connotation that an asserted invention should not be injurious to the well-being, good policy, or good morals of society.

Public policy takes into account the common sense of the community and issues that are controversial by nature, and issues that tend to be injurious to the public or contrary to the public good, and this is the general definition of public policy from *Black's Law Dictionary*.

The resulting outcome of the interpretation of the statute under a public policy reason is indeed uncertain. The *Juicy Whip* case, *Juicy Whip v. Orange Bang Company*, which is 185 F. 3d 1364, indicated that inventions are — that questions of viability of whether inventions are invalid if they are principally designed to serve amoral or illegal purposes.

And noted in this holding that has not been applied broadly in recent years, and that was a 1999 case. So we do agree that the outcome in the courts is uncertain, but we also believe that there is a public policy ground that is supported in the case law under the 101 statute.

With respect to your second question on a patent and trying to use TRIPS or WIPO to move patent rights into the United States, patent rights are territorial. They give the right to exclude use, import, sale, and manufacturing of the claim in the patent that was granted.

But they are territorial in right, and so any rights that are granted in another country can't be imported into the United States and vice-versa. A U.S. patent that issues, that right doesn't give any rights overseas.

It only gives the right to exclude for use in import and sale, and manufacturing within the United States.

**CHAIRMAN KASS:** Thank you. Mike Gazzaniga and Michael Sandel.

**DR. GAZZANIGA:** Are you aware of the history of why the bill failed in the Senate in '89, and what the reasonings were or the politics, or whatever it was?

**PROF. KEVLES:** I think it was — the bill passed the house — I am a little fuzzy on the chronology, but if I remember correctly, the bill had passed the house late in 1989. I'm sorry. Yes, I think late in 1989, and then there was a lot of — it didn't get anywhere in the Senate, and it was more or less bottled up.

And then there were the elections in 1990, and Congressman Kastenmeier lost I think in the primary, and was no longer in the Congress to push it, the new Congress to push it in 1991.

I should add though that the burden of my remarks about the history of patentability seeks implicitly at least to locate the development of patent policy and patent law in a larger social economic context.

I don't think you can — this is quite clear in the history of the *Diamond v. Chakrabarty* case, and in which it is clear that a subtext of everything that was going on was first the charge controversy arising from the advent of recombinant DNA in the mid-1970s, and second the emergence of the biotechnology industry from recombinant DNA, starting with Genentech and so on at the end of the
And we are familiar with the boom in biotechnology in the ’80s and since. At the time, in the late 1980s, with the end of the Cold War, there was as you will all remember, considerable attention being given to the competitive economic position of the United States in the world.

And a major feature of that discussion was the role of high technology in maintaining and indeed enlarging our country’s competitive position in the world. And this discussion had started in the 1970s, and it involved computers, and microelectronics, jet aircraft, and now biotechnology.

And if you look at the world trade balance figures, you can see starting way back that in conventional manufacturers our balance of trade was negative and decreasing. Whereas, in high technology at the time, it was positive and increasing.

And so those considerations figured I’m sure in the attitude of the Members of the Congress and other policy makers, and sort of people in our country who pay attention to those things.

So there was a strong inclination at the time not to do anything that would damage the development of this nascent industry, and indeed to do everything possible to encourage it. You can see strong expressions of that attitude in the debates going on right there at the end of the ’80s in parallel on the then new human genome project.

And where biotechnology was understood as a product, and would be an important product of the genome project, and not just information about human genes, but also the technology that would permit you to sequence them rapidly and so on.

And this was going to be very important in arming the United States economically against the Japanese, who were touted at the time to be highly competitive, and they were about to reduce the cost of every base — sequencing every base pair to 17 cents when it was a dollar or more, et cetera.

And so the climate at the time was simply adverse to paying serious policy attention, I think, to these sorts of issues that occupy us today, and I think that is the larger contextual reason that it just died in the Senate.

CHAIRMAN KASS: Michael Sandel.

PROF. SANDEL: Professor Kevles, in your paper you refer to the debate about patenting human genes, and the controversy over the claims filed on breast cancer genes as one example. Have the Europeans under their heading about moral questions, have they rejected or accepted patents on genes?

PROF. KEVLES: Yes, they have.

PROF. SANDEL: Which? Have they accepted them?

PROF. KEVLES: They have accepted them, but I should say that in 1988, and again, at the pending end of the Cold War, the emergence of hi-tech international economic competitiveness and so on, the Europeans, following on the exponential growth of the biotech industry in the United States during the ’80s and based in part on Diamond v. Chakrabarty, decided that they had better do something about — in the community, about their biotechnology.

And so they sought to issue a European Commission, which is the executive arm of the community, sought to issue a biotechnology directive. There was a rule in the community that said that you could not get a patent on things that were the result of the natural biological process, and I forget all the language right now.

And so what they wanted to do was to lay a solid foundation and intellectual property rights for biotechnology. It is a measure of the charged nature of this issue, especially in the European community, that it took 10 years for them to get this directive issued.

And a number of the objections raised to it that held it up were those of the type that I have reviewed in my brief remarks, and that I have reviewed more extensively in the written version that the council has in its possession.
In the end the — and then gene patenting because or grew into an issue during this 10 years. In the end the directive was issued in 1998, and it says that you can't get a patent on anything that impairs or is contrary to human dignity, including I think human organs.

But I don't want to be held to that. I didn't review that for this purpose today. But it does say that you can get patents on genes that are of demonstrated utility.

And this is a response to the attempts by Craig Venter, I think, when he was at NIH, and then later with Celera, or TIGR and Celera, to patent human genes wholesale on the basis of knowing their expressed sequence tags, which is just a small fraction of the gene itself.

And without really knowing for sure what the genes do. So it says that you can get — the European Director says you can get patents on genes. It does not constrain what the property right is, but it does make more explicit than might otherwise be the case what you have to know about the gene in order to get a patent.

PROF. SANDEL: But the patented gene means that you have exclusive property rights to any use that might be derived from that gene? What does it mean to patent a gene?

PROF. KEVLES: Well, it means — and Ms. Hauda can expand on that, but my understanding is that it has a — it means that you have the right to exclude others from making, using, selling, importing, whatever.

PROF. SANDEL: For any use of that gene?

PROF. KEVLES: For any use, that's correct, including research in the laboratory. Now, you can forego that, of course, and you can give royalty free licenses and so on, and say only that you can — that you have to pay royalties to us or whatever, to company X, if you develop a commercial product out of this research.

But that is not the way that it has been working in a lot of cases.

CHAIRMAN KASS: Ms. Kass, did you want to comment just on that?

MS. HAUDA: Yes, two things. With respect to the patenting of genes in the United States, the U.S. patent law also has a utility requirement, and the mere isolation of a gene won't result in the patenting of the gene.

The use has to have a specific substantial and credible use. And so there has to be — and so specific means that they need a specific use for it, and not just a use for further research to study the gene.

A substantial use of the gene means that it has to be a real world use. It can't just be a fluff type use, and it must be a credible use. So the utility requirement requires that applicants demonstrate some good use for their gene before it becomes patentable.

With respect to your second question on the patent rights given in a patent, the patent is — the exclusive right that is granted in a patent provides the owner of the patent, or an assignee of the patent, with the right to exclude others from making, using, offering for sale, selling, or importing into the United States the patented invention without the authorization of the right holder.

So with authorization, somebody else could use it. Ownership of the patent does not provide the owner with the right to make, use, offer for sale, or sell, or import the claimed invention, because there may be other legal considerations precluding this.

For example, the existence of another owner with a dominant patent, or failure to obtain FDA approval for use of the gene, or an injunction by a court against making the product of the invention, or national security related issues, for example.

DR. KRAUTHAMMER: Could you give an example of a patented human gene?

MS. HAUDA: Of a patented human gene?

DR. KRAUTHAMMER: Yes, just so we have some idea.
MS. HAUDA: Sure. An example of an actual gene that has been patented?

DR. KRAUTHAMMER: Yes

MS. HAUDA: Well, insulin and numerous cancer genes, such as the melanoma gene, has been patented.

DR. KRAUTHAMMER: Breast cancer genes?

MS. HAUDA: Yes, Broca-1 and Broca-2.

DR. KRAUTHAMMER: And if you wanted to do research on them, you have to have it licensed if you are going to even study it?

MS. HAUDA: There is a very narrow research exception, that if you are researching for non-commercial purposes, that would not be an infringement under the patent law. But if the research is for commercial purposes, then yes, you would need to get permission from the right-holder.

DR. KRAUTHAMMER: And if you wanted to develop a therapy different from the therapy produced by the patent holder, you would have to get a license from them; is that correct?

MS. HAUDA: Yes. If you want to work with that gene for purposes of commercializing and looking for a new therapy of that gene, you need to get permission from the right-holder.

But that is what allows the biotechnology industry to grow, is that relationship where it is beneficial both to the right-holder to license its gene out and get some benefit from his invention of what he is taught to use it for.

So it is not just the isolation. That person has taught a use for that gene, and the first person to isolate the gene and teach a use for it is the one that gets the grant to that gene.

Further research that wants to continue to use that gene in order to look for new therapeutic uses, for example, would need to get permission from the right-holder, who is the original person who isolated the gene and found a specific, substantial, and credible use for that gene.

PROF. SANDEL: Thank you.

PROF. KEVLES: I just wanted to ask for clarification on the research exemption. My understanding is that there is no statutory research exemption, and that this was an issue in the Kastenmeier hearings in 1987 and 1989.

That there is some common law precedent on specific cases for research exemptions, but that there is no blanket policy of research exemption that you can use something that is patented for basic research of a non-commercial nature; is that correct?

And is that is correct, where does the research exemption on genes come from?

MS. HAUDA: That is correct. There is no statutory research exemption that I am aware of, but there is case law that says a research exemption for non-commercial uses can non-infringement, and just —

PROF. KEVLES: It is not specific to genes?

MS. HAUDA: It is not specific to genes, no.

PROF. KEVLES: So if someone were doing basic research with it on a human gene, they would be vulnerable to action by the patent-holder, right?

MS. HAUDA: The patent holder certainly could bring an infringement suit, yes.

CHAIRMAN KASS: Robby George, then Janet.

DR. ROWLEY: I am directly related to this.
CHAIRMAN KASS: On this? Okay. Please.

DR. ROWLEY: Because at least in my own experience, and I am not sure whether Liz could comment as well, if you want to work on a gene or use a technology that has been developed by someone who owns or holds a patent on that, you can write for permission to use that and study it.

And you define how you want to use it and study, and then you get or there is an intellectual property agreement, a material transfer agreement, that you can sign. And it is signed between institutions. So the lawyers and the various institutions then will give you permission to work on it.

But many times those intellectual property transfers also do say in response to Mike's question that if you find some further use that was not included in the patent, that use then reverts to the person who made the original observation.

And sometimes these material transfer agreements can take months to achieve, and it is I think an impediment to free science. And I think that as a matter of fact there have been comments in Science Magazine and elsewhere on this very issue.

DR. FOSTER: Just one quick reminder from yesterday when Patricia Baird talked about the Breast Cancer I and Breast Cancer II gene in Canada, you will remember that they had an — well, they were required not only not to test for the gene in their own laboratories, but to send it to the laboratories of the patent holders for BCRA1 and BCRA2, with a marked increase in the cost.

Such that apparently Provence has decided that they cannot test women for this because of the expense.

PROF. KEVLES: I would just add to what Dr. Rowley said, that the situation is in some cases approaching paralysis, the paralyzing of research, and that the problem is compounded if the research being done in University A, which generates patented object or the material object, is supported by a biotech company, which will then have dibs on what the laboratory can do.

So you can imagine just the material transfer problem of arriving at an agreement when there is a corporate patron, a researcher in one university, and then the possibility of exactly the same in a second university.

CHAIRMAN KASS: We have run over. We started late due to a fault of the headquarters just on the starting time, and we have gone over and we have another panel.

Let me ask Robby George, who is on the list, if you want to comment, and then we will close this and take a break, and take the second panel. Robby, did you —

DR. GEORGE: I will waive it.

CHAIRMAN KASS: You will waive it? Okay. Since we are running late, let's keep it sharply to a 15 minute break. The second panel will convene, and then if our two guests now will stick around or can, we might at the very end if there is time bring you back and have a discussion with everybody included.

We will convene in 15 minutes, and thank you very much for the presentations.

(Whereupon, the meeting was recessed at 10:16 a.m., and resumed at 10:36 a.m.)

SESSION 6: REGULATION 4: PATENTABILITY OF HUMAN ORGANISMS 2: ETHICS AND PUBLIC POLICY

CHAIRMAN KASS: Would council members please return so that we can resume the meeting. We convene for our second session on the patentability of human organisms. This time is the question of ethics and public policy.

We are very fortunate to have three very well suited members for this discussion. Steve Holzman is the president and CEO of Infinity Pharmaceuticals.
He was the co-founder and co-chair of the Bioethics Committee of the BIO organization, and served on our predecessor body, the National Bioethics Advisory Commission.

Andrew Kimbrell is a public interest attorney interested in these patenting questions for a long time as the executive director of the International Center for Technology Assessment, and a more complete biographical sketch you will find at your place.

And finally Professor Arti Rai, who is a Professor of Law at the University of Pennsylvania, whose expertise is the area of biotechnology patenting, and who has provided us with a paper in advance, which I hope that everyone has had a chance to read.

We will go in the order in which I have just mentioned, and I turn it over to Steve Holtzman. Thank you all for coming.

MR. HOLTZMAN: Thank you, Chairman Kass, and thank you to members of the council for letting me speak here. As Leo mentioned, I spent the last five years attending some 40 plus meetings of the National Bioethics Advisory Commission.

I wish you well in the endeavor. I found few things actually as fulfilling in my entire life as sitting on such a council, and if you take your job seriously, you can do important things. So, go for it.

I have a power point presentation, and I know that is not considered good form for a philosophical reflection, but too many years in industry. And I put it on my company’s logo more than anything else not to advertise, but rather that I am up here speaking as Steve Holzman. I am not here speaking as the designated representative of the biotechnology industry.

There is probably some overlap of how I think the industry thinks, and traditionally the industry finds me a little odd in how I think, but that makes it consistent with the rest of the world. So here we go.

Leon called me up and said he wanted me to talk about three questions. The first was the impact in a narrow sense on the biotech industry if we prohibited patents on either or both processes of making isolated human embryos, or on claims covering the isolated human embryos themselves.

The second issue was to think in terms of the broader impact on biotech if we were to establish a class of biological methods and/or entities as prohibited subject matter under the patent system.

And the third, time allowing to provide some ethical reflections on the social meaning of allowing or prohibiting such patents. And he didn’t answer this, but it got me thinking about the role of bioethics councils.

So I want to start with three definitions. I am not saying that these are the right definitions. I am saying that for the purposes of this talk and a series of reflections, these are what I mean.

First off, by a human embryo, I mean a biological entity, which all things being, if you plant it in a woman’s uterus and leave it there for nine months, the result is a human child.

I actually think that is a very useful and ethical debate, and just call a spade a spade, as opposed to starting to get into counting angels on pinheads.

So that is what is in play in this discussion. It’s regardless of whether you achieve the diploid nucleus by in vivo or in vitro, by intercourse, by IVF, SCNT. I don’t really care, okay? And it is regardless of whether you are talking about a zigo, to pre-or-post neural streak, or blastocyst, et cetera.

I am putting them all in the same bucket for the purposes of this discussion. The second definition is a research purpose embryo, because I think that is really where the nub of the debate is.

And I mean an embryo created without a reproductive intent, but rather with the goal of using it, hence destroying it, in biomedical research or therapy.

In those terms, a spare embryo left over from a reproductive effort, if used as is, is not a research purpose embryo. However, a spare embryo in which SCNT is performed, creates a new embryo which may or may not be a research purpose embryo, depending on whether or not you put it back in the uterus or you destroy it. Finally — I’m sorry?
DR. GEORGE: I wonder if I could interrupt. I just did not understand that point. A second embryo is created from a spare embryo?

MR. HOLTZMAN: I think that is an important point. There is the problem with saying that we get around the problem of research purpose embryos by simply using spare embryos left over in IVF clinics when the reproductive project is finished.

When you then do SCNT on it, you effectively create a new embryo with the intent of destroying it and using it in research.

DR. GEORGE: So do we then have two embryos?

MR. HOLTZMAN: No, you have one. The first one ceases to exist.

DR. GEORGE: Leon, do you understand this?

CHAIRMAN KASS: I think so.

MR. HOLTZMAN: It may be that it is not that important for this discussion.

CHAIRMAN KASS: Let it go.

MR. HOLTZMAN: Okay. The third is to get some clarity on what is a patent right, and this is a definition which is not must mine. It is the right to prevent others as you have heard absent a license from making, using, importing, selling, or distributing the patent invention.

Hence, it is not a positive right. It is not a tangible property right. It does not block new patents. If I have a patent on fire engines, and you come along and notice this tall building and create a fire engine with extension ladders, you can get a patent on fire engines with extension ladders. Patents don’t block patents.

And then with respect to the basic research exemption, which is not in the statute, it does exist in common law in the case of Roche v. Bolar by implication, where effectively the court found that there is no such thing as basic research in a for profit entity.

Conversely, there is such a thing as basic research outside of the scope of patent prosecution in non-profit entities. And pragmatically there is a basic research objection, because businesses don’t go about suing universities unless and until the universities start acting as competitive businesses.

To the point that was raised by Dr. Rowley and Dan when he was up here about the problem of MTAs and what not. There has been a lot of work done on this, and there are significant issues.

I served on Varmus’ working group that came forward with a report on how we might better deal with it, which was largely ignored. I am currently serving on the National Academy of Sciences Council or working group coming forth with a report in the next few weeks on what we should do in the case of access to research materials that are published.

So if the council is going to get into that issue, there is a rich history there. There are issues. I actually don’t think they are essentially about patents by the way. I think they are about contractual rights pertaining to transfers of material.

Anyway, so question one, what is the impact narrowly on biotech industry if we prohibit either or both of these kinds of patents on processes, of making, or on the human embryos themselves.

So let’s get a conceptual picture of what we are talking about. You start with the starting material, and there is a process-A, and it gives you a product-A, and the product-A itself can be the subject of further processes to give you further products.

And let’s give an example of what might be in play here. So the starting material, it was oocyte, right? And so process-A might be a method of making an embryo especially suited for generating universal donor cells and multiple cell types of for transplantation.

Wherein, the method compromises, you add genes X, Y, and Z, and so that they can go on to immortilizing culture, and you delete Genes A, B, and C because those remove the MHC complex in
order to make them universal donors.

So the Product-A would be the embryo would be the embryo that resulted from such a process. And then what would you do with it? Well, you would do further processes to make particular universal cell lines; for cardiac, kidney, neuron, et cetera, and then Product B would be those kinds of tissues.

What is the relevant current policy as it stands right now? The process claims are all allowable. The human product claims are not allowable by policy, and as you have heard in the case of In Re: Allen, Quigg, from the USPTO, came forward with the statement that a claim directed to or including within its scope a human being will not be considered to be patentable subject matter.

And again as came up in the last session the key question is what is a human being. Do you mean a person, the kinds of things sitting around this table who are subjects of rights and responsibilities? Do you mean persons and embryos?

Do you mean persons and embryos in human cells? So what is patentable in the scheme I just gave you looks like this. All of the processes, currently those downstream products, the cells, and the Product-A, wherein that is the embryo, that is a little bit unclear, though pragmatically the way that it is playing out is that they are not being patentable.

And that is the de facto situation. They are not being granted. It’s claimed to follow from Quigg, but actually it really doesn’t follow from Quigg whatsoever, and I will talk about that in a bit. And the reason that they aren’t the de facto situation, and this is my analysis, is that it just was not an issue up until recently, number one.

And then, number two, now that it is, it is a political hot potato, and the USPTO is good to duck its head and just not issue the claims. But what are the practical implications of the current situation?

To understand it from a business perspective, you have to know one more piece of patent law, and it is 35 USC 271.G. And that is that it shall be an act of infringement to import, sell, or use within the U.S. a product which is made by a process patented in the U.S. if such action occurs during the term of such process patent.

In other words, a patent holder on Process-A can block or receive just compensation on the sale or use of products B, B prime, et cetera, if he can show that the competitor used a Product A made by Process A, even if the competitor did not practice Process A.

CHAIRMAN KASS: Would you do that again?

MR. HOLTZMAN: Okay. Take a moment and read it, and I will go back to the schema. Under 271G, if I have a patent on Process-A, I have the right to prevent others from importing, using, or selling Product A, okay?

So if you think that you have a commercial product that you care about are those Products B Prime through B Triple Prime, the sell lines, if I can show that someone has used Product A in making it, I have got them on an infringement under 271G, okay?

You wanted me to answer the narrow question and I am getting at it. This is it. So if you say the council recommends that there is no patents on the methods of making the human embryos, no Process-A claims, I would submit that it would significantly reduce, if not eliminate, incentive to private investment in the development of Product A, there is no protection.

If research to develop methods to produce A is privately funded, you would be a fool to publish it, and you would also be a foot to let Product A out and make it broadly available.

On the other hand, if you leave intact the process claims, but you say there shouldn’t be any product claims, no human embryo claims, what the industry will effectively do is operate as it does now. You rely on that 271G protection.

It is not as strong and compelling when you are trying to raise funds, and a lot of this is about young companies trying to raise funds, and it does fall on you that the burden of proof to show that when someone uses Product A, that in fact Product A was produced by Process A.

Another interesting issue that you will have to deal with is what is it when — what about when the
university, for example, practices Process A to make the embryo and then transfers it to someone else. Who do you go after?

And then there is the temporal concern. Someone practices the method, the protected method of making the embryo before your patent is actually issued, and then someone uses the product after the patent is issued.

They are outside of the scope of being able to go after them. So the bottom line conclusions, if there is no Process A and if there is no patents available in this area in either methods of making embryos, or embryos of themselves, you won't get early stage investment, and you won't get private investment in early stem cell research.

But if that is your goal, go for it. You will have to rely on the public sector to research and develop the products of Product A type, and concentrating private investment in the process downstream of making the actual cell lines. An interesting situation when we don't have Federal funding for making the embryos in the first place.

On the other hand, if you leave intact the Process A patents and say we don't want embryo patents, the Product A patents, industry investment and early stage stem cell research will continue relying on 271G protection, but it will be moderated exactly as it is now.

So, question two, the broader impact on the biotech industry of establishing a class of biological methods and/or entities as prohibited subject matter under the patent system. So you have already heard this.

In the United States, the criteria of patentability are four-fold; novelty, not obvious, utility, and enablement. In Europe, you have heard the situation is different, but I think there is a distinction that I think people fail to make in the last sentence.

There is a fifth criterion; the invention must not be contrary to public order. That is, it must conform to morality. But Article 53A is not relevant to a category of subject matter as such, but rather to the use of particular inventions.

It doesn't say, for example, that animal patents are not allowed. It rather says that you can make a distinction between the Onco-Mouse, a mouse whose utility lies in a system for developing cancer drugs, and hence is allowable under the fifth criterion.

But they can judge not patentable the transgenic mouse who glows blue in the dark and is therefore a designer fluorescent mouse because that is considered to be contrary to morality. It is an important distinction between what you are discussing here is whether there ought to be a law that goes to removing categories of subject matter.

You do not have a precedent for that in 53A. You have an otherwise where they have eliminated, for example, in certain countries patents on plant varieties and what not in species.

In terms of international trade, the U.S. in general has been a strong supporter of patent protection, particular in biotech. The U.K. has already issued claims covering human embryos, and you heard reference earlier to the TRIPS aspects of the WTO agreement.

It does allow countries to exclude from patent protections classes of technologies, but only if the development and use of the technology is prohibited in the country. That is an only if, and not an if, okay?

And no provision — there is no provision for exclusion of patent protection in the absence of the prohibition of use. So in other words, if you were to recommend no patents on the technology, I would suggest to be in conformance with this that you had better be recommending that the technology not be practiced.

Now, what about the role of morality and utility in the United States? We have heard some discussion, and let's be clear that there is nothing in the 35 U.S.C. 101 of what is patentable that makes any reference to patentability.

It is all about case law, and I would submit to you that there is now a well evolved tradition that patents are value neutral. That in this country, we regulate the use of inventions, and not the
issuance of patents.

The case from 1817 or whatever that was referenced was about the definition actually of a specific utility being sufficient. There was a tradition in the 1900s as manifested in the Reliance case up there that effectively — that if something is injurious, it lacks utility, and it was the doctrine of what is called beneficial utility.

But there has been a long tradition of cases throughout this century, and Fuller versus Berger, I think, says it very well, that utility cannot be negativized by the mere fact that the thing in question is sometimes injurious to morals, or to health, or to good order.

It would be fatal to patents for many of the noblest inventions of the 19th century, and the previous speaker mentioned the Juicy Whip case recently, where the invention effectively enabled one to defraud, but it was held to be patentable.

So when we think about how this has swung over and the broad issue in biotechnology, there have been a series of cases — let’s see, I put up four of them up there, three of which you have heard about, which have raised the morality issue.

And they are Chakrabarty v. Allen, which was the oyster case, where it was actually decided that crier organisms were not inherently unpatentable, and then the Leder mouse, and the Onco-Mouse.

The Quigg statement was in connection with Allen. We didn’t mention by the way Pasteur, some hundred years before Chakrabarty got a patent on an organism, which always strikes me as very interesting. So when we look at reactions to these cases, which leads to talking about bans on biological inventions, or can be read as such, I didn’t have time to research whether or not there was a public outcry when Pasteur got his patent on baker’s yeast.

But certainly in reaction to Chakrabarty, we get statements such as the World Council of Churches, a statement that the U.S. Supreme Court on patenting life forms rested upon a specific and highly reductive conception of life, which sought to remove any distinction between living and non-living matter.

The Chairman of this Council made the statement, and I hate to take things out of context, but that Chakrabarty teaches that a living organism is no more than a composition of matter, and no different than the latest perfume or insecticide.

And then in response to Allen and Leder, we had Rifkin saying that the PTO has decided organisms are indistinguishable from electric toasters and automobiles.

One can take these as statements suggesting there ought to be a ban on such inventions. What are some of the beneficial results of not overreacting and not banning that we have seen in the past? Well, in Chakrabarty, it is the intellectual property basis for the recombinant DNA-based biotechnology industrial revolution, which has produced over 120 drugs to date.

I submit to you that would have been bad overreaction. In the case of Allen and Leder — and I should say that I am intimately familiar with this, because I founded the first transgenic animal company, and I was the person testifying on Capitol Hill in ’88 about animal patents.

Transgenic animals, whether it be by gene-addition or knockout, are the single most powerful tool we have for understanding gene function today, and understanding the role of dysfunctional genes in disease initiation and progression, which is the whole basis of a new kind of medicine that will actually hope to prevent and cure, as opposed to merely palliate symptoms.

And furthermore the prospect of transgenic animals that are a source of important medicines and treatments would not exist, and those medicines are things that can only be produced through those animals, such as certain proteins, antibodies, and organs for transplantation.

So the bottom line is from the industry’s perspective, of my view of the industry’s perspective, is to talk about banning a set of or subject matter as patentable is a precedent setting Pandora’s Box which we do not want to open because we do not believe it is controllable.

And we are put in the unfortunate situation of what I call the how long has it been since you stopped beating your wife problem, and assigned by culture. So you believe that we should have a patent law
that views human embryos as morally equivalent to toast and perfumes, and answer yes or no.

But that is the situation, and so we are forced to duck and weave on this one, but we have deep concerns that I just have tried to articulate. The third question was ethical reflection on the social meaning of allow or prohibiting patents on human embryos, and for my two cents in the role of bioethics councils in such debates.

The first thing is that patents — you know, you just listen to the dialogue around the table a few minutes ago, patents are — somehow when we talk biology — as bad things, bad things, patents. But in fact patents have a very noble history.

They are enshrined in the Constitution, not merely in legislation, all right? And I am going to give you a moment to read this, because it is one of my favor pieces of writing by Jefferson, because it really goes to the heart of what is a patent and why we have them.

Because inventions, that is, creative ideas, cannot be the subject of tangible property rights, and that we want people to share them. And his image of the taper is so beautiful because in doing so they are not diminished.

However, as a society to encourage that sharing, the creation and dissemination of knowledge, we want to ensure that there is a proper incentive system for doing so. All right.

Now, that ties interestingly when you think about that to the question that has come up also is can nature be patentable. And you heard people say, yes, nature is not patentable, or referring, for example, to the Tungsten case, which I think is from the early 20th century.

But it is very, very, clear — and I think this is the best statement I have ever been able to find of it in Merck versus Olen, that nature is patentable if that which is natural which you are seeking to patent meets the criteria of novel, non-obvious, a utility, and enabled.

The particular case here had to do with Vitamin D-12, and other cases in this realm as we mentioned was the prostaglandins. That you isolate so that the logical form of the patent claim is that you present something that doesn't exist on its face and nature, but you isolate it.

And again as the court points out in Merck, all of the tangible things with which man deals, and for which patent protection is granted, are products of nature.

And I think here we need to start doing some philosophy, and make some key distinction. The first is that a patent right is not a property ownership right in the physical embodiment. The patent right is the right to prevent others, that is, from profiting from the invention by making or using, selling or distributing, embodiments of the invention.

In a moment, I am going to ask you to think here about copyrights, and patents, and just for the moment assume that they are equal. This is a disk, and I own this disk that I am holding, all right? I can play it. I cannot copy the sympathy. I cannot resell copies of the sympathy.

If any of you are authors of books on which you have copyrights, the question came up about whether or not if you are the patent holder on BRCA1, you have the right to prevent others from using it if in fact it would be cheaper for them to do so.

If you are a copyright holder on a book and I can't afford your book, but I could afford to go down to a copy shop and copy it so I could read it, you have a right of enforcement against me.

The second is that the physical substance is not the invention. It is not the patentable subject matter, and it is not the idea; the physical substances, the embodiment of the invention.

It makes sense to say I am holding in my hand Shostakovitch's Fifth, but when I drop it and break it, the symphony is not destroyed, all right? So if you keep that in mind, the basis of the patent system of granting intellectual property rights is two-fold.

One is a natural product rights orientation, in terms of getting the fruits of one's labor. They are not able to be protected like tangible property. I can't put a fence around it like I can put on land. And then in the utilitarian concept, there is a public interest in sharing the ideas, and we want to reward the inventor and encourage the dissemination.
So with that as a backdrop, I want to suggest to you that there is enormous wisdom in Quigg in response to Allen, and it is no what you have heard articulated today here by the patent office, or perhaps even by Quigg himself.

He wrote that a claim directed to or including within its scope a human being will not be considered to be patentable subject matter. That is not a moral argument, and it is not about being contrary to public policy pace what we heard from the USPTO.

And for that matter, neither a human invention or a patent on it would directly contravene the 13th Amendment. Rather, I think what we have in front of us here is what Wittgenstein would call a piece of philosophical grammar; an elucidation of the concept of a patent, and it goes something like this.

It makes no logical sense to grant an intellectual property right, consisting of the right to prevent others from making, using, or selling embodiments of your invention, if it is in the nature of all such embodiments of your invention that they cannot be the object of a tangible property right to begin with.

In other words, being able to be owned is the precondition of one having a right over the embodiment so as to be within one's rights to make, use, or sell it.

So is there a gap in the law? In Leon's invitation to me, he wrote we seek to discover whether there is a gap in the present law that would allow for the patenting of a living human organism, and if so, whether it should be closed?

I would suggest to you that there is absolutely no gap in the logic of the law. An invention could be patented only if the living human organism, which is its embodiment, can be the subject of a property right.

And so what we are faced here with is thinking through this thorny set of issues, and I don't pretend that what I presented to you is necessarily easy to follow.

Leon is very — with wisdom, has written of the wisdom of repugnance and the role of bioethics councils, and in the background papers that were prepared for this council beforehand, there was good attention paid to the fact that it can be a visceral response to repugnance.

But it is the role of such councils to elucidate the roots of the repugnance, because otherwise we could find ourselves prohibiting miscegenation, for example, at a certain time in history.

And what we need to do here, and what you need to do, and I hope that we all do, is provide a non-sound bite discourse that enables us as a people to get it right, and to make those key distinctions, and to debate the right issues.

I think there are great examples of this in predecessor councils. I think the President's Council in Splicing Life in 1981, at a time when there was visceral repugnance to the notion of genetically engineered human beings, and eugenic concerns, came forward with what is now an obvious distinction between somatic and germline gene therapy.

And drew the important similarities of somatic gene therapy and currently accepted medical practices. When I transplant an organ, I do a gene therapy of 40,000 genes, for example, somatically.

And that the key eugenic concerns are only in play in germline cases, and that allows progress on one front, and with deep social reflection and deliberation on the other.

And similarly the last council NBAC I think contributed to that in the cloning debate, and again an obvious distinction now between reproductive and non-reproductive cloning, and in stem cells by calling attention to what it believed to be the moral legitimacy of supporting Federal funding for using, but not generating, ES cells.

So what does that mean for you? Focus on the real questions. This is really what is in play. We are undergoing a revolution in biology which is as profound as the Copernican revolution; not only scientifically, but in terms of our understanding of ourselves and our relationship to nature.

And it forces us to ask questions about can we maintain an attitude of reverence; that is, taking
something in its perfection consistent with an engineering perception or prospective. That is, that we are going to manipulate it.

And then focus on just allowing ownership and inter alia patenting, and focus on the ownership of human embryos, and does that fundamentally and irrevocably commit us down a path of reductionism and an overwhelming materialistic view of life.

You might in that sense start to investigate our attitudes to the human, and here are some various human parts and organisms. Think about how differently you feel about these things, and how we as a society stand in relationship to them.

Deeply interesting to me is, for example, you cannot sell blood. You can only donate blood in this country. On the other hand, you can see plasma. Why is that?

And I would submit to you that most of us at first blush think of oocytes very, very differently than sperm, and how we think they ought to be regulated apart from issues having to do with the safety of the woman from getting the superovulatory regime.

Broaden the range of cases of reflection when you think about research for purpose embryos, because not all research purpose embryos have the same social meanings.

Every time in these debates every one has in play the notion of the — of what would happen to our views of reproduction in the family if we allow the creation of embryos for the purpose of destroying them.

But go read U.S. Patent 4,987,080, called, "The Method of In Vitro Maturation of Oocytes." There is an invention and it doesn’t work very well, in which, for example, if a woman has an ovary removed because it has a cystic condition, you can keep it alive in culture, and it will produce oocytes for you.

There is no mother, and there is no father in play, and there is no reproductive project in play. If I take one of those oocytes out of that machine, and IVF it, or SCNT it, and then go on and do experimentation, do you feel the same repugnance. Do you feel in the same ways that what you are imagining is your paradigm case when you thought of repugnance in research purpose embryos.

Don’t get caught on the one-sided diet of examples. So I would submit to you that you will do yourself and the public a disservice to get sidetracked on to the patent issue unless you use it to confront the real issue, which is the creation, ownership, and use of research purpose embryos, and to do so in all its richness.

And once you have done that, and if you conclude in your wisdom that you should recommend that there ought be no creation, ownership, and use of such things, then your conclusions will follow logically into the patent system, and there will be no patents on such things.

I would oppose you, but I would feel that you were being consistent. Thank you.

CHAIRMAN KASS: Thank you very much. The second presentation by Andrew Kimbrell.

MR. KIMBRELL: Thank you, Dr. Kass, and I want to thank the council for inviting me this morning for I think a long overdue discussion. You know, when I was first working with Senator Hatfield to set up the first Bioethics Advisory Committee, the very first thing they were supposed to look at was patents, and they never got to that.

And so I think it is quite extraordinary, and I personally appreciate it very much, not just for inviting me, but that we are talking about this subject this morning this morning.

I would like to do three things with my talk. The first is to try and give you an idea of where I think we are on this issue. The second is, and this actually feeds very nicely off of Steve’s presentation, the second thing is to try and provide more or larger bioethical context about the human body, and some of the issues that surround that.

And the third is some suggestions, at least from my part as an attorney, on where I think we might go with this and some of the precedence that you might look at to try and resolve some of these admittedly extremely thorny issues.
And that is even before somebody brought in the ideas of Wittgenstein. First of all, I think I differ from the previous speakers in telling you that I think that we are way past the line that others have talked about.

Just a few weeks ago — and by the way, we will be providing the council with two papers that Peter DeMauro of my patent watch program, and Doug Hunt, of my human genetics program, will be providing the council.

And so we will have all of this in writing with footnotes for you. First of all, we believe that the patent office, in patent 6,311,429, has actually already allowed the patenting of embryos, fetuses, and actually borne children.

This was a patent that was granted in April of 2001 for the process essentially of the cloning of mammals, the cloning that you have all heard about.

And both the patent holders and the attorneys involved believed exactly as Steve was saying, that 35 U.S.C. 71G extended that process to all products thereof, specifically claimed by the patent holders and into the subsequent media uproar, and the attorneys admitted that though they had no intention of using it, that the scope did go that far.

Subsequently, we have discovered yet another patent, which I will provide you, that is a patent on germ line modification. This is genetic engineering germ line modification of mammals, and once again you heard Karen Hauda say that we are very, very careful to use that word non-human before all claims.

In both of these patents, the word non-human is not there, and the University of Missouri patent that is on cloning, and on human clones, the word human is there. So the idea that the patent office has consistently used non-human when it is granting patents on mammals or on cloning, or on germ line genetic engineering of mammals, is not the case.

It did not happen in April of 2001, and it did not happen in April of 2002, and there is numerous pending patents that we have identified and that we can provide you that again specifically asks for the patenting of human embryos, fetuses, and in certain cases the extension into borne children.

So the urgency of the discussion today isn't something theoretical, or that we are afraid that we are going to extend In Re: Allen further, that extension has already happened. That extension has already happened with granted patents.

And if you have been listening to the debate on the floor, when a bill is introduced in the Senate just last week to try and forbid the patenting of embryos, and fetuses, you will have heard Senator Kennedy and Hatch say that they do not oppose the patenting of embryos and fetuses.

They believe that kind of patenting is important for research. In that regard, let me clarify something that was discussed earlier. I was lobbying on the Hill trying to support the Patent Reform Act of 1989.

That was subsequent to the In Re: Allen decision that you have heard about that allowed for the patenting of animals. We are trying to get a research exemption in that bill both for researchers and for farmers, and so they would not have to pay patent fees on animals.

At that point, Henry Hyde, who was on the subcommittee, asked Bob Kastenmeier, well, what about humans, and what about human organisms in all phases of development, and Bob Kastenmeier said I don't know.

So Henry Hyde asked the patent office at that time are embryos and potentially fetuses patentable. The patent office said, yes, they are. That is why Henry Hyde put that amendment into the 1989 Patent Reform Act.

And the reason that the patent office gave at that time — and I was glad to hear today that they seemed to have changed that to some extent, but this shows you how mutable this is at the patent office; is the reason that you cannot patent persons was because of the 13th Amendment considerations in the Constitution, and therefore, human life forms that were not considered persons, were patentable, because they would not face that same Constitutional objection.
Let me add by the way, that if you look at what has happened since In Re: Allen, that is, the decision that allowed for the patenting of animals, that there are literally hundreds of animal species that have now been patented, and a significant percentage of those animals have human fetal organs, including brains, pituitary glands, virtually every fetal organ, implanted in them.

And this includes several patents which we will provide you that talk about the patenting of 36 week old fetal tissue in mammals that range from mice through beagles.

Now, I may not be necessarily able to talk about the delicacies of Wittgensteinian embodiment, but I can tell you that we have patents currently for 36 week old fetal organs in animals, from mice to beagles, and we have already allowed through our patents on cloning and our patents on germline modification, the patenting of human embryos, fetuses, and even born children.

So that is the situation from our point of view that you are facing today when you look at this issue, when you look at how we are to treat this issue.

And I thought that once given that perspective of where we are, and what is actually happening, I personally would call that both an ethical and legal free fall, not only at the patent office, but also in Congress, that should have been overseeing this since 1980.

Note that there has been no legislation since the Chakrabarty decision that allowed the patenting of a microbe. The patent office extended that to plants in '85, and to animals in '87, and to human genes, organs, animals containing human organs, and now to cloned and modified human embryos, fetuses, and born children from a microbe.

And I ask you today — it was a 5 to 4 decision in Chakrabarty, a very narrow decision, and most people thought it would go the other way, but do you really think that it still would have been a 5 to 4 decision if instead of an oil eating microbe, which is what they were looking at patenting in 1980, if they were looking at cloned human beings or fetuses with human fetal brains, or rather mice with fetal brains, and beagles with fetal brains, and do you really think that would still have been a 5 to 4 decision to allow the patenting of life.

Having said that, I do agree with Steve on a couple of things, and I am glad that he explained the extension of 271G, because then I didn't have to, and it is a hard thing to explain, and I think he did an excellent job at that.

I do agree with Steve that we have to look at this in the larger context of what I would call the engineering and comodification of life. This is not an isolated incident. You know, so often — and I am guilty of this a lot, but we tend to look at these biotechnology issues and other issues with kind of a technological amnesia.

We kind of forget the historical basis, and so very briefly, because I don't want to overextend the time, I do think it is important to — or at least from my perspective, that we look at the context.

The issue of the comodification of the human body — really, the first case that I know of and that I have been able to document, was really in 1962, and it had to do with the sale of blood.

Many doctors, and doctor organizations, refused to take blood that was from people — it was sold blood. It was commercialized blood. Instead, they were only taking blood that was donated. Several commercial blood banks sued these doctors, saying that blood is a commodity, and by discriminating against us because we are using blood that is sold, you are essentially interfering with our trade, and they went before the Federal Trade Commission.

They won that case, and went to an appellate court, which said that blood is indeed a commodity and indistinguishable from other commodities, and can be sold.

And contrary to what Steve said, blood is still sold in this country, and it is sold internationally. It is a multi-billion dollar a year industry. However, Congress did step in and made sure that there was special protection for donated blood.

The same issue came up when technology was able to develop just the transfusion technology and led to this controversy over blood, because blood suddenly became valuable, and we began to learn how to transplant organs.
So, not surprisingly, organs because very valuable, and as many of us remember, for many, many years, all the way through to the early '80s, there was advertisements in the local newspapers for corneas, for kidneys, for you name it. Organs were for sale as they remain in many countries around the world.

It wasn’t until the Organ Transplant Act of 1984, one of the first things that I was involved with when I came into Washington, that we were actually able to get Congress to agree that organs, as far as transplantation, should not be a commodity. They should not be treated as a mere commodity.

Unfortunately, organs still can be sold for research, and Congress sort of cut that deal. Subsequent to that, we had the whole issue of fetal tissue, and can fetal tissue be a commodity. Can that be sold.

Well, for many years it was, and some would argue that it still is. At least in 1988, as part of the Public Health Act, we were able to pass a law for baby open sale of fetal tissue. However, fetal tissue is still sold under the guise of fees, access fees, and as I said before is patented.

The next major controversy that at least I was involved in, involved surrogate motherhood. Can you sell motherhood. Can you sell the baby that results from that. Again, our nation is sort of split on that, and you have got 16 States that have forbidden surrogate motherhood as the illegal sale of a child and gestation.

And as the infertility industry develops, sperm and eggs have become very valuable. Most States allow their sale as commodities. Many of them have been patented.

And then finally with the advances in genetic engineering, we arrive at this table today on what do we do with human genes, stem cells, and now embryos, fetuses, and perhaps even borne children.

How far will we allow the extension of the market, the extension of our economic life, into the body proper. How far will we let engineering principles into the human body, and what is at stake if we do that.

So this is obviously a thumbnail sketch and our paper will go into more detail, but I did want you to be able to see — some may call it a slippery slope, and some may say we are just skiing downhill.

But I did want you to see both — not just from Chakrabarty, but with these concepts of the commercialization and the engineering of the human body that this is certainly a continuation of a longer discussion.

Let me read you a couple of things about the potential implications of this. I was asked to be a speaker at the 16th International Congress of Genetics, and I was especially taken by the keynote address of Dr. Robert Haynes, a very respected geneticist.

And I would like to read you from his keynote address. "For 3,000 years at least a majority of people have considered that human beings were special, were magic. It is the Judeo-Christian view of man. What the ability to manipulate and patent genes should indicate to people is the very deep extent to which we are biological machines."

"The traditional view is both on the foundation that life is sacred. Well, not anymore. It is no longer possible to live by the idea that there is something special or unique, even sacred, about living organisms."

And that was his keynote speech. Much of my work in those years was working with the World Council of Churches, and Steve actually put up one of the things that I wrote for the World Council of Churches up there on the implications of patenting and comodification on our concept of the human being.

Virtually every religious tradition has had a very different view, and the Office of Technology Assessment, which I was an advisor at that time, had this to say about the ownership and sale of the human body.

"Virtually all religious traditions offer insights about the value and significance of the human body. For them, the human body is created in the image of god, and therefore, there are limits on what human beings can do with their own bodies, and those of others. There are limits on what can be sold."
Now, we get a lot of religious groups to sign on to that, and a lot of people just from the ethical communities as well, and published an ad in the New York Times, and Senator Mark Hatfield joined in that.

The Times answered us in a lead editorial, called "Life Industrialized." And I would like to read you from the New York Times about — and this was specifically about the patenting of animals and potentially human genes and organs, and we hadn't even gotten to the embryos and fetuses.

The editorial said, "Life is special, and humans even more so. But biological machines are still machines. They can now be altered, cloned, and patented. The consequences will be profound, but taken a step at a time, they can be managed."

And that is the lead editorial in the New York Times about the patenting of life. "Biological machines are still machines. They can now be altered, cloned, and patented."

So I would maintain that there is a very concrete philosophical issue, and not an easy one certainly, that we are dealing with in this whole history of commodification, and now specifically including all life, and specifically human life forms, under Section 101 of the Patent Act.

And that is exactly what we as a community, and we as a polity, what our view of the human body should be. And what I would suggest to you — you know, Chesterton once said that Christianity was not found wanting, but rather found too difficult, and therefore never tried.

What I would suggest to you is despite all the failings in much of our Judeo-Christian culture, and those of many other faith traditions, they have an extraordinary image of the human body, which is the very basis for the rights that we have in our Constitution.

And the basis for such prohibitions on torture that we have and slavery, and these are the basic efforts that inform our rights, and I would ask you what rights in here to a patented industrial machine manufacturer or composition of matter, and what dignity inheres to that.

I can't help but see Dr. May over here, and he had one of the most marvelous quotes that I have heard in a long time, and he said, you know, if you sell the Nobel Prize, you undermine what that would mean. You take all the value out of it.

If you were to sell the Congressional Medal of Honor, it would have no value. If you sell children, you undermine the dignity of what it means to be a human being. What I would suggest to you, all legalisms aside, is that when you patent under Section 101 of the Patent Act, embryos and fetuses in human beings, you have in a very profound sense undermined the dignity, integrity, of what it means to be a human being.

I would like to conclude by putting sort of more of a legal view on this, and disagreeing again with some of the previous speakers on this. I do not see how it is possible, and I don't believe reading the law that it is possible to suggest that our government should interfere in a free market system by granting a monopoly, which is essentially what a patent is.

Without some consideration as to the usefulness, and therefore the public interest being served by that interference in the market. For almost every technology we are taking, the patent office is the first port of call. It is the first policy decision where government appropriations are used to either support or not support a particular technology or invention.

And the court's have consistently said that usefulness cannot and should not be conceived as a requirement of patents without infusing in that usefulness whether this — and you have heard the quotes from a number of cases, and I have one as recently as 1964, that says public interests and public morals should be part, and need to be part, of the usefulness review, and it has been in Europe.

And in that regard let me read you actually what has gone on in Europe, which is that you have heard about Article 53, but no one so far has mentioned the biotechnology directive of 1998, which was adopted by the EPO.

And Article 6 of this directive contains a number of categories of areas where patents are not allowed currently, and that includes human persons at any stage of development. That includes human cloning, in all of its forms.
And that includes human germ-line manipulation, as well as the creation of human and animal chimeras, as currently their directive. So we would not — this country would not be cutting new legal ground, and should create the same categories as non-patentable.

Nor if we were to do so, it would be to put ourselves in an uncompetitive situation, at least with our European counterparts, because they had already done so. Further, I think that it is important, and I have it here somewhere, that we take a look at the international agreements that we are part of, to see whether any ban or prohibition on these processes again of human cloning, and the germ-line modification, and the uses of human embryos, whether if with all forms of human life forms, if we were to ban patenting on those, would that in any way put us into conflict with our international obligations under TRIPS, and I read for you, "Members may exclude from patentability" — and this is TRIPS, The Trade-Related Aspects of Intellectual Property Rights, 1994, part of the General Agreement on Trades and Tariffs.

"Members may exclude from patentability inventions, the prevention within their territory, the commercial exploitation of which is necessary to protect "ordre public" or morality, including to protect human life or health."

Furthermore, let me read you from NAFTA, the North American Free Trade Agreement, Article 1709.2, provides that a party may exclude from patentability inventions if preventing in his country the commercial exploitation of the invention necessary to protect "ordre public" or morality, including protection of human life or health.

And these are agreements that we have legislatively approved, and again already on the books. Again, we would be cutting no new legal ground should we comport our domestic patent law to those. Well, how should we do that, and what can the patent office do.

And Ms. Hauda’s plea for legislation is certainly one that I feel, and we certainly feel that the current legislation pending at least, while not perfect, would be important.

But it is certainly within the Patent Office’s purview to set up a subject matter advisory committee that would review the usefulness requirement of patents and terms as the Europeans do, and many of our other trade partners, in terms of ethics.

Now, the problem with a subject matter advisory committee is that it has the unfortunate acronym of SMAC, but it would be an enormously useful tool that would comport and harmonize us with our trade partners.

And what they would be able to do is that i would recommend that they do exactly what the Europeans have done; set up several categories which are unpatentable, and again all forms of human cloning, all human life forms, germline genetic modification, certain kinds of human and animal chimeras, and those are the categories that I would recommend setting up.

I am sure that many others will have others, or recommend that some of those not be included. Additionally, they would set up requirements as far as publication, for instance, in the Federal Register, of patents that might — for instance, any patent that claims human material would be published in the Federal Register for comment.

That doesn’t mean that the patent necessarily would not be allowed, but it means at least there would be a full public review of it. This should be done at an advisory committee level, and that way the examiners will not have to remember to put in non-human.

You will not have as we have seen two patents granted by examiners which actually include a human. This advisory committee would come in and the series would be promulgated, and therefore the examiners would not have to make these ethical decisions on their own.

I would like to conclude by making just one quick comment, because whenever I have spoken about this, inevitably people say the only problem with this is that we need to cure disease, and we need to come up with new medicines.

And Steve just said something, very, very similar, and very well. Let me say that before 1987 that we made extraordinary advances in medicine without deciding that we had to patent animals and fetal organs in animals.
Until the last 10 years or so, we made extraordinary advances in medicine without needing to patent embryos, stem cells, genes, and now fetuses, and perhaps even borned children.

If a researcher out there who is going to cure AIDS, and who can patent the process, can patent the medication, can patent surgical techniques used, will get world renowned for curing the disease, if that is not enough incentive for that researcher to actually cure that disease, both financial and personal.

And if he says also that I need to patent the mouse I am working with, or I need to patent the genes I am working with, I would suggest that that person is in the wrong profession, and that they should leave medicine and make a living on the stock market floor.

Our medicine has survived beautifully without this kind of patenting, which I do not believe has anything to do with actual creation of new medicines. It is not necessary for that. This is simply with the corporate enclosure of the human body, which is as I have suggested leaves us into a comodification mechanism of the human body which undermines our fundamental values. Thank you.

CHAIRMAN KASS: Thank you very much. Professor Rai.

PROF. RAI: Okay. I have been told that I need to wait until it counts down. We now have lift-off, I guess. I also wanted to thank Dr. and Professor Kass for inviting me to address this very august group, and I have been asked to speak on the very specific question of whether a change in the patent law is necessary as an ethical matter, or is a constitution matter to address the patenting of human organisms.

Before I comment on that question, I just want to clarify a couple of things. The first is that I do think that I seriously disagree with Mr. Kimbrell's suggestion that patents on human organisms or product patents on human organisms have been granted, and I think the 271G issue is a lot more complicated than what he has suggested.

But in any event, the other thing that I want to clarify is the types of entities to which I am referring when I use the term human organism, there is a lot of potential for confusion, and misunderstanding obviously, and I need to focus on organisms that are already either full persons, like all of us standing around here or sitting around here, or are like embryos and fetuses capable of becoming full persons.

I probably need to encompass within my use of the term primeras that would have a plausible claim to Homo Sapien status, but I think that issue is a bit of a red herring, because if we start creating those kinds of human, we are going to have a lot more problems than simply patenting.

We are going to have to then determine how to interpret our Constitution as an initial matter, and so I think that is probably something that is perhaps even beyond the scope of this panel to — well not beyond the scope, but certainly other bodies would be interested in how the Constitution would apply to those chimeras.

I don’t mean to include parts of humans. In other words, I don't mean to include organs, or more relevantly for this discussion, genes, I think. With respect to genetic information the law is clear, and I think there is really no going back, and as an economic matter, they probably should be no going back.

As Professor Holtzman mentioned, the National Academy of Sciences is doing a very extensive study on whether the scope of patents on genetic information may be too large and as a consequence may be inhibiting medical progress as a consequentialist matter, and I think that is the real issue, is it inhibiting medical progress.

But that is something that the National Academy of Sciences is looking into, and actually the Federal Trade Commission and the Department of Justice are also taking a look into that problem.

So in any event, as Dr. Holtzman suggested, there are a lot of other agencies in town interested in that question. Okay. So back to the question that I was asked to look at, which is, is a change to the patent law needed, and the short answer in my estimation is probably not. Why not?

For three reasons, which I will just summarize briefly and then I will proceed to explicate in a little
more detail. First, it would appear that much of the current concern about patenting human organisms of various sorts is really grounded in ethical concerns about the underlying activities that produce such organisms.

So depending on the group involved, this may involve opposition to reproductive cloning, or to therapeutic cloning, to pathogenesis, or what have you. In my estimation, it would be a serious mistake to use the patent law as an instrument of wide-ranging moral regulation.

As you probably already know, there is no constitutional impediment to Congress regulating the underlying activities directly, and in fact there are lots of bills in Congress to regulate those underlying activities directly.

And obviously Congress has shown no hesitation in looking at such legislation that would directly look at activities like cloning or what have you.

And I am not suggesting anything substantive on what we should do with respect to that regulation, but the patent law is the wrong place to look in my estimation. And in fact there may even be a Constitutional problem, which I would be happy to get into in the Q&A, with using the patent power that Congress has to import morality judgments, general morality judgments.

Second, even to the extent that one is comfortable with the underlying activity, and let’s assume that one is comfortable with the underlying activity and let’s say therapeutic cloning, but is concerned with the comodification, and that word has been used a lot already, the comodification of the products of the activities, the patent law is still not the place to turn.

As a general matter, patents advance comodification much less than do other types of property rights, and in particular rights in tangible property. So, for example, when Congress choice to limit the comodification of organs in the context of organ transplantation, it wisely chose if you believe in the limitation of comodification, to limit tangible property rights in those organs.

It didn't go and modify the patent statute, and insofar as I know, one could patent a new and non-obvious organ if one chose to. It seems to me that the single situation in which patents on human organisms may raise ethical concerns that do specifically involve the patent law, is the case which is far from reaching thus far, where patent applications have claims that cover fully developed human beings, as I will talk about persons within the meaning the of the Constitution.

And in that case though, I think the PTO does have the authority to reject those applications as raising serious Constitutional issues under both the 13th Amendment and the 14th Amendment.

Okay. So let me turn to the first issue, and I am going to go quickly through this one because I think that some of these, that some of the prior speakers have touched upon this issue, which is if we are concerned about the ethics of the underlying activities, then patent law is not the place to look.

And historically unfortunately when people have been concerned about the ethics of the underling activity, they have tended to look to the patent law because often times patents reveal what companies are up to well before the company itself is willing to come forward with that information.

So, for example, the heated debate in the 1980s over the transgenic mouse, known as the Harvard Onco-Mouse, was really spearheaded by groups that were opposed to the creation of transgenic higher life.

Earlier on, the patenting debate that surrounded the Supreme Court’s 1980 decision in Diamond versus Chakrabarty, which you have heard a large amount about, was in fact spearheaded by groups that opposed the creation of any sort of recombinant life.

So the underlying activity was what they were really seeking to target. Similarly, it seems to me here that the current debate about patenting is a bit of a sideshow. What we are really concerned about, or the groups that are concerned about patenting, are really concerned about is the ethics of creating those organisms through cloning or other artificial means in the first instance.

Now, as the Supreme Court recognized in Diamond versus Chakrabarty was that regulating scientific research, and the morality of scientific research through the mechanisms of the patent law, is a very misguided enterprise.
First of all, at least some scientists will engage in the research independent of whether the possibility of patents exist. Sociologists of science have long observed that scientists seek prestige and honor, at least as much as they do money. So they will continue to engage in the activity.

And in addition, and perhaps more importantly, pecuniary rewards can accrue through mechanisms other than patents, and most obviously trade secrecy is a mechanism that is often used, particularly for protecting processes.

Process patents can be very weak, and oftentimes biotech companies just keep processes as trade secrets. And in addition to being the first to market with a particular invention is also a time honored mechanism for securing pecuniary rewards.

So to the extent that we are concerned about the ethical horribles that may result from a particular technology, we should just regulate that technology directly.

It seems to me, therefore, that it is not surprising that the patent statute, the language of the patent statute, as has been mentioned, contains no suggestion that Congress intended to import general morality judgment into the patentability determination.

There is nothing in the language as Dr. Holtzman has mentioned, and as I have discussed, in fact it may be it seems to me, that it would be troubling as a constitutional matter for Congress to enact a patent statute that did have something to morality judgments, because its authority under the copyright and patent clause of the Constitution that Dr. Holtzman has already shown us, is limited to authorizing patents and copyrights for the purpose of promoting the progress of science in the useful arts.

And that terminology has not been read to encompass morality concerns. It has been read to encompass purely utilitarian concerns. Now, there has historically as has been mentioned existed within the American patent law, particularly in the 19th Century, a purely judge-made doctrine known as moral utility, and a few decisions from the 19th century in particular relied upon that doctrine.

But it seems to me that the Federal Circuit has made it pretty clear that that doctrine, if it isn't dead, it is pretty much dying. And most patent scholars, I think, would assume these days that even devices that were made for illegal purposes, and therefore could not be used under some other law, could be patentable.

And as several people have mentioned, because the patent right doesn't confer any affirmative right of use, one can have a patent on something and still be barred from using it. So those are two very distinct issues.

And let just talk briefly about the European experience that some of the other speakers have already alluded to. It seems to me that the experience of countries that have more robust morality requirements within their patent system really underscores the problems that arise when one tries to import general morality judgments into patentability.

For example as has been mentioned, Article 52(a) of the European Patent Convention, provides that patents shall not be granted for, "inventions of publication or exploitation of which would be contrary to ordre public or morality."

Well, the patent examiners who examined the Harvard Onco-Mouse patent application in Europe had to deal with 53(a). They were forced to deal with 53(a) by an appeals board; that they initially didn't want to deal with it, and then the appeals board told them that they had to deal with it.

And so they determined that in order to figure out what 53(a) meant with respect to the Harvard Onco-Mouse, they would have to determine first the utility of the invention to mankind in remedying, quote, widespread and dangerous diseases. Second, the possibility of cruelty to animals; and third, the possibility of uncontrolled release of unwanted genes into the environment.

Well, patent examiners are scientists who are hired for the purpose of examining patents on technical grounds, such as novelty, lack of obviousness, and adequacy of disclosure. They don't have any training in ethical issues, or for that matter in making judgments about environment risks, and I would be very concerned if patent examiners were called upon to do that.
Now, concerns about comodification. Some would argue or perhaps agree with me that the right to patent law should not be modified to address generalized ethical concerns about scientific research, but perhaps reform would be appropriate for specific concerns regarding comodification.

In other words, we might be concerned that the research products that are the subject of patents could be sold and bought like ordinary property. So to give this example again, we might be comfortable with therapeutic cloning as an ethical matter, and in fact even endorse it, but oppose treating the human embryo product of that therapeutic cloning as ordinary property that can be bought and sold at will.

Here even it seems to me that when patents fall short of claiming full human beings, it is not clear why we should be focusing our comodification worries on patents. In fact, whether patents are allowed or disallowed it seems to me affects comodification levels very indirectly at best.

The patent grant confers on its holder simply the right to exclude others from making, using, offering, or for sale, or selling the invention. It doesn't confer any affirmative right to use the invention.

So as I mentioned several times now, if we were to allow patents on a particular invention, we could still prohibit selling or otherwise trafficking in the invention, and it seems to me that is precisely the situation we are in with respect to human organs and transplantation.

I don't see any impediment to patents on human organs, but there is a significant legal impediment to trafficking in human organs. Transversely, the decision to ban patents on particular inventions doesn't eliminate comodification.

Absent other Federal or State laws, individuals can still sell and buy human organisms as tangible property, and that is the real property right that one has to keep in mind. It is not at all addressed by the patent system.

Now, there is one context where patents on human organisms could raise patent specific concerns, and this is the context that is far from arising currently, but it is worth keeping in mind.

If product patents were granted on full human beings, and not just human embryos, and not fetuses, but full human beings, these patents might give the patent owner the power to interfere quick significantly with the autonomy of the fully developed human being.

And this is because under the patent law the patentee's power to exclude, quote, others, from using the invention would presumably encompass the power to restrict the patented being, himself or herself, from "using himself or herself."

So as a consequence the patentee might have the authority to forbid the patented being from seeking employment, or perhaps engaging in any type of association.

In addition, because the patent statute also allows the patent owner to prohibit "others" from making the patented invention, the patentee might have control over the patented beings' reproduction, and such severe limitations of autonomy obviously would represent a serious ethical concern that is specific I might add to the patent statute.

Well, this is where the Constitution comes in. It seems to me that ethical concerns about the patenting of full human beings could be addressed through the Constitution and specifically the 13th and 14th Amendments.

The 13th Amendment, as many of you probably know, bans not only slavery, but also what is known as involuntary servitude. And it seems to me that a patent on a human people could be deemed to impose an involuntary servitude.

Now, the 15th Amendment, jurisprudence, involuntary servitude, has needless to say focused on cases where there has been a physical or legal compulsion to work. So it has focused on cases involving bondage, and peonage of various sorts.

But it seems to me that property rights that entirely disallow an individual from choosing his or her employment, or choosing to work in the first place, could fall within the scope of the amendment.
In addition, the patentee's control of the patented beings' right to reproduce it seems to me might implicate the protections of the 14th Amendment. The 14th Amendment protects reproductive decision making, and there is a — well, lawyers would immediately point out, well, where is the State action here.

It seems to me that the State action here is provided by the fact that the patent is a right explicitly granted by the State. So the 13th and 14th Amendments provides the best justification for the PTO's current policy to the extent that it disallows product patents on full human beings.

Now, some commentators in the legal literature have argued that the PTO doesn't have the authority to make those Constitutions calls. That only courts have the authority to make this Constitutional call. I think that this argument is quite mistaken.

Obviously the PTO doesn't have the ultimate authority on any Constitutional question, but as has been mentioned by some of the previous speakers, there is a canon of statutory interpretation that the PTO can and should employ.

And in fact the Supreme Court has suggested that agencies do employ when interpreting statutes, which is try to interpret them so that your interpretation doesn't raise serious Constitutional concerns.

And the Supreme Court has consistently struck down agency interpretations that raise serious Constitutional concerns. Now, of course, an agency can't do that where the statute is really clear and says you must grant patents on human beings, full human beings.

But here the statute doesn't say that. It is at least arguably ambiguous on the question of full human being and it seems to me that under the avoidance canon here could usefully be invoked by the PTO to say that we are not going to grant patents that raise serious Constitutional questions.

And it seems to me that courts would view this issue very seriously or similarly, and they would probably view product patents on full human beings as being a serious tension to the Constitution.

A court would have two options. They could either use the statutory interpretation mechanism, or because they are Article 3 courts, they could just directly declare such product patents to be an unconstitutional application of the patent statute.

Now, it is important to emphasize that these Constitutional arguments, and I repeat do not, apply to patents claiming human organisms that have not been born, such as embryos or fetuses.

The Supreme Court has explicitly stated that a fetus is not considered a person within the meaning of the constitution and if a person is not considered a person, it is unlikely that an embryo would be.

Consequently, under current law there is no Constitutional bar to patents with claims that are strictly limited to human embryos or fetuses. So to the extent that the PTO's current policy denies patents on human embryos or fetuses, it probably lacks Constitutional justification.

But if we are concerned about protecting the interests of human embryos and fetuses, and there might be a good reason to be so concerned, we can urge Congress to pass legislation directly addressing those interests.

And as I have noted earlier Congress has pretty much plenary authority under the Commerce Clause power to address these general ethical concerns, as well as more specific concerns about comodification.

So in conclusion, it seems to me that the issue of patenting is almost in all respects really quite orthogonal, that is, at right angles, to ethical debates on research involving the creation and manipulation of human organisms.

It would be a serious mistake to modify the patent statute in response to concerns about research that are not patent specific. And the isolated circumstance where a human organism or research does raise ethical concerns that specifically implicate the patent system, and that is the case of a product patent on a full human being, these ethical concerns it seems to me can be addressed through the Constitution. Thank you very much.
CHAIRMAN KASS: Thank you very much. Michael, did you want to raise a question? I thought you were leaning forward. I guess I would like to invite the participants in the first panel to join us at the table.

While they are joining us, let me start with a question to Professor Rai. You say that the patent protection does not confer any affirmative right on the use or upon the patentee. But it does so in the absence of a bar, is that not correct?

PROF. RAI: Yes, in the absence of some. In general, in human action, that's true through.

CHAIRMAN KASS: But it is not simply the exclusion of others from access to this and use of this. But it is generally for the sake of one's own use of this; is that not correct?

PROF. RAI: That is correct.

CHAIRMAN KASS: Is this not then an encouragement, as least the encouragement, of use? I am sure that people could get patents for things they have no interest in developing, but in the context we are speaking, the awarding of the patent in the absence of a bar gives governmental and premature an encouragement by granting such a patent?

PROF. RAI: Yes.

CHAIRMAN KASS: And isn't it true that while the decision to ban patents wouldn't necessarily eliminate commodification as you say, there the law would simply be silent; whereas, the granting of the patent is in fact an encouragement to the commodification, an official encouragement; is that correct?

PROF. RAI: I suppose, because I think of patents as rights of exclusion rather than rights of use. I don't see them as affirmative, other than in a purely symbolic way affirmative encouragement.

CHAIRMAN KASS: But the purpose of the patents is in fact to encourage development use as you yourself said?

PROF. RAI: Right. But I think it is a modification.

CHAIRMAN KASS: It is technically a right of exclusion. It is a right of exclusion for the sake of encouragement of the use.

PROF. RAI: Yes, but when I use the term commodification, I am thinking of sale and purchase of items in a market system, which I don't think a patent necessarily — it doesn't necessarily set up a system where you are going to have exchanges of items.

CHAIRMAN KASS: But in the context in which we are speaking now, the commercial interest in developing a patent has nothing to do with the buying an selling of the possible products of these patents?

PROF. RAI: Oh, of course it does, but it seems to me in a much more direct way. I am not suggesting that if you resist into commodification that patents won't help your cause a little bit. But it seems to me that given that the patent law is really not designed to deal with moral issues, that is really not the way to do it. And in fact I do think that Congress would have a serious Constitutional problem on its hands if it said that pursuant to our authority under the copyright and patent clause, we are going to ban certain categories of matter from being patentable.

I think it would have a serious problem on its hands, because the clause does talk about using copyrights and patents to promote the progress of science in the useful arts.

CHAIRMAN KASS: And there is also the preamble to that Constitution, and it also doesn't say that — it says that in order to promote progress in science that Congress shall, but it doesn't say that the only reason that it shall is governed by that. There is a preamble that governs the entire Constitution in the service of which that is.

And let me agree with the general conclusion. I personally don't think that the patent office is the right place to deal with moral questions. I don't. But in order to make that point, it doesn't seem to
me that you have to deny the role of patenting in the comodification of things that come before the patent office.

And also that what you call symbolic, that symbolic things are in fact crucial to questions, if not of autonomy, but to questions of dignity, self-perception, the kind of community that we are.

And therefore I want to grant some of the large points. I don't think the patent place is the right place to do this. But to write a kind of brief which says that there is really nothing at stake in this, there is nothing sort of morally and culturally at stake in this, seems to me an exaggeration.

**PROF. RAI:** Oh, I think there is a huge amount at stake. I don't think that the best way to address this, and as I have said many times, is the best way to address it is through the patent system, and we

**CHAIRMAN KASS:** Michael Sandel.

**PROF. SANDEL:** I don't have a view on whether the patent law is the best way of getting at comodification issues, and I think that by the way that all three of these presentations have been fascinating, and I hope that their papers that are lying behind them or closely connected so that we can have access to them so we can pour over them at greater leisure.

But as thinking about a project, or an agenda for this council on these kinds of issues, it seems to me that this is a crucial area. And the question is how do describe, how to focus, the discussion and the inquiry if we take this up as a project.

I don't know that patent law as such would be the best way to define that, but it seems to me the broader issue, and all the speakers have addressed this one way or another, is the comodification of life, or of life forms.

And that it seems to me is not only of enormous interest and ethical importance, but also for public policy now, and especially in the area of bioethics.

And I would suggest that we not restrict this inquiry in terms of the subject matter to embryos, or genes, or organs, but leave open the range of application, and address broadly speaking the comodification of life, or of life forms, insofar as it bears on bioethical questions.

There was some discussion that Mr. Kimbrell brought up of the scientists account, the mechanistic account, the human body as a biological machine. And I don't think it is true that as a philosophical matter that it is incompatible to view human life under two descriptions.

One under the description of sanctity and dignity, and the other under the description of a mechanistic account. Philosophically, you can have both descriptions, but the important question for us is, is that as a matter of social practice, what social practices, and what forms of buying and selling, and patenting, will crowd out or undermine the self-understandings and the social practices associated with a certain human picture.

I don't think that we can say, though I sympathize with a lot of the points that Mr. Kimbrell — a lot of the things that he objects to, I also object to, but I don't think we can just take for granted the comodification as such destroys the value of a thing.

It does in the case of a Nobel Prize by definition, because if it is bought, it is not an honor. But there are other cases where that is not true. For example, buying kidneys. The kidney might work perfectly well as a kidney, and the kidney is not destroyed by the buying of it, but yet it is a further moral question whether we want to commodify kidneys.

And then there are intermediate cases between the Nobel Prize on the one hand and the kidney on the other, and these are the really interesting and difficult questions.

For example, a market in children or babies for adoption. Well, you might argue that — some would
argue that the child is still a child, and whom you can love, and cherish, and bring up, and others would argue that the market in and of itself would gradually erode the understanding and social practices associated with children and child rearing, and the relation between the two.

But in any case, I think this should be the focus, the issue, to what extent does the comodification of life or life forms run the risk now under present circumstances of eroding a certain picture of human life, and the practices associated with it.

And then specifically what bioethics public policies do we need to consider as a result, and then leave open for the moment whether it is patent law that we need to address, or direct legislation, or some other thing.

CHAIRMAN KASS: Thank you. Paul McHugh, Robby George, Elizabeth, Gil, and Bill.

DR. MCHUGH: I just want to underline what Michael said, but also add a certain sense of the combination of the combination of presentations we have heard.

We have heard today that patent law isn't the way to do things, and that might be right. I don't know. But we have also heard that this is a copernican revolution in our world, and by the way our experience here in the council as we have talked about the meanings of these new biologies do make us all think that this is a copernican revolution.

It is certainly a big revolution how we understand what cells are capable of, and what is built into the human genome, and therefore what we could do about it. I just want to emphasize the fact that if this is truly a copernican revolution, then we should revolutionize the way that we are thinking about what our policies are, and what our laws are intended to do.

I mean, the fact that our laws have been suitable up until this time in managing through patent methods the things that you say might or might not be suitable for the next era that we are entering.

We are entering an entirely new era that the constitution, as somebody said, is not a suicide pact. We can do things to change it, and we should it seems to me given what we have been discussing here today.

CHAIRMAN KASS: Robby. By the way, I want to make sure that we also leave some time for further comments either from our guests or one another, and to respond to things that are said.

DR. GEORGE: Leon, my questions are going to be on a different line, and so if people want to respond to Paul's, they probably should now before I distract them.

CHAIRMAN KASS: Why don't you put it in.

DR. BLACKBURN: In his testimony, Kimbrell ended with an implied plea for medical science to return to perhaps business as usual as it were before the 1980s, and then he cited his reason for this the extraordinary advances in medical sciences.

And while true to some degree, I think we have to be reminded that in fact while we have had those medical advances, we are still left with a somewhat erroneous impression as to where this set of advances has gotten us.

And in a large number of quite prevalent diseases, we have not gotten very far, and in a way that you could say that all the easy ones have been done, and the ones that have been left are the ones that are complex and often very prevalent human diseases.

And that's why I think that the challenge that they are presenting now does argue alone the lines that Paul was saying, although for somewhat different reasons, and I think we do have to go beyond businesses, and I think we have to be very open to thinking about going business as usual, because we have got a lot of very challenging and intractable, currently intractable, medical problems that still lie ahead of us.

CHAIRMAN KASS: Perhaps this would be a time to get any of the five who would like to comment, but particularly the second panel to either of these comments.

MR. KIMBRELL: Yes, I would like to agree that obviously there is a larger focus than patenting,
but patenting is still a very legitimate focus. It is an extraordinary policy decision made by our
government.

As far as being an appropriate place for morality, almost 200 years of legal precedent say that it is an
important place, and they expect the utility requirement in patent law to be one that includes the
public interest and includes an ethical consideration.

The European Patent Office believes that it is the right place, and TRIPS believes it is the right place,
and NAFTA agrees that it is the right place.

So I think for those legal precedents behind us, I think it is very important to say maybe it is the right
place. As far as it being an incentive, which indeed it is for industry, and for science, or for science
and the useful arts, I also don't happen to think that science and the useful arts are amoral.

I believe that science has to be moral, and that the useful arts and industry has to be moral. I don't
believe that by just using those terms that you have entered an amoral realm in that regard. One
other thing is that as far as Professor Rai is concerned, I am no more comfortable with the examiners
being ethical or ethical examiners on patents as I am on being constitutional lawyer as far as
deciding what is constitutional or not.

So I disagree with her suggestion that we can leave that to the examiners to decide what is
constitutional. I have not suggested that. I think legislation is appropriate, and I think whatever is
done at the patent office should not be done at the examiner level as I said, but with an advisory
committee that matches those of our European partners and others that takes a look at these issues.

CHAIRMAN KASS: Do you want to respond directly to that, because I think Professor Kevles does
on a general point?

PROF. RAI: Yes, I do actually. I don't think anyone would suggest that the PTO should be the final
decider of what is constitutional. Everything that the PTO does can and should be reviewed by courts,
and certainly any denial of a patent application on a full human being, the product of a patent
application on a full human being.

I think the first thing that would happen is that we would go right to the Federal Circuit and the
Federal Circuit would have to face the constitutional issue.

And it would do so and obviously evaluate the question without any deference to what the PTO had
said, but the way that our system works is that sometimes you go through an administrative agency
first, and the Supreme Court has suggested that the administrative agency should at least consider
constitution questions when it goes through the interpretative process.

It is not the final arbiter by any means, but it can take those into consideration, those questions into
consideration.

CHAIRMAN KASS: Professor Kevles.

PROF. KEVLES: Just a few points briefly. One is that I want to endorse as strongly as I can what
Professor Rai has said about the patent as a kind of surrogate issue for what really concerns people,
and the endorsement arises again from what I know how to do best, which is an historical analysis.

Namely, if you look at when the patent issue arose, it arose just after the recombinant DNA debates.
And the issue of whether we should be engaged in genetic engineering of higher organisms or not,
including the possibility of human beings, and the revival of a kind of eugenics, and all those issues
were prominently raised in the '70s.

And people lost. The dissidents lost because genetic engineering then proceeded, and it was
demonstrated as safe, et cetera, and we know the rest of the story. And it is just after then that
Chakrabarty came up and the issue and that people began to focus on patents.

And the patents even then seemed to strike me historically as the emergence of a surrogate issue for
what is really of concern. Secondly, we ought to focus on what is really of concern, and partly of what
was of concern is comodification.

And here I want to I think endorse what Professor Sandel said, and that is by pointing out to you the
huge consequences that can arise from the absence of patents. And again the historical case would be hybrid corn, and hybrid chickens.

Those were devised as technical means of not producing better corn and better chickens, and this is in the ‘20s and ‘30s, but also as ways of protecting intellectual property rights on the part of the breeders in the absence of patent protection.

And that rights are protected because the parental generations, their genetic composition if you will, is known only to those who devise them. That is, the companies, like Pioneer Hybrid in the case of hybrid corn.

And the farmers are compelled to buy the seed from those generations, and if the farmer seeks to harvest the seed and plant it for the next generation, he regenerates. So they are forced to go back to the companies, and this is long before Monsanto gets into the business, half a century almost.

And I am not quarreling with this as a system. I developed, and it worked, and has produced profits, and produced higher productivity in agriculture, and in the corn business, the chicken business, and other areas.

But what I think we have to bear in mind is that there is no simple solution to these things, and that these things have to be addressed in a rather explicit way.

And, for example, if one could imagine that in the absence of patent protection, of say human embryos, which right now don't enjoy the status and protections of personhood, that there could be universities and/or corporations that would devise certain forms of human embryos, that would fall within the trade secret area, and there could be a market in them which would make us I think no less unhappy than we would be if we had a blatant patent on one of these things.

CHAIRMAN KASS: Steven Holtzman.

MR. HOLTZMAN: I want to fully endorse the inquiry that Michael is suggesting, because that is the inquiry, and I think talking about things being symbolic as I said to you on the phone and in my slide, it is about the meaning of these social practices.

And with the revolution in biology, the whole way we come to understand ourselves and how we stand in relation to each other, ourselves, and nature, gets changed, or at least gets challenged. Let's put it that way, and the social practices we adopt affect who we are in the society that we decide to make, and that is the question in front of us.

What I would encourage the council and with all due respect, I find focusing our patents spitting out the sound bytes, and distorting what was in the University of Missouri claims, and distorting what is in TRIPS, to make more sound bytes, it just doesn't contribute to an enlightened dialogue that will get us beyond where we stand today and have stood for the last 10 years.

And so I would encourage that we get down and we talk about do we want embryos to be bought and sold, and if so, under what conditions, under what kinds of regulations, and what are the implications of that for children.

Think through the broad range of cases. I would submit to you hat when you think of an embryo, we have a different picture of an embryo, just as we have a different picture of a family, that corresponds to 20, 30, 50 years ago, and what it is today.

It is not saying that today is right, and maybe what we want to do is try to go backwards, and we have to confront those facts, as opposed to flipping out just sound bytes.

MR. KIMBRELL: I certainly don't think that part of that dialogue should be ad hominem attacks, and I certainly don't think that anything that I said was meant to be a sound byte, and the University of Missouri and the patent attorneys who did that admitted that it did and was intended to —

MR. HOLTZMAN: There was no product claim in it, and —

(Simultaneous conversation, inaudible.)

MR. KIMBRELL: Second of all, I think that the biotechnology could be viewed as a side issue. The
vast majority, and I think it is very important to examine the actual live patents that have been granted.

The vast majority are not on generically engineered organs. The vast majority of plants have not been genetically engineered that have been patented. The vast majority of animals that have been patented have not been genetically engineered, and they are not products of recombinant DNA technology.

The vast majority of genes have not been genetically, Even the stem cells that have been patented — up to this point, many of them have not been genetically engineered. The vast majority of life forms have been patented since Chakrabarty are not products of recombinant DNA technology.

So I think when you are looking at this patenting issue, I totally agree that it is not synonymous with the biotechnology industry and it should not be viewed as a vote on biotechnology. It should be viewed as a very important ethical question on whether we want to legally define life within Section 101 definitions.

It is not just a legal issue. It is an ethical issue, and I think a very worthy one, and as the stakes get higher and higher, a critical one for this group. And I think to ignore this issue may be convenient, but I think it is going to lead to problems, extremely difficult ethical problems in the future.

CHAIRMAN KASS: Robby George and then Gil.

DR. GEORGE: I wanted to explore a little bit with Professor Rai the constitutional question, the one area in which you were suggesting that we have an exception and the question of patenting could raise constitutional questions.

And I am curious at getting at the details of why that should be, and then why only that should be, and at the heart of it I think is the distinction that you are drawing between human beings — three categories — human beings, or full human beings I think you said, embryos, and fetuses, and then parts of human beings, such as organs and genes, and so forth.

And I certainly understand the distinction between a human being and a part of a human being, and I think that is a biological distinction and can be fully and accurately described as such. It is that intermediate category that has vexed us in our discussions on other issues as well.

Because it seems to me straightforwardly that the embryonic or fetal — just at the infant and adolescent stages, are simply stages in the determinant life of the functioning human organism; that is to say a human being.

So I wonder is the distinction between full human being and embryo and fetus a biological distinction like the distinction between human being and part of human being, or is it a value distinction. In other words, is what is driving that train a value judgement that we can happen to make, and that at some stages of development human beings lack viability and what have you, and in stages they have it.

PROF. RAI: Yes, that is a great question, and I totally agree with you that it is a value judgment. It is not a value judgment that I am making, however. It is a value judgment or a constitutional judgment that thus far the Supreme Court appears to have made, and that is all that I am suggesting.

The Supreme Court has thus far said or appears to have said, or continued to endorse the Roe proposition that only post-natal beings are persons within the meaning of the constitution.

DR. GEORGE: That's what I thought.

PROF. RAI: That is the express language I think in Roe.

DR. GEORGE: Right and I want to get at that, because that is a very interesting question about the interpretation of Roe. When Justice Blackmun discusses the question of whether the unborn human being is a person within the meaning of the constitution, and concludes that the unborn human being is not a person for constitutional purposes, you may recall that the argument has to do with the fact that there aren’t, for example, post-natal applications of constitutional provisions, like the provision that to become President, a person must be 35 years old, and obviously that can’t apply to
the pre-natal state.

And needless to say, Justice Blackmun has come in for tremendous criticism as to that, and I am interested now in your interpretations of it, because as I hear what you are saying, and please correct me if I am wrong, you seem to be suggesting that we could infer from Blackmun and the Court’s conclusion, that the unborn human being is not protected as a person by the constitution, such that the right of the woman to terminate pregnancy is protected in the constitution and not contradicted by competing personal claims of the embryo.

PROF. RAI: Right.

DR. GEORGE: I thought that you were suggesting that leads to the inference that statutorily Congress, for example, and leaving the patent office out for a moment, would lack the authority to treat or confer the rights of the person on whatever now — birth is not in the picture now. So in other words, the human being at an earlier stage of development would lack that as a delegated power or what have you.

And would lack it when I think — and I am criticizing what I think you said, but when I think that would make sense at all, because plainly Roe is simply in those passages saying that Congress cannot confer rights or States cannot confer rights on the unborn human being that would conflict with Constitutionally protected rights.

It would be an entirely different matter the question of whether Congress can confer personal rights on a dog.

PROF. RAI: Absolutely. I absolutely agree with you. I didn’t mean to suggest that Congress lacked the constitutional power to confer personage on pre-natal humans. I didn’t mean to suggest that, although clearly which power it would attach to exactly, I had not really thought through which power it would be.

But I don’t mean to suggest without having thought about it, anything along those lines. You are absolutely right that in the abortion context, there is a competing constitutional right; whereas, in these cases, there would not be.

DR. GEORGE: Yes, that’s right.

ADJOURNMENT

CHAIRMAN KASS: We are already over. First of all, I want to thank the three panelists for really a very stimulating and very, very helpful presentation. Steve, if we can get copies of those slides. We have got the transcript, and its patented, and we will take it out on a license, and the same from you, Andrew. We would be delighted to have that.

Thanks to the council members, and — please.

PROF. KEVLES: I, too, found the discussion here this morning fascinating. Will the transcripts be available to everybody?

CHAIRMAN KASS: The transcripts of all of our meetings are now on an expedited track, and if things go well, they would be on our website maybe as early as the end of next week. It is www.bioethics.gov. Members of the Council, thank you very, very much. We will be in touch with you very early in the week about the next steps. The meeting is adjourned.

(Whereupon, at 12:24 p.m., the meeting was concluded.)
Leon R. Kass, M.D., Ph.D., is the Addie Clark Harding Professor in the Committee on Social Thought and the College at the University of Chicago and Hertog Fellow in Social Thought at the American Enterprise Institute. He was chairman of the President's Council on Bioethics from 2001 to 2005.

A native of Chicago, Dr. Kass was educated at the University of Chicago where he earned his B.S. and M.D. degrees (1958; 1962) and at Harvard where he took a Ph.D. in biochemistry (1967). Afterwards, he did research in molecular biology at the National Institutes of Health, while serving in the United States Public Health Service.

Shifting directions from doing science to thinking about its human meaning, he has been engaged for more than 30 years with ethical and philosophical issues raised by biomedical advance, and, more recently, with broader moral and cultural issues. From 1970-72, Dr. Kass served as Executive Secretary of the Committee on the Life Sciences and Social Policy of the National Research Council/National Academy of Sciences, whose report, Assessing Biomedical Technologies, provided one of the first overviews of the emerging moral and social questions posed by biomedical advance.

He taught at St. John's College, Annapolis, MD, and served as Joseph P. Kennedy, Sr., Research Professor in Bioethics at the Kennedy Institute of Ethics at Georgetown University, before returning in 1976 to the University of Chicago, where he has been an award-winning teacher deeply involved in undergraduate education and committed to the study of classic texts.


His widely reprinted essays in biomedical ethics have dealt with issues raised by in vitro fertilization, cloning, genetic screening and genetic technology, organ transplantation, aging research, euthanasia and assisted suicide, and the moral nature of the medical profession.

Dr. Kass is married to Amy Apfel Kass, Senior Lecturer in the Humanities at the University of Chicago and Senior Fellow at the Hudson Institute. The Kasses have two married daughters and four young granddaughters.
ELIZABETH BLACKBURN, PH.D.

COUNCIL MEMBER

January 16, 2002, to March 10, 2004

Elizabeth Blackburn, Ph.D., Professor, Department of Biochemistry and Biophysics, University California San Francisco.

Professor Blackburn, a distinguished cell biologist whose research is on telomerase and chromosome telomere structure, holds a number of awards and prizes, including the California Scientist of the Year Award (1999); American Association for Cancer Research-Pezcoller Foundation International Award for Cancer Research (2001); the General Motors Cancer Research Foundation Alfred P. Sloan Award (2001); and the 26th Annual Bristol-Myers Squibb Award for Distinguished Achievement in Cancer Research (2003). She is an elected Foreign Associate of the National Academy of Sciences (1993), and was elected as a Member of the Institute of Medicine (2000). Dr. Blackburn is an elected Fellow of the American Academy of Arts and Sciences (1991); the Royal Society of London (1992); the American Academy of Microbiology (1993); and the American Association for the Advancement of Science (2000). She has also served as President of the American Society for Cell Biology (1998).
REBECCA DRESSER, J.D., M.S.

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Daniel Foster, M.D.

COUNCIL MEMBER

Daniel Foster, M.D. John Denis McGarry, Ph.D. Distinguished Chair in Diabetes and Metabolic Research, University of Texas Southwestern Medical School. Dr. Foster, whose research is in intermediary metabolism, has received the Banting Medal, the Joslin Medal, the Tinsley R. Harrison Medal and the Robert H. Williams Distinguished Chair of Medicine Award for his work. He is a member of the Institute of Medicine of the National Academy of Sciences and is a Fellow of the American Academy of Arts and Sciences. He was chairman of the Department of Internal Medicine at UT Southwestern for 16 years.
Francis Fukuyama is Bernard L. Schwartz Professor of International Political Economy at the Paul H. Nitze School of Advanced International Studies of Johns Hopkins University.

Dr. Fukuyama’s book, *The End of History and the Last Man*, was published by Free Press in 1992 and has appeared in more than twenty foreign editions. It made the bestseller lists in the United States, France, Japan, and Chile, and has been awarded the *Los Angeles Times*’ Book Critics Award in the Current Interest category, as well as the Premio Capri for the Italian edition. He is also the author of *Trust: The Social Virtues and the Creation of Prosperity* (1995); *The Great Disruption: Human Nature and the Reconstitution of Social Order* (1999); and *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2002). His most recent book, *State-Building: Governance and World Order in the 21st Century*, was published by Cornell University Press in the spring of 2004.

Dr. Fukuyama has written widely on issues relating to questions concerning democratization and international political economy. He has, in recent years, focused on the role of culture and social capital in modern economic life, and on the social consequences of technological change.

Francis Fukuyama was born in Chicago on October 27, 1952. He received his B.A. from Cornell University in classics, and his Ph.D. in political science from Harvard. He was a member of the Political Science Department of the RAND Corporation from 1979-1980, then again from 1983-89, and from 1995-96. In 1981-82 and in 1989, he was a member of the Policy Planning Staff of the US Department of State, the first time as a regular member specializing in Middle East affairs, and then as Deputy Director for European political-military affairs. In 1981-82 he was also a member of the US delegation to the Egyptian-Israeli talks on Palestinian autonomy. From 1996-2000 he was Omer L. and Nancy Hirst Professor of Public Policy at the School of Public Policy at George Mason University.

Dr. Fukuyama is a member of the President’s Council on Bioethics. He holds an honorary doctorate from Connecticut College and Doane College, and is a member of advisory boards for the National Endowment for Democracy (NED), *The National Interest*, the *Journal of Democracy*, and The New America Foundation. As an NED board member, he is responsible for oversight of the Endowment’s Middle East programs. He is a member of the American Political Science Association, the Council on Foreign Relations, the Pacific Council on International Policy, and the Global Business Network. He is married to Laura Holmgren and has three children.
MICHAEL S. GAZZANIGA, PH.D.

COUNCIL MEMBER

Michael Gazzaniga, Ph.D., is the outgoing David T. McLaughlin Distinguished University Professor in Cognitive Neuroscience and Director of the Center for Cognitive Neuroscience at Dartmouth College and the incoming Director of Sage Center for the Study of Mind at the University of California, Santa Barbara. Dr. Gazzaniga conducts research on how the brain enables the mind. He is a fellow of the American Neurological Association, as well as the president of the American Psychological Society and a member of the American Academy of Arts and Sciences and the Institute of Medicine. His publications include *Cognitive Neurosciences III* (2004), *The New Cognitive Neurosciences* (2000) and *The Mind's Past* (1998). His new book, *The Ethical Brain*, was published in 2005.
Robert P. George is McCormick Professor of Jurisprudence and Director of the James Madison Program in American Ideals and Institutions at Princeton University.


In 2008, Professor George received the Presidential Citizens Medal at a ceremony in the Oval Office of the White House. He is a winner the Bradley Prize for Intellectual and Civic Achievement; the Sidney Hook Memorial Award of the National Association of Scholars; and the Philip Merrill Award for Outstanding Contributions to the Liberal Arts of the American Council of Trustees and Alumni.

A graduate of Swarthmore College and Harvard Law School, Professor George earned a doctorate in philosophy of law from Oxford University. He was elected to Phi Beta Kappa at Swarthmore, and received a Knox Fellowship from Harvard for graduate study in law and philosophy at Oxford. He holds honorary doctorates of law, letters, science, ethics, civil law, humane letters, and juridical science.

Professor George is a member of UNESCO’s World Commission on the Ethics of Scientific Knowledge and Technology. From 1993-98, he served as a presidential appointee to the United States Commission on Civil Rights. He is also a former Judicial Fellow at the Supreme Court of the United States, where he received the 1990 Justice Tom C. Clark Award. He is the recipient of a Silver Gavel Award of the American Bar Association, the Paul Bator Award of the Federalist Society for Law and Public Policy. In 2007 he gave the John Dewey Lecture in Philosophy of Law at Harvard. In 2008 he gave the Judge Guido Calabresi Lecture at Yale and the Sir Malcolm Knox Lecture at the University of St. Andrews in Scotland.

Professor George is a member of the Council on Foreign Relations, and serves as Of Counsel to the law firm of Robinson & McElwee.
MARY ANN GLENDON, J.D., M.COMP.L.

COUNCIL MEMBER

Mary Ann Glendon, J.D., L.L.M. Learned Hand Professor of Law, Harvard University. Professor Glendon teaches and writes on international human rights, comparative law, and constitutional law issues. The National Law Journal named her one of the "Fifty Most Influential Women Lawyers in America" in 1998. She is the author of Rights Talk; A Nation Under Lawyers; and A World Made New: Eleanor Roosevelt and the Universal Declaration of Human Rights.
ALFONSO GÓMEZ-LOBO,
DR. PHIL.

COUNCIL MEMBER

Alfonso Gómez-Lobo, Dr. phil. Ryan Family Professor of Metaphysics and Moral Philosophy, Georgetown University. Professor Gómez-Lobo specializes in Greek philosophy, Greek historiography, the history of ethics, and contemporary natural law theory. He is the recipient of several awards, including a research fellowship from the Guggenheim Foundation. His latest book, *Morality and the Human Goods*, was published by Georgetown University Press in 2002.
WILLIAM B. HURLBUT, M.D.

COUNCIL MEMBER

William B. Hurlbut, M.D. Consulting Professor, Department of Neurology and Neurological Sciences, Stanford Medical Center, Stanford University. Dr. Hurlbut's main areas of interest involve the ethical issues associated with advancing biotechnology and neuroscience, the evolutionary origins of spiritual and moral awareness, and the integration of philosophy of biology with theology. He has worked with the Center for International Security and Cooperation on a project formulating policy on Chemical and Biological Warfare and with NASA on projects in astrobiology. He is the author of "Altered Nuclear Transfer," a technological proposal to our nation's impasse over stem cell research.
CHARLES KRAUTHAMMER, M.D.

COUNCIL MEMBER

Charles Krauthammer, M.D., Syndicated columnist. Dr. Krauthammer, a board-certified psychiatrist who received his medical degree from Harvard Medical School and practiced psychiatry at Massachusetts General Hospital for several years, writes a nationally syndicated editorial page column for The Washington Post Writers Group. He won the 1987 Pulitzer Prize for distinguished commentary. For 20 years, he has written articles on several bioethical topics, including human experimentation, stem cell research, cloning, euthanasia, and assisted suicide.

Dr. Krauthammer was a recipient of the Inaugural (2003) Bradley Prize, awarded by the Lynde and Harry Bradley Foundation, as well as the recipient of the 2004 Irving Kristol Award, given by the American Enterprise Institute.
William May, PhD

Council Member

January 16, 2002, to March 10, 2004

William F. May, Ph.D. Cary M. Maguire Professor of Ethics Emeritus, Southern Methodist University. Professor May, a distinguished and widely respected medical ethicist, was head of the Maguire Center of Ethics at SMU. He is also a founding fellow of the Hastings Center for Bioethics. His numerous books include Beleaguered Rulers: The Public Obligation of the Professional (2001) and The Physician's Covenant: Images of the Healer in Medical Ethics (1983); and The Patient's Ordeal (1991).

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PAUL MCHugh, M.D.

COUNCIL MEMBER

Paul R. McHugh, M.D. is the University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine. He was the Henry Phipps Professor of Psychiatry, Director of the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine, and psychiatrist-in-chief at the Johns Hopkins Hospital from 1975-2001. He is the author of 4 books and more than 150 papers.
GILBERT MEILAENDER, PH.D.

COUNCIL MEMBER

Gilbert Meilaender, Ph.D. Richard & Phyllis Duesenberg Professor of Christian Ethics at Valparaiso University. Professor Meilaender is an associate editor for the Journal of Religious Ethics. He has taken a special interest in bioethics and is a Fellow of the Hastings Center. His books include Bioethics: A Primer for Christians (1996, 2005), Body, Soul, and Bioethics (1995). He has recently edited (together with William Werpehowski) The Oxford Handbook of Theological Ethics.
JANET D. ROWLEY, M.D., D.Sc.

COUNCIL MEMBER

Janet D. Rowley, M.D., D.Sc. Blum-Riese Distinguished Service Professor of Medicine, Molecular Genetics and Cell Biology, and Human Genetics, Pritzker School of Medicine, University of Chicago. Dr. Rowley is internationally renowned for her studies of chromosome abnormalities in human leukemia and lymphoma. She is the recipient of the National Medal of Science (1999) and the Albert Lasker Clinical Medicine Research Prize (1998), the most distinguished American honor for clinical medical research.

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MICHAEL J. SANDEL, D.PHIL.

COUNCIL MEMBER

Michael J. Sandel, D.Phil., Professor of Government, Harvard University. Professor Sandel, who was a Rhodes Scholar, teaches contemporary political philosophy and the history of political thought. Sandel's books include Democracy's Discontent: America In Search of a Public Philosophy (1996) and Liberalism and the Limits of Justice (1982). He has received fellowships from the Ford Foundation, the American Council of Learned Societies, and the National Endowment for the Humanities.