



## **Patenting of Biological Entities**

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# Patenting of Biological Entities

## Abstract:

Having first probed the question of gene patenting in 1981 and again in 1987, this ITEST workshop, was partially motivated by the proposed moratorium on new patents by representatives of major religious leaders in the United States. The essayists: a geneticist working on the Human Genome Project, and a patent lawyer, assessed the “state of the art” of gene patenting in the 1990’s. An ethicist and two theologians presented the pros and cons of the procedure and the ramifications for the human being who may be affected, however tangentially, by patenting.

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## Foreword:

On May 18, 1995 at a joint press conference, representatives of United Methodist, Southern Baptist, Jewish and Muslim organizations joined Jeremy Rifkin, president of the Foundation on Economic Trends, in calling for a moratorium on the issuing of new patents on genetically engineered animals and human genes, cells, organs, tissues and embryos. This ITEST Workshop was held partly in response to that call for a moratorium on new patents and partly to update ITEST members on the issue of patenting and any new thinking that might influence it.

This is not a new issue for ITEST. In fact, it represents the third occasion for conferences or workshops that ITEST has sponsored on this topic. The group initiated this study of patenting with its Conference on the topic, *The Patenting of Recombinant DNA*, held in March, 1981. A further workshop was held at Adamstown, Maryland, on *Biotechnology and Law*, in April, 1987. It was thought at that time that the topic of patenting and law was of sufficient importance that periodic updates were necessary to the group.

In both 1981 and 1987 a consensus of sorts emerged: we should move ahead cautiously with bioengineering and there was nothing basically wrong with the patenting of biological material. It was natural that this topic be taken up again by ITEST. Patenting may have been the occasion for this workshop but the questions ranged far beyond that issue. In our discussions we considered such questions as what is patenting and what does it do? What privileges does it confer on the patent holder and what requirements does it set? Who can apply for a patent and who is liable to get one? What does it mean to talk about God’s “ownership rights”? What is

life? What about profit? Is the involvement of a corporation(s) somehow evil in itself? What about genetically engineered microbes or plants? Why aren't they listed in the call for a moratorium? How would research be funded if patents were banned? May humans actively intervene in the physical composition of living things, including the human body? What is involved in such intervention?

The discussion of biotechnology is an important subset of a more general relationship between faith and science. That in turn is a subset of the still more general problem of the relation of Christianity to "profane" learning. That in turn involves us in the issue of faith, knowledge and praxis. Mr. Rifkin says we are at the beginning of an historic discussion. In some sense that may be true, but in any real sense that effort has been going on for a long time. Its specifically Christian beginnings can be found as early as the *Hexaemeron* of Basil in the 4th century. The question remains the perennial question asked by the Psalmist about three millennia ago: What is the human that you should spare a thought for him, the son of man that you should care for Him?

Mr. David Saliwanchik emphasized and deepened the lessons that ITEST had learned about patenting in the previous two meetings it held. That is not surprising in that his father, Mr. Roman Saliwanchik, was the presenter at those meetings. Roman Saliwanchik wrote in 1981: "Contrary to the concerns of some, the patenting of a living microbe is neither a patent on life itself nor *carte blanche* with regards to patenting higher forms of living entities. Patenting 'life itself' is not an issue to rational minds. On the other hand, patenting higher living forms, such as farm animals, cannot be dismissed as a possibility." Full publication of the data and material of the subject of a patent is required by law. In exchange for the privilege of an exclusionary right for twenty years from the filing date for the patent, the patentee gives full disclosure of the material of the patent.

There was lengthy discussion of the patenting of the sequences (with nothing added) of the human genome. These sequences have been almost routinely filed by such labs as Human Genome Sciences, Incyte and others. Dr. Robert Waterston and other researchers, on the other hand, routinely place the results of their work on the Web every night – putting it in the public domain. This brought us into the discussion of the requirements for a patent: new, non-obvious and useful.

Dr. Mitchell ably stressed, among other things, the notion of divine ownership. This is one of the "ultimate questions" that must be treated in any religious approach to things like experimentation and patenting. Does God's ownership preclude human ownership? Is the term used (ownership) meaningful? Is God's "ownership" (dominion was offered as a substitute) such that humans are precluded from such activity as patenting? The participants tilted one way or another in answering that question. Dr. Mitchell's concern that patenting may lead to the "commodification" of human biological products seems to have some validity. It is certainly worth consideration. On a deeper level, a key issue in the discussion of ownership is our relationship with God and, reductively, with each other and with the whole of creation. This conversation will (must) continue since its basis is mystery.

Father Keefe's paper was an overview of the theological aspects of law and the rule of law. Questions of ownership, freedom and the nature of law are important background issues for patenting and other directly related matters. Father Keefe's development links such disparate issues as justice, equity and ownership with marriage as a covenant and sacrament. Basically, in the common law tradition, law is much more dependent on praxis than on necessary reason, on logic. He convincingly grounds freedom in covenant with God.

Mr. Robert Morris stressed the difference between patenting and copywriting. In not permitting the copywriting of the human genome the Patent Office has done us an enormous favor, according to Morris.

Patenting may seem a mere practical issue to be disposed of by easy arguments on one side of the issue or other. From a Christian point of view, it is a narrow issue but one which leads into a much broader, deeper and more urgent issue set. Again, it is the question of the Psalmist: "What is man that you should give a thought to him . . . ." The whole subject of cloning which is agitating people at the time of this writing is part of this discussion.

While cloning may have taken all of us by surprise, it did not astonish Dr. John Matschiner. At one point in the conversation, he made the point: "Given the fact that the Supreme Court has denied the rights of an embryo to life, are we to look forward to cloned human embryos? Cloned adults? The answer is obvious: 'Yes,' of course, that's down the road and not that far away."

There is more than enough material in this volume to keep scientists, ethicists and theologians talking for a long time. That should help keep them busy. Seriously, though, there is a great deal to be talked about and done. If a consensus developed, it was one of "Yes, let's allow patenting of biological material, but let's do it with caution, questioning our assumptions from time to time." That is, "let's do it but carefully" seemed to be a modest consensus. There was no "firm and forever" type of agreement. These questions need far deeper reflections than has been given them to date.

Our bodies are important to our salvation and glorification. Can the Christian community simply ignore the questions, challenges and tremendously exciting vistas opened up by our physicality? If our bodies are not important, if we are not meant to rise bodily recognizably ourselves why did Christ ascend bodily into heaven? This is our real task and that of the community, the Body of Christ: to discern more deeply God's wishes and prospects for our bodily future. Let me finally quote St. Paul: ". . . our homeland is in heaven, and from heaven comes the savior we are waiting for, the Lord Jesus, and He will transfigure these wretched bodies of ours into copies of his glorious body."

We need further thought. Will we give it to the Church?

Robert Brungs, SJ  
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