Intellectual Property in Molecular Medicine

A subject collection from *Cold Spring Harbor Perspectives in Medicine*

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Front cover artwork: The figure on the *left* is a cartoon representation of the complex structure of the BRCA1 RING domain and the BARD1 RING domain (based on PyMOL rendering of PDB 1jm7). The figure on the *right* is a cartoon representation of the molecular structure of the protein registered with the PDB code 1n0w (BRCA2). Both were the subjects of patent applications filed by Myriad Genetics and other institutions in the 1990s because mutations in the genes encoding BRCA1 and BRCA2 are linked to breast and ovarian cancer. Subsequently, lawsuits were filed against Myriad Genetics by several entities alleging that patents for human genes are invalid. (The image on the *right* can be found in Wikipedia under "PBB Protein BRCA2 image." It is reprinted here courtesy of Public Domain via Wikimedia Commons. The image on the *left* has been released into the public domain by its creator and original copyright holder, Jawahar Swaminathan and the MSD staff at the European Bioinformatics Institute. The image is currently licensed under Public Domain via Wikimedia Commons. This applies worldwide. As such it is entirely free to reproduce, create derivative works, or make commercial use of as one sees fit, without any requirement to give the creator credit. However, as a courtesy, a link back to http://www.ebi.ac.uk/ would be appreciated.)

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Contents

Preface

THE YEAR 1980 WAS TRANSFORMATIVE FOR BIOTECHNOLOGY. By a narrow decision of 5–4, the U.S. Supreme Court, in *Diamond v. Chakrabarty* (447 U.S. 303, 206 USPQ 193) (1980), found that Ananda Chakrabarty's patent application covering oil-digesting bacteria constituted patentable subject matter under U.S. patent law and paved the way for the commercialization of biotechnology to become the highly dynamic industry it is today. Other countries, such as Australia, Canada, and the United Kingdom, soon followed suit and found microorganisms to be patentable subject matter. No one could have foreseen then the breakneck speed at which biotechnology would advance and the accompanying patents that would be granted. The Supreme Court's statement in *Chakrabarty* that "anything under the sun made by man" is patentable subject matter gave the United States Patent and Trademark Office (USPTO) license to broaden the boundaries of patentable subject matter in the life sciences and grant patents in respect of a wide variety of biotechnological innovations. Entrepreneurial scientists and patent lawyers have, in turn, tested the limits of these boundaries and have occasionally been pushed back by the courts. Even though "anything under the sun made by man" may be patentable subject matter, recent cases challenging the patentability of genes and diagnostic methods, at least in the United States, clearly suggest that "anything under the sun made by man," at least with respect to the patentability of biotechnological inventions, is not a settled point of law. In the United States, the *Association for Molecular Pathology v. Myriad Genetics, Inc.* (133 S.Ct. 2107) (2013) and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (132 S. Ct. 1289) (2012) cases have rekindled the debate on the patentability of biotechnological inventions, primarily the patentability of genes and diagnostic methods.

In 2012, as the debate on the patentability of genes and diagnostics was heating up in the United States, we decided it would be beneficial to organize a conference on the patentability of this subject matter to be hosted by Cold Spring Harbor Laboratory in March 2013. The aim was to bring together individuals from around the world with various backgrounds to explore the scientific, legal, ethical, and social issues related to the patenting of genes and diagnostic methods. One question that was raised repeatedly was whether those addressing and deciding on such important issues were well enough versed with the underlying science to make the proper arguments and ultimately decide for or against the patentability of complex biotechnological inventions. We now know the vastly different outcomes on the eligibility of genes as patentable subject matter in the United States and Australia based on decisions handed down by the United States Supreme Court (USSC) and the Federal Court of Australia Full Court (FCAFC). Although patent law and the application of it is highly jurisdictional, a reading of both decisions clearly shows that the Justices on the FCAFC were heavily influenced in their decision to allow the patentability of genes, in Australia, by the underlying science (*D'Arcy v Myriad Genetics Inc.* [2014] FCAFC 115). In fact, portions of the FCAFC decision and the Justice's reasoning read much like a molecular biology text. On the other hand, in the United States, where genomic DNA was held to be nonpatentable subject matter (although cDNA was found to be eligible), it is not difficult to see that the Justices on the USSC struggled with the science and relied instead on analogies and metaphors that had little or no bearing on the complex science used to isolate the *BRCA1* and *BRCA2* genes. Further, the USSC's

decision has been exacerbated by the USPTO's proposed original guidelines[1] to its examining corps when determining subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, and natural products as a result of the USSC's *Myriad* and *Mayo* decisions. The proposed highly controversial guidelines would have effectively prohibited obtaining patent protection for most products derived from nature. However, after much public feedback, the USPTO has now significantly scaled back these restrictions.[2] One of the tests that will be applied to the eligibility of inventions related to products of nature is whether the claimed subject matter is "markedly different" from what is found in nature. This test will undoubtedly be subjective and the question of how "markedly different" the claimed subject matter as a whole is from what is found in nature will remain uncertain until the courts provide more clarity in the future. Only time will tell what impact, if any, the USSC's decisions and the USPTO's guidelines, once adopted, will have on the biotechnology industry.

Canadian courts have often stated that a patent should be approached with a mind *willing* to understand[3] (our emphasis). But, by the same token, we would argue that a patent should also be approached with a mind *able* to understand. We have attempted here to bring together a collection of views on patent law, by distinguished experts, as they apply to biotechnological inventions for scientists, graduate students, and technicians—individuals at the forefront of innovation in the life sciences. The chapters are also meant for technology transfer professionals and those involved in the commercialization of biotechnological innovations with little to no patent law background. The various chapters try to introduce to the reader basic principles of patent law as they may apply to the life sciences in various major jurisdictions. Our instruction to the authors was to remove as much legal jargon as possible and introduce the concepts with as many real examples as possible. We are grateful to all our contributors for the immense time and effort put into writing these chapters and simplifying complex legal concepts that are often taken for granted in their daily work.

We strongly feel that those at the front lines of biotechnological innovation should increasingly be exposed to concepts of patent law and should have a good working knowledge of how patent law works to protect their hard work that may eventually be commercialized. To that end, we are grateful to Richard Sever of Cold Spring Harbor Laboratory Press for initiating this project and allowing us to coedit this volume—an area not within the Press's comfort zone. Finally, we would like to thank Barbara Acosta, also of Cold Spring Harbor Laboratory Press. Barbara was assigned as project manager and kept the whip cracking to make sure we were on track and on time as much as possible.

A note of caution: This is not a text on patent law. No single book can attempt to explain the complexities of patent law and its varied application in various jurisdictions. Accordingly, these chapters do not, by any means, cover all aspects of patent law. We do not expect nor advise the reader begin to

[1] *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products* ("*Revised Guidance*"), which was attached to the Memorandum issued on March 4, 2014 by Andrew Hirshfeld, Deputy Commissioner for Patent Examination Policy entitled, *2014 Procedure For Subject Matter Eligibility Analysis of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products* ("*Cover Memo*").

[2] *DEPARTMENT OF COMMERCE, United States Patent and Trademark Office, 37 CFR Part 1 [Docket No. PTO-P-2014-0058] 2014, Interim Guidance on Patent Subject Matter Eligibility* issued December 15, 2014. This Interim Eligibility Guidance supplements the June 25, 2014, Preliminary Examination Instructions in view of the Supreme Court decision in Alice Corp. (June 2014 Preliminary Instructions) and supersedes the March 4, 2014, Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 2014 Procedure) issued in view of the Supreme Court decisions in *Myriad* and *Mayo*.

[3] *Whirlpool Corp. v. Camco Inc.* ((2000), 9 C.P.R. (4th), 129 (S.C.C.)) at paragraph 49; citing *Lister v. Norton Brothers and Co.* ((1886), 3 R.P.C. 199, (Ch.D.)) at page 203. The actual quote from *Lister* is that a patent "must be read by a mind willing to understand, not by a mind desirous of misunderstanding"; *Teva Canada Limited v. Novartis AG*, [2013 FC 141] at paragraphs 73 and 282.

attempt to draft his or her own patent application or analyze an issued patent for validity or invalidity based on the information in these chapters. The reader will be quick to realize that ultimately patent law is highly complex, jurisdictional, fact-specific, and unfortunately not an exact science. We hope, however, that after having read these chapters, the reader will have a better appreciation of how patent law works, especially as it applies to the life sciences, and be *willing* and *able* to have a meaningful discussion with their patent counsel when deciding to apply for patent protection.

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