The Ethics of Intellectual Property Rights in Biomedicine and Biotechnology: An Introduction*

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Because clinical research devours the greater part of the cost of introducing a new drug to the market, now estimated at $0.25-1 billion, patent protection is important to the pharmaceutical industry. Indeed, it is indispensable, as without the prospect of the sale of the drug and the resulting profits, financing the research necessary for new drug development would be virtually impossible.

For many years the medical world has opposed the introduction of patents in health care, this being dictated by concerns for assuring suitable medical care to all in need of it. Opinions concerning the legitimacy of patenting medical achievements are divided; for example, a recognized British expert believes that objections to surgical patents are irrational and emotional (see: Melzer D., *Lancet*, 1998, 351, 518). It is evident from this that there is an urgent need for further analysis of the current situation, including patent decisions which have been taken and their consequences.

Patent issues in health care are, therefore, controversial: the issuing of patents in certain areas of medicine (e.g. surgery) or in genetic research is often criticized as a restraint on the unencumbered practicing of medicine for the good of all patients. An example of this may be the patenting of the genome of the SARS virus, which recently caused the dangerous epidemic in Asia.

* Most papers included in this special issue were presented at the Fifth International Bioethics Conference, "The Ethics of Intellectual Property Rights and Patents," held in Warsaw, Poland on 23-24 April, 2004.

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The patent system originated on the basis of various considerations, its principle motive being to stimulate innovation and encourage investment in scientific research and progress. By issuing patent protections, the government makes it possible that individuals engaged in scientific research are provided access to the necessary financial means to conduct the research and a return of the costs borne, which would not be possible if uncontrolled copying of inventions were permitted. In this way, the patent system ensures an appropriate sharing of costs among all those who will benefit from the technology covered by the patent. Because profits from patents depend on meeting market demands, this encourages potentially useful scientific research and the introduction of these results into practice.

An important area of consideration with regard to the ethics of intellectual property and patent rights is biotechnology. Many people are of the opinion that the authors of patents have the ethical responsibility to share the commercial benefits derived from their innovations with patients. Some believe that the fruits of genetic research ought to be available to all, while persons profiting financially from patents should allocate a certain (indeed, insignificant) percentage of these profits to the health care system or other charitable cause. The reservation is also raised that the patent system limits the access of researchers to inventions and innovations, particularly when patents are the property of private persons and not governmental institutions.

There are many other ethical problems in this area, as for example the high price of patent-protected drugs and, in connection with this, their inaccessibility to the poor, as well as the unequal distribution of benefits from patent rights between highly and poorly developed countries. For this reason it is believed that policy reforms in the issuing of patents are absolutely necessary (e.g. Gold et al., *Lancet*, 2002, 359, 2268). It is worth adding that Professor Gold, who was one of the lecturers at this conference, recently published a subsequent article expressing the view that we are dealing with a serious and growing crisis of confidence in the current patent system, which demands fundamental reform (R. Gold, *Lancet*, 2003, 361, 2002).

This conference, as those before it, took place under the auspices of the Secretary General of the Council of Europe and under the patronage of the Polish Minister of Health and the Minister of Science. As mentioned above, patenting in medicine involves not only the intellectual property rights of the inventor and producer, but the rights of the patients participating in the research as well. Therefore, a special session within the framework of the conference devoted to the problems of protecting the rights of human research subjects was also organized, during which the director of the agency established by American medical and academic institutions for the protection of patient rights presented the introductory report.

In view of the unusual importance and topicality of the issue, as well as its not only scientific, but also moral and ethical significance, the prominence of the lecturers and supporting institutions give hope that this conference will be another important international event and may lead to the drafting of a set of opinions, which would be highly valuable to the worlds of science and medicine, as well as to scientific workers, physicians, and today's academic youth.

We are proud to add that this is the fifth international conference devoted to ethical problems in science and medicine organized in Warsaw in recent years which included:

Scientific integrity – 1995;
http://surfer.iitd.pan.wroc.pl/events/integrity.html

Scientific misconduct: an international perspective – 1998;
http://surfer.iitd.pan.wroc.pl/events/misconduct.html

Conflict of interest and its significance in science and medicine – 2002;
http://surfer.iitd.pan.wroc.pl/events/coi.html

Placebo: its action and place in health research today – 2003
http://surfer.iitd.pan.wroc.pl/events/placebo.html

The ethics of intellectual property rights and patents – 2004
http://surfer.iitd.pan.wroc.pl/events/patents.html

I also wish to express my deep satisfaction that *Science and Engineering Ethics* has become a forum for publishing the proceedings of our conferences. I hope that we will continue this good tradition in the future.

Professor Andrzej Górski
Conference Chairman