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Annual Review of Law and Ethics

Band 9 (2001)

Herausgegeben von
B. Sharon Byrd
Joachim Hruschka
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Schwierige Fälle der Gen-Ethik
Hard Cases in Genethics

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Vorwort

Dieser Band des *Jahrbuchs* faßt die Beiträge zu einem Symposion zusammen, das die Herausgeber im Rahmen der Begleitforschung zu den rechtlichen, ethischen und gesellschaftlichen Implikationen des Deutschen Humangenomprojekts (DHGP) in der Zeit vom 31. März bis zum 4. April 1999 in Memphis, Tennessee, zu dem Thema „Hard Cases in Genethics" veranstaltet haben. An dem Symposion haben teilgenommen: *Kurt Bayertz* (Münster), *Cornelia Bormann* (Bonn), *B. Sharon Byrd* (Jena), *Ellen Wright Clayton* (Nashville), *Lloyd R. Cohen* (Arlington), *Thomas Crofts* (Perth), *N. Ann Davis* (Claremont), *Andreas Drechsler* (Bonn), *Gerti Dieker* (Portola Valley), *Roger B. Dworkin* (Bloomington), *Lawrence A. Frolik* (Pittsburgh), *Margaret Gruter* (Portola Valley), *Jan C. Heller* (Seattle), *David Heyd* (Jerusalem), *Joachim Hruschka* (Erlangen), *Jan C. Joerden* (Frankfurt [Oder]), *Eike-Henner W. Kluge* (Victoria), *Thomas Nenon* (Memphis, Tennessee), *Lorenz Schulz* (Frankfurt am Main), *Albrecht E. Sippel* (Freiburg), *Peter Stanglow* (Frankfurt [Oder]), *S. Edward Stevens, Jr.* (Memphis, Tennessee), *Gregory Stock* (Los Angeles), *Arnd Wasserloos* (Frankfurt [Oder]), *Erin Williams* (Rockville), *Richard M. Zaner* (Nashville), *Arnulf Zweig* (New York). Die Veranstalter danken dem Bundesministerium für Bildung, Wissenschaft und Forschung (BMBF) und dem Deutschen Zentrum für Luft- und Raumfahrt (DLR) als Projektträger des Ministeriums für die Finanzierung des Symposions. Für vielfältige Unterstützung bei der Durchführung des Symposions in Memphis gebührt Prof. Dr. *Thomas Nenon* und Prof. Dr. *S. Edward Stevens, Jr.* (beide Memphis) herzlicher Dank. Für ihre Hilfe bei der Vorbereitung des Symposions und der Drucklegung dieses Bandes des *Jahrbuchs* danken die Herausgeber insbesondere Frau *Anette Hübner* im Interdisziplinären Zentrum für Ethik in Frankfurt (Oder) und Frau *Ayke Darius* im Institut für Strafrecht und Rechtsphilosophie in Erlangen. Herrn *Lars Hartmann* im Verlag Duncker & Humblot in Berlin ist für die verlagsmäßige Betreuung der Publikation zu danken. Die diesem Band angefügten Verzeichnisse haben Frau *Cornelia Winter* und Frau *Anja Richter* (beide Frankfurt [Oder]) erstellt, denen die Herausgeber dafür zu Dank verpflichtet sind.

In seinem zehnten Band (2002) wird sich das *Jahrbuch für Recht und Ethik* schwerpunktmäßig dem Thema „Richtlinien für die Gentechnologie – Guidelines for Genetics" widmen. Das *Jahrbuch für Recht und Ethik* stellt im übrigen auf seiner Internetseite

http://www.uni-erlangen.de/JRE

im Hinblick auf die schon erschienenen und die projektierten Bände weitere Informationen zur Verfügung, insbesondere auch englische und deutsche Zusammenfassungen der Artikel sowie Bestellinformationen.

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Schutz und Gewinnung genetischer Information – Protecting and Obtaining Genetic Information

The *Relaxin* Opposition Revisited

Roger Brownsword

I. Introduction

The particular focus of this paper is the *Relaxin* Opposition[1], the leading case at the European Patent Office on the patentability of inventions involving human genetic material. Without doubt, *Relaxin* is a "hard case", in the sense that it raises deeply contested issues at both bio-legal and bio-ethical levels. Without doubt, too, although *Relaxin* resolved those issues as between the parties to the particular dispute (and in relation to the particular claims made), the question of whether inventions of this kind should be treated as patentable – especially the question of whether human gene sequences or copies thereof (that is, genes isolated from the human body) should be patentable – remains a question that divides opinion around the world.

My discussion of the *Relaxin* case is presented in four parts. First, I will simply outline the issues raised by *Relaxin.* Here, it is important to understand that the Opposition was argued (and duly rejected) within the legal framework established by the European Patent Convention (EPC), Article 53(a) of which provides for the exclusion of patents on grounds of (im)morality. Secondly, I will review the case in the light of the legal framework (particularly the morality exclusion provided for by Article 6) now laid down by the Directive on the Legal Protection of Biotechnological Inventions,[2] a framework that does not replace but rather sits alongside the EPC. Thirdly, I will consider whether the opponents' dignity-based objections, in the *Relaxin* case, derive any support from, so to speak, the "new bioethics", this comprising the new EU Directive, the Council of Europe's Convention on Human Rights and Biomedicine[3] (the so-called Bioethics Convention) and the UNESCO Declaration on the Human Genome and Human Rights,[4] each of

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1 OJ EPO 6/1995, 388; [1995] EPor 541.

2 Directive 98/44/EC; OJ L 213, 30. 7. 98, p. 13.

3 *Council of Europe*, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (DIR/JUR (96) 14) (Strasbourg: Directorate of Legal Affairs, November 1996).

4 This Declaration, adopted unanimously by the General Conference on November 11, 1997, is the result of more than four years work by UNESCO's International Bioethics Committee.

which treats respect for human dignity as a cornerstone of bioethics and biolaw. Finally, I will present some brief remarks about the quest for rational law and the attempt to instate a defensible patent regime in Europe.

Stated shortly, the gist of my discussion can be captured in the following points: (i) that, in principle (and, not least, for the sake of consistency in European patent law), the kind of objections presented by the opponents in the *Relaxin* case must also be arguable under the new Directive; (ii) that, on one reading, the Directive provides that, in cases such as *Relaxin* (where human tissue is donated to researchers), a pre-condition to patentability is that informed consent is given both to the taking *and to the future commercial exploitation of inventive products arising from the research;* (iii) that appeals to human dignity in the new bioethics might encourage a (misconceived) objection to the *Relaxin* patents along the lines that tissue donors act immorally in the sense that their participation in the research compromises their own dignity; (iv) that such an objection is out of place in a culture (of the kind now organised around the European Convention on Human Rights) that adopts a rights-led approach to the valuation of individual autonomy; and (v) that a rationally defensible patent regime will make the focus for moral exclusion from patentability the question of whether (dignity-supported) human rights are likely to be (or already have been) compromised by the applicant.

II. The *Relaxin* Opposition

The *Relaxin* Opposition, where the patent at issue covered claims *inter alia* to "a DNA fragment encoding a polypeptide having human H2-relaxin activity" (Claim 3 of 21), arose under the European Patent Convention (EPC). According to the EPC, patentability is determined initially by Article 52(1), which provides:

> European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

However, the technical criteria in Article 52(1) must be read in conjunction with the exclusionary provisions of Article 53. First, Article 53(a) provides that patents shall not be granted for

> inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

Secondly, Article 53(b) provides that patents shall not be granted for

> plant or animal varieties or essentially biological processes for the production of plants and animals; this provision does not apply to micro-biological processes or the products thereof.

Both limbs of Article 53 have given rise to interpretive difficulties in the face of patent applications involving genetic engineering – notably, in the *Onco-mouse*[5]

application (which concerned a transgenic test animal for cancer research), and subsequently in the *Plant Genetic Systems* case[6] (which concerned a genetically modified herbicide-resistant plant). However, with regard to patents on human gene sequences, Article 53(a) is the key exclusionary provision – and, in *Relaxin,* it was on the basis of this first limb of Article 53 that the opponents argued for revocation of the patent.[7]

The opponents' objections were articulated in three specific arguments: (1) that the "isolation of the DNA relaxin gene from tissue taken from a pregnant woman is immoral, in that it constitutes an offence against human dignity to make use of a particular female condition (pregnancy) for a technical process oriented towards profit"; (2) that patenting genes of this kind "amounts to a form of modern slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises throughout the world" – thereby infringing "the human right to self-determination"; and (3) that the "patenting of human genes means that human life is being patented", which is "intrinsically immoral." The Opposition Division rejected all three arguments.

Having conceded that the patenting of human DNA would be immoral "if it were true that the invention involved the patenting of human life, an abuse of pregnant women, a return to slavery and the piecemeal sale of women to industry", the Opposition Division rejected each of the specific objections. As to the first argument, the Opposition Division pointed out that those who had donated the tissue had done so consensually; and, moreover, there was no reason to doubt the morality of procedures of this kind (for many life-saving substances, such as blood-clotting factors, had been developed in this way). The second argument, it was said, betrayed a fundamental misunderstanding. A patent covering DNA encoding human H2-relaxin did not confer on the proprietor a right to any part of any particular human being. No woman was enslaved by the patent; the right to self-determination simply was not affected. As for the idea that the patent entailed the dismemberment and piecemeal sale of women, quite the contrary was the case – the whole point of the invention was to enable human H2-relaxin to be produced in a technical manner outside the human body. Finally, the Opposition Division dismissed the argument that patents on genes (even on the whole human genome) amounted to the patenting of human life. There is, the Opposition Division said, more to a human being than the sum of its genes. Furthermore, if the opponents had no objection to the patenting of human proteins, they could not consistently object to the patenting of human genes encoding such proteins.

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[5] OJ EPO 11/1989, 451 (first decision by examiners); OJ EPO 12/1990, 476 (Board of Appeal); OJ EPO 10/1992, 590 (reconsidered decision by examiners).

[6] Opposition Proceedings EP 0 242 236 B1 (Opposition Division); T 0356/93 (Board of Appeal).

[7] Generally, see *Deryck Beyleveld* and *Roger Brownsword,* Mice, Morality, and Patents (London: Common Law Institute of Intellectual Property, 1993); and *Sigrid Sterckx* (ed), Biotechnology, Patents and Morality (Aldershot: Ashgate,1997).