

Book Review: Biotechnology, Patents and Human Rights in Europe: Innovations concerning the human body

Review by Isaac Maka

Helena Zakowska-Henzler, Zaneta Zemla-Pacud, and Tomasz Zimny. Biotechnology, Patents and Human Rights in Europe: Innovations concerning the human body. Edward Elgar Publishing, 2023. 226pp.

I began this book believing it would be a struggle. The technical concepts introduced by the authors showed a heavy subject matter. For the random individual interested in this highly important area of the law, but without any specialist knowledge of it, it might be difficult to navigate some of the complex concepts introduced. For example, “polymerase chain reaction,” “recombi-

nant monoclonal antibodies,” and “oligonucleotide-based site-directed mutagenesis.”

Credit to the authors, however, these technical areas are brought together in a fluid and lucid way with opinion and comment given where possible.

The book comprises six chapters. Chapter 1 gives an overview of various technologies developed in the past few decades which have heavily influenced the medical industry. So, for example, the different types of patents out there lodged with the various authorities around the world. DNA and mRNA are common examples that are widely known. There is also a constructive discussion of the different methods of modification of nucleic acid sequencing such as transgenesis of genetically engineered organisms to produce medication, e.g., for the treatment of diabetes or Hepatitis. Other examples discussed include; Gene editing, Gene therapy, stem cells, and cells-based therapy involving the use of human cells for research. The conclusion, skillfully put, is that technologies have advanced significantly in this area of life science and patent law has also transformed as a consequence. The commercialisation of technologies encroaching on the delicate interests of individuals is a serious question and posed with many dilemmas. The lifesaving needs of COVID-19 vaccines around the world and the basis on which developed countries were able to use them first, at the expense of others, is an example of note.

Chapter 2 compares the various solutions used in national patent laws of selected countries. The authors undertake an excellent comparison of how countries seek to protect individual interests in the use and patentability of biological material of human origin. For ex-

ample, the authors explain the approach to human biological material as an invention. They then go on to discuss the duty and approaches of various states in the difficult balance between protecting the patentability of processes involving the human body versus the human rights and dignity of the individual. There is a comparison of the French code versus Polish, German, and Italian approaches alongside that of the UK. Reference is made to the jurisprudence of the ECJ and the US Supreme Court. The conclusion drawn is that the European legislators seem to have adopted a stance that while a human gene sequence may be a patentable invention, the conditions for granting such a patent to such an invention should be restrictive. However, the laws of member states differ between simply implementing the text of any directive compared to going further as shown in French and Italian laws. These laws, for example, exclude the patentability of DNA sequences. The Italian code goes further than the EU Directive 98/44 EC itself by formulating exclusions relating to human cloning. This comparison shows the nuances even within EU member states, no doubt stemming from historical, cultural, and religious influences within.

Chapter 3 deals with the question of the possible impact of patent protection for inventions versus a person's ability to exercise those fundamental rights concerning their own body. There is a discussion with examples of the conflicts that have arisen due to new possibilities concerning biological material that arise from patents on inventions in which such material is used. Another section of the chapter is devoted to the identification and determination of those human rights from

which entitlements and competencies to decide one's own body are derived, and to answering whether those rights refer to the elements detached from the human body. The authors refer to International Conventions dealing with the rights of the individual and human rights, including, for example, ECHR and the impact of Article 8 (2) and the interference with a right to a private and family life. So, for example, the rights of a donor to privacy versus the greater ability to develop science and technological progress in the name of saving more lives and advancing health. The authors reach a fair conclusion that a delicate balance is necessary, which preserves the myriad of conflicting rights at the same time without inhibiting advancement.

Chapter 4 analyses how relevant IP rights, impact the right to health and the right to benefit from science. It talks about a common legal fiction, namely the common recognition of public health as a collective dimension of the right to the health of individuals. Although the book primarily focuses on patents, it highlights the tensions regarding safeguarding access to medicines and incentives for genuine innovation, on the one hand, and protecting investment in new medicinal products, on the other hand. The right to health care is not uniform, and competent state authorities are given substantial discretionary power to shape health care systems based on specific budgets for that purpose. Against this, there is a real need for science to conduct itself freely and a right to benefit from this and a guarantee of freedom to carry out or to participate in research. The balancing of these competing interests often leads to different rules and regulations, with an emphasis in some countries on free market entrepreneurship to others em-

phasizing the need for data protection and confidentiality. There is this strong protection or diminished access to innovative products and technologies in some countries versus open access and perhaps exploitation or lack of regulation in others.

Against this background, Chapter 5 deals with current, groundbreaking technological healthcare innovations regarding prominent examples of COVID-19, mRNA vaccines, personalised medicine innovations and genome editing technology CRISPR-Cas9. Several recommendations are made with a focus on compulsory licensing, changes in the pharmaceutical industry and the effective enforcement of second medical use patents and strategic usage of regulatory exclusivities and rewards within the current system. Biotechnology holds great promise for medicine. However, to what extent does it have to be that the first party over the line gets the honey at the expense of others? The authors make some very interesting recommendations which are aptly discussed between abolishing the IP system versus statutory licensing and revision of EU and other legislation. The authors determine that a complementary approach is better than a confrontational approach, treating human rights as a valuable and necessary complement to IP rights. There is a need for new public law instruments and private ordering mechanisms, which drive innovation but at the same time conserve access, which is necessary, for example for future pandemic preparedness and to save lives. A profound reform of the IP system is said deemed inevitable, which remunerates sharing knowledge and is not based on exclusivities.

Chapter 6 deals with the rights of the patentee influencing the freedom of states to establish or change patent protection rules. The authors note that although the principle of human rights law significantly limits the state's discretion to interfere with the rights arising from a patent, the nature of a patent as a right granted by the state with specific social and economic aims results in a wide enough discretion for states to act in pursuit of broader aims. States should identify the purpose of the patent protection including the function it seeks to serve, ensuring its realisation of other human rights and public interests, and set the framework accordingly. The authors conclude that perceiving IP rights through the prism of human rights, which are universal and not limited by geography or temporally, holds great potential for creating comprehensive and global legal solutions for the long term which benefit individuals, societies, and global welfare. The COVID-19 pandemic is a case in point and whilst it is hoped this was an isolated incident, it shows the need for a global response and to ensure there is maturity and balance within IP frameworks around the world to tackle these problems head-on.

The authors pose some fundamental questions and draw attention to some pertinent human rights questions. Delving into this complex area involving legal and ethical disputes, a more balanced patent system which protects and advances human rights and intellectual property at the same time is called for.

This book is thoughtful and well-written. It raises crucial legal, ethical, and moral questions that humanity will need to ask itself with the continuing advancements in medicine, artificial intelligence, pandemic prepared-

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ness, and patents. In short, this is a serious and even must-read for any scientific academic and practitioner in this area, as well as any competent lawyer or civil servant seeking to regulate and understand the different and competing interests.