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 investigation 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.

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Gene Patents and Collaborative Licensing Models

Patent Pools, Clearinghouses, Open Source Models and Liability Regimes

Edited by

Geertrui Van Overwalle
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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...
Preface

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

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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>3GPP</td>
<td>3rd Generation Partnership Project</td>
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<tr>
<td>ACMG</td>
<td>American College of Medical Genetics</td>
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<td>AD</td>
<td>Alzheimer Disease</td>
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<td>AFLP</td>
<td>Amplified Fragment Length Polymorphism</td>
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<td>AFJ2</td>
<td>Second Amended Final Judgment</td>
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<td>AI</td>
<td>artificial intelligence</td>
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<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
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<td>AIPPI</td>
<td>Association Internationale pour la Protection de la Propriété Industrielle</td>
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<td>ALRC</td>
<td>Australian Law Reform Commission</td>
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<td>ASCAP</td>
<td>American Society of Composers, Authors and Publishers</td>
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<td>ASTP</td>
<td>Association of European Science &amp; Technology Transfer Professionals</td>
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<td>AUTM</td>
<td>Association of University Technology Managers</td>
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<td>BCLC</td>
<td>Breast Cancer Linkage Consortium</td>
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<td>BSD</td>
<td>Berkeley Software Distribution</td>
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<td>BIEM</td>
<td>Bureau International des Sociétés Gérant les Droits d’Enregistrement et de Reproduction Mécanique</td>
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<tr>
<td>BIOS</td>
<td>Biological Innovation for Open Society</td>
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<td>BMI</td>
<td>Broadcast Music, Inc.</td>
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<tr>
<td>BRCA</td>
<td>Familial Breast and Ovarian Cancer (gene)</td>
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<tr>
<td>BRT</td>
<td>Belgische Radio- en Televisieomroep</td>
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<tr>
<td>BSD</td>
<td>Berkeley Software Distribution</td>
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<td>BUMA</td>
<td>Dutch Association for Performance Rights</td>
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<td>B2B</td>
<td>business-to-business</td>
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### List of abbreviations

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

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 ‘GNU’s Not Unix’, 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