Gene Patents and Collaborative Licensing Models

Concerns have been expressed that gene patents might result in restricted access to research and health care. The exponential growth of patents claiming human DNA sequences might result in patent thickets, royalty stacking and, ultimately, a 'tragedy of the anticommons' in genetics.

The essays in this book explore models designed to render patented genetic inventions accessible for further use in research, diagnosis or treatment. The models include patent pools, clearinghouse mechanisms, open source structures and liability regimes. They are analysed by scholars and practitioners in genetics, law, economics and philosophy.

The volume looks beyond theoretical and scholarly analysis by conducting empirical investgation of existing examples of collaborative licensing models. Those models are examined from a theoretical perspective and tested in a set of operational cases. This combined approach is unique in its kind and prompts well-founded and realistic solutions to problems in the current gene patent landscape.

GEERTRUI VAN OVERWALLE is head of the Research Group 'Gene Patents and Public Health' at the Centre for Intellectual Property Rights of the Faculty of Law at the University of Leuven, Belgium. She has recently also been appointed Professor of Patent Law and New Technologies at the Tilburg Institute for Law, Technology and Society at the University of Tilburg, the Netherlands.

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Gene Patents and Collaborative Licensing Models

Patent Pools, Clearinghouses, Open Source Models and Liability Regimes

Edited by

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Contents

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The group's common interest is in the interaction between knowledge flows and development, interpreted broadly to include both capacity building and the lifting of restrictions on the ability of individuals and groups to pursue their own projects.

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Preface

At present the genetics community is increasingly concerned that patents might lead to restricted access to research and health care. Thoughtful observers are increasingly expressing concerns that the exponential growth of patents claiming human DNA sequences may lead to patent thickets, royalty stacking and, ultimately, to a 'tragedy of the anticommons' in the genomic field. An anticommons effect may also arise from blocking patents. Concerns have also been voiced with regard to downstream research as new genetic inventions might not find their way into products and a translational gap might emerge.

In an attempt to capture and comprehend these recent developments, and to reflect on potential remedies, the Centre for Intellectual Property Rights of the University Leuven (Belgium) organised a two-day international workshop on '*Gene Patents and Clearing Models: From Concepts to Cases*' on 8–9 June 2006. This workshop took place in the framework of a research project on 'Gene Patents and Public Health' sponsored by the Fund for Scientific Research Flanders (FWO, Belgium – Grant number G.O120.04), EuroGenTest (a Network of Excellence set up under the European Union Framework Programme 6 – Contract number 512148) and the Vancraesbeeck Fund (K.U.Leuven, Belgium). For the research that led to the workshop and the present book, as well as for the workshop, we are very grateful to those organisations.

The workshop aimed at exploring models designed to render patented genetic inventions accessible to further use in research and to diagnosis and/or treatment in further depth, and to investigate alternative models. The models include patent pools, clearinghouse mechanisms, open source models and liability regimes. There is a clear need to examine in more depth to what extent these schemes can be tailored to meet the needs of promotion and protection of innovation in human genetics.

The workshop aimed at combining both theoretical concepts and practical issues involved in applying these models in genetics, by inviting academics as well as business people and practitioners. The workshop equally aimed at developing a multidisciplinary point of view, by

confronting the views of legal scholars, geneticists, economists and philosophers.

The present book contains all papers presented at the workshop, as well as a few contributions by scholars not present, which were added later. In covering the various models the same format is followed in the first four parts of the book. First, the model is described and the concepts underlying the model are explored in depth. Then, a few cases are offered where the model has been put to work in practice. Finally, a critical analysis of the potential of the model for application in the genetic field is developed. In the fifth chapter the various models are examined from a wide panoply of perspectives: a clinical geneticist's view, a patent practitioner's perspective, through the lens of competition law, an economic perspective and an institutional perspective. The sixth and last chapter recapitulates the major findings and tests them against a set of pre-assumptions.

The present book moves beyond theoretical and scholarly analysis into empirical investigation of existing examples. Collaborative licensing models are first examined from a theoretical perspective, whereupon the findings are tested in a set of operational cases. This combined approach is unique in its kind and may prompt both well founded and realistic solutions to the current problems in the current gene patent landscape.

We hope that this volume thus reflects our ambition to step 'beyond the veil of ignorance'[1] into open, reflective, critical and constructive 'model mongering',[2] an enticing exercise in which we would like to invite all our readers to participate.

GEERTRUI VAN OVERWALLE

[1] Rai, A.K., Reichman, J.H., Uhlir, P.F. and Crossman, C., 'Pathways across the valley of death. Novel intellectual property strategies for accelerated drug discovery', Chapter 17 of this volume p. 270.

[2] Hope, J., 'Open source genetics. Conceptual framework', Chapter 12 of this volume p. 172, with reference to John Braithwaite.

Foreword

Some thoughts on the multidisciplinary approach to the study of patents and health care

At the start of this enticing book, allow me to take you through a few considerations, which may be more philosophical than genetic.

The first thing is to agree on definitions. Indeed, this is more than semantics. If you want to be understood by people from other disciplines you must be sure to speak the same language. To give you an example: the contributions in the present book all deal with 'patents'. For me as a medical doctor, patent means open as in a patent foramen ovale, a hole in the heart. I understand that in IPR circles, patent also mean open, but did this book not come about in an attempt to keep them patent to access?

Anyway, '*interdisciplinarity* is a type of academic collaboration in which specialists drawn from two or more academic disciplines work together in pursuit of common goals' (a definition found in Wikipedia). Interdisciplinary programmes may arise from a shared conviction that the traditional disciplines are unable or unwilling to address important problems. They can also arise from new research developments, such as nanotechnology, which cannot be addressed without combining the approaches of two or more disciplines. In our field, bioinformatics is a nice example, since it combines molecular biology with computer science.

Interdisciplinary research should be distinguished from *transdisciplinary* research. According to the Swiss National research fund, it is intended to make a contribution towards solving socially relevant issues and involves practitioners from beyond the realm of science. I guess what we are doing in the Eurogentest Network of excellence is transdisciplinary, since we involve patient and family representatives in our activities.

Now, there are varying degrees of interdisciplinarity. In *multidisciplinarity*, researchers from two or more disciplines work together on a common problem, but without altering their disciplinary approach or developing a common conceptual framework.

True interdisciplinarity can only be claimed when researchers from two or more disciplines pool their approaches and **modify them** so

that they are better suited to the problem at hand. There is a holistic aspect in true interdisciplinarity. Indeed the researchers accept from the outset the idea that all the properties of a given system (biological, chemical, social, legal etc.) cannot be determined or explained by the sum of their component parts alone. The system as a whole determines in an important way how the parts behave. Aristotle already recognised this when he said: 'The whole is more than the sum of the parts.' A holistic approach has become a necessity in many disciplines. In biology, we know that cells, tissues and organs are more than the genes and pathways which they express. *Systems biology* has indeed become a trendy phrase. In philosophy, sociology and psychology holistic approaches are also well known. In medicine *holism* is almost synonym of psychosomatic medicine. Alternative medicine has capitalised on this since it recognises that emotional, mental, spiritual and physical elements of each person comprise a system, and that the whole person must be treated, the symptoms as well as the causes of the illness.

Reductionism is the opposite of holism. Scientists may need to have a reductionist approach to extract a particular mechanism from a complex biological problem. This is a well-known successful approach in science. Nevertheless, in the back of their minds, good scientists will remain aware of this necessary, but temporary reductionist approach.

Let us go back then to inter- and multi-disciplinarity and analyse how these principles are being applied in the present collection and in the genetics field in general. Does the study of IPR issues in genetics by lawyers and geneticists constitute an example of multidisciplinary or a true interdisciplinary approach?

If we consider the sex of the investigators, we have to conclude that the approach is definitely multidisciplinary. Females and males work on the same issues. Their perspective, timing, emotions and approaches will be different. To become truly interdisciplinary the investigators would have to learn to find a common ground and appreciate the qualities and shortcomings of the sex of their colleagues. For obvious reasons I will not go into this issue any further.

The second issue is the difference in scientific approach. Geneticists place emphasis on qualitative and quantitative 'rigour' and as a result may think that their approach is 'more scientific' than that of their colleagues from the humanities. In addition, they are used to face the unexpected outcome from an experiment. Lawyers may associate quantitative approaches with an inability to grasp the broader dimensions of the problem. On the other hand their approach is just to make sure that the unexpected is covered by the texts.

While geneticists are very keen to determine the sequence of a piece of DNA with great accuracy, by repeating the exercise a few times, they will readily accept that a well-written scientific text has a clear and obvious meaning. They have a kind of holistic approach when it comes to interpreting texts. Lawyers on the other hand make a living finding different interpretations of the same word, the same sentence or the same text. It is not clear, however, whether at the end the patent still covers what it is supposed to cover. One also wonders sometimes if a patent could ever be written and submitted if more than one lawyer worked on it. One also wonders why some patent applications, written by geneticists, could stand any challenge by lawyers.

A third issue is the difference in autonomy that the two parties may enjoy. Biomedical research is known to be expensive and to drain a good part of the budgets reserved for research. Legal investigations, with the exception of the legal fees, are cheap, require access to a library and a PC and are funded accordingly. As in other situations in society, the rich and the poor may not have the same ambitions and goals.

Is a multidisciplinary or even true interdisciplinary approach of IPR issues in genetics/diagnostics therefore even possible? It is clear that if left only to geneticists or lawyers, we may end up as already said: with something quite useless. 'To be aware of one's shortcomings, is the first step towards improving oneself,' as Socrates used to say. Therefore, combining the expertise, even in a 'multidisciplinary' approach, will create a more holistic approach, which will be much more useful to all parties involved and to the aim of the collaboration.

One has to keep in mind, however, that even if multi- and interdisciplinarity is very trendy in our universities, it may be less obvious when one applies for funding. We all know examples, where multidisciplinary projects have not received the expected financial support. The quantitative scientist will have judged that the project is too descriptive, while the qualitative scientists will have found it poorly written or not understandable.

In conclusion, I guess there is only one way in which this collaboration could become truly interdisciplinary and that is by becoming a *discipline* itself. If it succeeds, it might even solve the problem of its research funding, make even its own tenure and promotion decisions. Other examples of such integrations do exist: neuroscience, biomedical engineering and bioinformatics, to cite only a few examples, have been successful in this, here or in other places in the world. Whether the academic authorities will follow in this particular topic, I would not be too optimistic.

In any case, I would like to congratulate all contributors to the present book in trying to talk to each other and even to try to understand each other's language, and to grow into a multidisciplinary approach. Of course my congratulations also go to the organiser of the workshop and the editor of the present volume, Geertrui Van Overwalle, for being the necessary catalyst in this process.

JEAN-JACQUES CASSIMAN

Abbreviations

3GPP	3rd Generation Partnership Project
ACMG	American College of Medical Genetics
AD	Alzheimer Disease
AFLP	Amplified Fragment Length Polymorphism
AFJ2	Second Amended Final Judgment
AI	artificial intelligence
AIDS	Acquired Immunodeficiency Syndrome
AIPPI	Association Internationale pour la Protection de la Propriété Industrielle
ALRC	Australian Law Reform Commission
ASCAP	American Society of Composers, Authors and Publishers
ASTP	Association of European Science & Technology Transfer Professionals
AUTM	Association of University Technology Managers
BCLC	Breast Cancer Linkage Consortium
BSD	Berkeley Software Distribution
BIEM	Bureau International des Sociétés Gérant les Droits d'Enregistrement et de Reproduction Mécanique
Biotechnology Directive	EU Directive on the Legal Protection of Biotechnological Inventions, 1998
BiOS	Biological Innovation for Open Society
BMI	Broadcast Music, Inc.
BRCA	Familial Breast and Ovarian Cancer (gene)
BRT	Belgische Radio- en Televisieomroep
BSD	Berkeley Software Distribution
BUMA	Dutch Association for Performance Rights
B2B	business-to-business

CAMBIA	Centre for Applications of Molecular Biology in International Agriculture
CBD	Convention on Biological Diversity
CC	Creative Commons
CCS	Copyright Collection Societies
cDNA	complementary DNA
CF	Cystic Fibrosis (Mucoviscidosis in some languages)
CFTR	Cystic Fibrosis Transmembrane Conductance Regulator (gene and protein)
CGIAR	Consultative Group on International Agricultural Research
CH	clearinghouse
CIMMYT	International Maize and Wheat Improvement Centre
CISAC	Confédération Internationale des Sociétés d'Auteurs et Compositeurs
CJ	Court of Justice (EU)
CMM (detection)	Chemical Mismatch (detection)
CMT-1A	Charcot-Marie-Tooth disease, type 1A
CPC	Community Patent Convention
CRO	Collective Rights Organisation
CRUK	Cancer Research UK
CSCE	Conformation Sensitive Capillary Electrophoresis
DArT	Diversity Array Technology
DG	Directorate General
DGGE	Denaturing-Gradient Gel Electrophoresis
DH	Department of Health (UK)
DHPLC	Denaturing High-Pressure Liquid Chromatography
DMD	Duchenne Muscular Dystrophy (disease, protein and gene)
DNA	Desoxyribonucleic Acid
DOJ	Department of Justice (US)
DRM	Digital Rights Management
EBI	European Center for BioInformatics
EBoA	Enlarged Board of Appeal (EPO)
ECJ	European Court of Justice
EC Treaty	Treaty of the European Communities
EEA	European Economic Area
EGE	European Group on Ethics in Science and New Technologies

EMD	Enzymatic Mismatch Detection
EMEA	European Agency for the Evaluation of Medicinal Products
EPC	European Patent Convention, 1973
EPIPAGRI	European Collective Management of Public Intellectual Property for Agricultural Biotechnologies
epo	Erythropoietin
EPO	European Patent Office
ESGH	European Society of Human Genetics
EST	Expressed Site Tag
EU	European Union
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration (US)
FIPC	French Intellectual Property Code
FMF	familial Mediterranean fever
FRAND	Fair Reasonable and Non-Discriminatory
FS	free software
FSF	Free Software Foundation
FTC	Federal Trade Commission (US)
FTO	freedom to operate
GATT	General Agreement on Tariffs and Trade (WTO)
GBIF	Global Biodiversity Information Facility
GBS	Global Bio-Collecting Society
GCP	Good Clinical Practice
GEMA	German Gesellschaft für musikalische Aufführungs – und mechanische Vervielfältigungsrechte (Germany)
GFP	Green Fluorescent Protein
GM	genetically modified
GMS	Genetic Microsystems
GNU	recursive acronym for '*G*NU's *N*ot *U*nix', the name for the complete Unix-compatible *operating system*
GNU/Linux	Linux kernel (see 'Linux') together with other *operating system* elements supplied by the GNU-project
GPL	General Public License
GRDC	Grains Research and Development Corporation
Guidelines EPO	Guidelines for Examination in the European Patent Office
GUS	glucuronidase