# Patenting and Licensing in Genomics: Impact on Access to Genetic Tests and Debates about Patenting in the Public Interest

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## Introduction

Intellectual property rights, such as patents, award inventors a temporary (generally 20 year) right to exclude others from making, using, selling, or importing their invention. They are granted to individuals and institutions by governments to encourage public disclosure of their inventions, and as an incentive to invent. Disclosure is thought to stimulate both follow on research and, in some cases, public benefit. By enabling the collection of fees when a patent holder licenses their rights to others, patents also offer inventors an opportunity to transfer a package of rights, creating an incentive for licensees to invest in further development. There can be wrinkles in the system, however. For example, if an invention is covered by two patents in the hands of different owners, both are prevented from using the invention unless they can come to an agreement. Clarity in the patenting system is also important. Uncertainty about the patentability of an invention may induce the inventor to keep it as a trade secret, instead of filing a patent and then disclosing the details about their invention to others.

A series of U.S. Supreme Court decisions, and a parallel case in Australia, invalidated patents on molecules with naturally occurring DNA (or RNA) sequences, and associations between sequence variants and health conditions. A controversy erupted that remains unresolved, with some urging statutory reversal of the Court decisions and others opposing restoration of patent-eligibility.

As a government-granted right to exclusively exploit an invention, patents can increase prices and restrict use. This is a cost society pays to motivate invention and disclosure of discoveries. Intellectual property rights can also be used in ways that do not foster social benefit from the discovery. For example, they have been used to clear the market of existing genetic tests, thereby

limiting rather than promoting availability of testing. An ongoing concern is whether patents and/or licensing practices negatively affect research and commercial development efforts for new genetic diagnostics and therapies. Patents and licensing practices can have an impact on genetic research and genetic test development if researchers have limited access to existing inventions; patent enforcement via litigation can affect patient access to genetic tests by raising costs; and patents and licensing practices can impact the quality of genetic tests by limiting incentives for others to improve upon the genetic test, or to verify results from the laboratory with exclusive patent rights. Where patents and licensing practices have created a sole provider of a genetic test, patients have been unable to obtain access to a sole provider's test when the provider does not accept the patient's insurance or health plan (a problem in particular for those covered by Medicaid). Patents and liscensing practices can also limit the exchange of materials and information between researchers, which can lead to reductions in subsequent scientific research and product development. They can also delay the widespread adoption of new technologies.

Evidence that would guide policymakers and the courts about the effects of patents and licenses on patients' access to tests, and the costs and quality thereof, is still accumulating. According to the most thorough empirical analysis to date, it appears that patenting genomic inventions is only one factor—often not the most important—that can impede information flow in biomedical research, although a few cases of restrictive licensing practices have caused controversy due to their potential negative effects on public health. A few scholars are calling for Congress to consider a research exemption to patent infringement that would enable research uses of patented inventions (such as to allow for independent verification of genetic tests).

The application of intellectual property rights in biotechnology also raises several normative questions. Among them are the appropriateness of applying the traditional system of intellectual property rights directly to biotechnology, without modification to incorporate relevant values. Patent criteria could be used to exclude processes such as human germline genetic modification or patenting of embryos (which is, for example, explicitly proscribed in Europe). Some argue the patent system is unfair to U.S. taxpayers who fund federally conducted and federally sponsored research, and then pay higher prices for patented goods and services through federal health programs (e.g., Medicare, Medicaid, the Veterans Health Administration, Children's Health Insurance Program, the military health system and TriCare, Indian Health Service, and Federal Employees Health Benefits Program). Further, the research institution that employed the researcher will receive some of the royalties that accrue from the patent on that invention. What does this revenue do for universities? There are also concerns that unpatented contributions that are nonetheless instrumental to team-based discoveries are not equitably compensated. When the use of genetic material from a particular individual or a particular small group of people is of special value, there are more questions about whether researchers and their commercial sponsors should share financial benefits from the resulting intellectual property rights with them. The pricing of products based on federally funded research and development, conflicts of interest for inventor/entrepreneurs that could motivate the pursuit of profitable over socially-beneficial research, and the ability of the patent system to recoup the public investment in research for members of the public are ongoing concerns.

The overall societial welfare generated by biotechnology patents depends on the outcome of the tradeoff between government incentives for research innovation, patient access to technologies, and any effects of intellectual property on subsequent innovation. A simplistic "patents good, patents

bad" framing gets in the way of formulating policies that will stimulate innovation while ensuring broad and fair access to genetic testing and other applications. The following rich literature amply makes that point.

**Methods and reader guide**

We identified over 50 scholars who had worked on related topics and asked them for literature suggestions, collected the suggested literature into a spreadsheet, and augmented those suggestions with our own list. The scholars who made suggestions are: Geertrui van Overwalle, Jacob S. Sherkow, Kathy Liddell, Osmat Azzam, Sean Tu, Joshua Sarnoff, Jorge Contreras, Lisa Larrimore Ouellette, Aaron S. Kesselheim, Shobita Parthasarathy, and Kevin Noonan. Several of these individuals met with us on December 3, 2024 and refined the literature selections and categories.

As you read this literature collection, several points are worth bearing in mind. First, much of the literature uses the term "gene patents." Indeed, one of the article clusters below addresses the controversy that erupted when *Science* published a Policy Forum asserting that 20% of human genes were subject to a patent claim. But just as the notion of a "gene" is fuzzy at the edges, the fuzziness is compounded when couched in the language of patent claims. Patents contain many legal terms of art that need to be interpreted with care. When a gene patent refers to the DNA that encodes a naturally occurring protein, it is a useful shorthand. But even then, the DNA may be modified as a means to produce a therapeutic protein (a drug), or it may be edited from its natural form to eliminate introns or substitute sequences. In most cases in which DNA is used to produce a protein or other product (an RNA, for example), the DNA will be modified. In the context of diagnostics, however, any change that deviates from the one in a person's body is a mistake; in diagnostics, the purpose of making the DNA is to accurately determine the patient's DNA sequence. Many patents cover one or the other of these uses, sometimes both. In much of the literature below, gene patents refer to patents that claim methods of detecting DNA changes associated with disease or medical conditions, or the DNA molecules that would be produced in a diagnostic test. But, there is no precise definition of a gene patent.

Second, there is no comprehensive compendium of clinical genetic tests. The Genetic Test Registry, particularly the "human tests" list, is a global source maintained by the National Center for Biotechnology Information at the National Library of Medicine.

One of the most useful sources on clinical testing in the United States is Concert Genetics, a private organization that helps payers and laboratories identify what tests are available, and how they are coded and billed. Concert's 2018 report on the "Landscape of Genetic Testing" is particularly helpful, and several other reports update those data.

Third, one of the features of the debate about patenting in genomics is about contrasting frames. Patent policy is generally framed as an innovation incentive, in particular, the value of inducing private investment leveraged by time-limited exclusive rights. But, most of the bioethics critique centers instead on the effects on access to patented goods and services, a major theme of health policy rather than innovation policy. These contrasting frames are readily apparent in the articles, books, and reports comprising this collection.

Finally, several of the topics below are not about access to clinical genetic testing, but have been included because they seemed likely to be of interest for ELSI scholars interested in intellectual property in genomics. The value of including these topics emerged from the email traffic and the group call that we convened when assembling the collection.

## Bioethics literature on patents before the Supreme Court decisions of 2010-2015

- Philosopher-bioethicist, Baruch Brody, wrote a three-part series of articles for the *Kennedy Institute of Ethics Journal* that reviewed how patent controversies played out in Europe and the United States.
    - Brody, B. (2006). Intellectual property and biotechnology: The U.S. internal experience—Part I. *Kennedy Institute of Ethics Journal, 16*, 1–37.
    - Brody, B. (2006). Intellectual property and biotechnology: The U.S. internal experience—Part II. *Kennedy Institute of Ethics Journal, 16*, 105–128.
    - Brody, B. (2007). Intellectual property and biotechnology: The European debate. *Kennedy Institute of Ethics Journal, 17*, 69–110.
- The Nuffield Council on Bioethics in the United Kingdom addressed *The Ethics of Patenting DNA* in a 2002 discussion paper. Sandra Thomas, the director at the time, called it one of the hardest reports for the Council to complete. She, Michael Hopkins and Max Brady summarized some of the empirical findings in *Nature Biotechnology* later that year.
- The American Association for the Advancement of Science compiled an essay collection *Perspectives on Genetic Patenting*, edited by Audrey Chapman (AAAS, 1999). It is out of print, and AAAS is looking into making it available, at which time, CERA will update this page.
- The U.S. National Academies issued a 2005 report, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health*. David Magnus addressed the physician's perspective on disease gene patents in Disease Gene Patenting: The Clinician's Dilemma and co-edited a volume of essays *Who Owns Life?* with Arthur Caplan and Glenn McGee in 2002 (Prometheus Books).
- Philosopher and bioethicist, Dan Brock, teamed with human geneticist, David Weatherall, and social scientist, Heng Leng Chee, to address *Genomics and World Health* for the World Health Organization (WHO) in 2002. The trio had a skeptical take on DNA patents, expressing concern about patents hindering research and applications (chapter 7). WHO circled back to intellectual property and appointed a commission, but its reports—its main report *Public Health, Innovation and Intellectual Property Rights*, in particular—centered on pharmaceuticals; diagnostics were bundled with vaccines and drugs without distinguishing diagnostics in general, or genetic testing in particular, from therapeutics and vaccines.
- Philosopher David Koepsell published *Who Owns You?* in 2009 with the subtitle "The Corporate Gold Rush to Patent Your Genes," and then revised it after the *Myriad* case (discussed below) with a new subtitle "Science, Innovation and the Gene Patent Wars" in 2015 (Wiley, 2009 and 2015). In the process, he was drawn into advocacy. Koepsell analyzed the basis for gene patents through principlism and moral philosophy, but highlighted the real-world health impact he came to appreciate once he got engaged in the topic. In a wonderful spirit of academic debate, Kevin Noonan, a well known practicing patent lawyer, wrote a foreward for the second edition that challenged not only the somewhat misleading title of Koepsell's book (patenting genes is not "owning you"), but adopted a more utilitarian ethical analysis. Their disagreements starkly highlight different perspectives on the role of patents.
- The Congressional Office of Technology Assessment (OTA) prepared a report on *The Human Genome Project and Patenting DNA Sequences* in 1994. While it was approved for publication, it was never fully released because the agency was defunded and the report drowned as OTA sank. That report was itself a response to a brouhaha surrounding patents on genes

being discovered by DNA-sequence-based methods, specifically, short sequences used to identify protein-coding genes, a history recounted by Daniel Kevles and Ari Berkowitz.

## Patenting and licensing and the effects on clinical genetic testing

The role of patenting and licensing in access to clinical genetic testing, and in genomics more generally, has been a contentious topic since DNA patents began to issue in the 1970s. The issues smoldered for years, as indicated by the articles and books above. Patents on genes that were modified and used to develop therapeutic proteins such as insulin and growth hormone engendered some grumbling, but the conflagration erupted mainly over genetic diagnostics. Patenting the gene associated with Canavan Disease led to litigation. This and other cases attracted some attention—mainly negative media coverage—as did patents on Alzheimer's genes, cardiomyopathies and arrhythmias, and other conditions. But as the authors note, the grandmother of gene-patenting controversies was patenting of *BRCA1* and *BRCA2*, genes associated with breast, ovarian, and other cancers. Those controversies gave rise to the volumes noted above, and set the stage for a U.S. Federal Advisory Committee and legal action to ensure access to genetic testing:

- The Secretary's Advisory Committee on Genetics, Health and Society, a U.S. Federal Advisory Committee, prepared the *Gene Patent and Licensing Practices and Their Impact on Patient Access to Genetic Tests* report from 2006 to 2010. Eight case studies of ten clinical conditions informed the study, published as a special issue of *Genetics in Medicine*. This is one of the most thorough analyses of this topic. The recommendations of the committee were never implemented, but the report set the stage for later events.
- One of those case studies was about Long-QT syndrome patents (by Misha Angrist, Subhashini Chandrasekharan, Christopher Heaney and Robert Cook-Deegan, "Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long-QT Syndrome"). Long-QT patents are also covered from a patent-practioner's perspective in chapter 17 of Jorge Goldstein's book *Patenting Life* (Georgetown University Press, 2025). Long-QT testing also became the basis for a settlement in Canada that set a precedent for ensuring access to genetic testing through the provincial health systems (Katherine Bonter, Carmela DeLuca, and Christi Guerrini, "Gene Patents in Canada: Is There a New Legal Landscape?").

The SACGHS report cited above was a response to the ongoing roiling debate. Some of this history is reviewed in a pair of *Annual Review* articles from 2010 and 2015. In addition:

- Mildred Cho and colleagues surveyed clinical testing labs in 2001 and documented that 22 patents were inhibiting testing on 12 commonly-tested disease genes. This paper was a major impetus for the SACGHS report cited above.
- Lori Andrews and Jordan Paradise raised a red flag in an article that was well-known to the ACLU team that brought the *Myriad* case.
- Joshua Sarnoff argued that the Supreme Court decisions on patentable subject matter drew on a long and deep history, and were not legal mistakes but well justified.

After the Supreme Court decisions, a couple of papers addressed their impact on clinical practice:

- Sherkow, J. S., & Abbott, R. (2018). Fortune and hindsight: Gene patents' muted effect on medical practice. *British Medical Bulletin, 126*, 37–45.
- Cook-Deegan, R., Geary, J., Hapke, K., Skvarkova, Z., Filipek, M., & Leaver, J. (2024). Sorry you asked? *Mayo, Myriad* and the battles over patent-eligibility. *Journal of Law and the Biosciences, 11*, 1–37.

## The Supreme Court Cases that invalidated "gene patents" and associations between genotype and phenotype (including diseases and conditions)

Mary-Claire King and colleagues announced the discovery of linkage between the putative gene BRCA1—associated with inherited risk of breast and ovarian cancer—and markers on chromosome 17 in October 1990, the same month the Human Genome Project officially began. The gene itself was identified, sequenced, and patent applications filed in 1994, followed the next year by BRCA2 on chromosome 13. These were not the only, or even the first, genes patented, but the BRCA patents were by far the most conspicuous and controversial, shown by analysis of newspaper articles and other public media, as well as policy reports.

- Caulfield, T., Bubela, T., & Murdoch, C. J. (2007). Myriad and the mass media: The covering of a gene patent controversy. *Genetics in Medicine, 9*, 850–855.
- Gold, E. R., & Carbone, J. (2010). Myriad Genetics: In the eye of the policy storm. *Genetics in Medicine, 12*, S39–S70.
- Caulfield, T., Chadrasekharan, S., Joly, Y., & Cook-Deegan, R. (2003). Harm, hype, and evidence: ELSI research and policy guidance. *Genome Medicine, 5*, Article 21.

The events surrounding BRCA ignited a hot controversy that persists about whether, how, and to what degree patenting and licensing practices foster or hamper access to clinical genetic testing.

Two U.S. Supreme Court Cases, *Mayo v Prometheus* (2012) and *Association for Molecular Pathology v Myriad Genetics* (2013), rekindled the debate. *Mayo* arose from a licensing dispute between the Mayo Clinic and Prometheus, a biotech company that had secured rights to a diagnostic method patent (not based on DNA, but relevant to claims on diagnostic methods). The *Myriad* case arose from the American Civil Liberties Union (ACLU) challenging the very idea that a human gene could be patented. The Court decided both cases unanimously (9-0), invalidating the underlying patent claims to naturally occurring DNA sequences (*Myriad*) and method claims affecting clinical decision-making based on measuring natural phenomena (*Mayo*).

The highest court in Australia likewise invalidated a claim to the *BRCA1* sequence in *D'Arcy v Myriad Genetics* (2015). A decade-long debate led up to that case. The Australian Law Reform Commission produced *Genes and Ingenuity: Gene Patenting and Human Health* in 2004, and a 2008 ruckus over BRCA patents in Australia led to the Committee on Community Affairs of the Australian Senate to prepare a report on *Gene Patents* in 2010.

The U.S. *Myriad* case attracted an immense amount of attention. It reached well beyond patent scholars and the usual battles between companies over patent rights. It was not one company suing another, but was framed as a civil rights case, challenging whether genes should be patented at all. It engaged patient groups, health care providers, and clinical laboratories, not just patent lawyers, venture capitalists and biotechnology analysts. It has its own rich literature. The history of the *Myriad* case is key to understanding how patents and genetic testing are connected.

- *The Genome Defense* (2021) by patent scholar Jorge Contreras is a great place to start. It was written for a general audience, not just those immersed in patent arcana.
- Jorge Contreras also teased apart the narrative streams and constituency perspectives in an article that is **particularly good for teaching**: Contreras, J. (2016). Narratives of gene patenting. *Florida State University Law Review, 43*, 1133–1199.

Sandra Park, one of the ACLU attorneys who brought the case, and Tania Simoncelli, the ALCU science advisor who first urged ACLU to pursue it, wrote several articles explaining the rationale:

- Simoncelli, T., & Park, S. S. (2015). Making the case against gene patents. *Perspectives on Science, 23*, 106–145.
- Park, S. S. (2014). Gene patents and the public interest: Litigating Association for Molecular Pathology v Myriad Genetics and lessons moving forward. *North Carolina Journal of Law & Technology, 15*, 519–536.
- Park, S. S. (2018). The challenge to gene patents as feminist patent litigation. *Technology & Innovation, 19*, 659–670.

These websites collected key documents relevant to the case:

- The fight to take back our genes. ACLU.
- Association for Molecular Pathology v. Myriad Genetics, Inc. SCOTUSblog.

A lively retrospective on the case after a decade is: Sherkow, J. S., Cook-Deegan, R., & Greely, H. T. (2024). The *Myriad* Decision at 10. *Annual Review of Genomics and Human Genetics, 25*, 397–419.

Several short articles explained the Supreme Court decision for various audiences:

- Cartwright-Smith, L. (2014). Patenting genes: What does Association for Molecular Pathology v Myriad Genetics mean for genetic testing and research? *Public Health Reports,129*, 289–292.
- Rai, A. K., & Cook-Deegan, R. (2013). Moving beyond 'isolated' gene patents. *Science, 341*, 137–138.
- Gold, R. E., Cook-Deegan, R., & Bubela, T. (2013). *AMP v Myriad*: A surgical strike on blockbuster business models. *Science Translational Medicine, 5*, 192.
- Kesselheim, A. S., Cook-Deegan, R. M., Winickoff, D. E., & Mello, M. M. (2013). Gene patenting—The Supreme Court finally speaks. *New England Journal of Medicine, 369*(9), 869–875.
- Klusty, T., & Weinmeyer, R. (2013). Supreme Court to Myriad Genetics: Synthetic DNA is patentable but isolated genes are not. *AMA Journal of Ethics, 17*, 849–853.
- Sherkow, J. S., & Scott, C. (2014). Myriad stands alone. *Nature Biotechnology, 32*, 620.
- Offit, K., Bradbury, A., Storm, C., Merz, J. F., Noonan, K. E., & Spence, R. (2013). Gene patents and personalized cancer care: Impact of the Myriad case on clinical oncology. *Journal of Clinical Oncology, 31*, 2743–2748.

Several scholars examined the effect that the Supreme Court decisions had on venture capital investment.

- Taylor, D. O. (2019). Patent eligibility and investment. *Cardozo Law Review, 41*, 2019–2116.
- Taylor, D. O. (2019). The Supreme Court's revolution in patent eligibility law: Alternative protections for biotechnology. *Nature Biotechnology, 37*, 227–30.
- Hoyt, S. (2022). The impact of uncertainty regarding patent eligible subject matter for investment in U.S. medical diagnostic technologies. *Washington and Lee Law Review, 79*, 397–452.

In the aftermath of *Mayo* and *Myriad* and a subsequent 2014 case, *Alice Corp. v CLS Bank*, which reinforced the Mayo decision, the American Bar Association, Intellectual Property Owners, and American Intellectual Property Law Association all urged the restoration of patent-eligibility.

- American Intellectual Property Law Association. (2018). *AIPLA/IPO/ABA—IPL Joint Principles Paper on Section 101*.

- Suchy, D. P. (2017, March 18). Letter from the American Bar Association, Section on Intellectual Property Law, with *Supplemental Comments on Patent Eligibility* to The Honorable Michelle K. Lee.
- Intellectual Property Owners' Association, Section 101 Legislation Task Force. (2017). *Proposed amendments to patent eligible subject matter under 25 U.S.C. §101*.
- American Intellectual Property Law Association. (2017). *AIPLA legislative proposal and report on patent eligible subject matter*.

Senators Thom Tillis (R-NC) and Christopher Coons (D-DE) introduced legislation in the 117th and 118th Congresses, and held hearings on defining patentable subject matter by statute, narrowing exclusions from patent-eligibility, abrogating and superseding the Supreme Court decisions. A House companion bill was introduced in September 2024. These bills did not emerge from committee. They may be introduced again in the 119th Congress starting January 2025.

- Patent Eligibility Restoration Act, S.2140, 118th Cong. (2023).
- Patent Eligibility Restoration Act, H.R.9474, 118th Cong. (2024).

Many patent scholars and others analyzed the pros and cons of restoring patent-eligibility to its pre-*Mayo* state. Several articles were based on empirical analysis and legal scholarship, some of which cast doubt on the narrowness of the rulings, some of which assessed the impacts, and all of which assessed how the landscape changed:

- Rai, A. K., Chien, C. V., & Clark, J. (2025). Molecular diagnostic patenting after Mayo v Prometheus: An empirical analysis. *Journal of Empirical Legal Studies*. Advance online publication. (Forthcoming 2025, but available through SSRN).
- Knowles, S., & Prosser, A. (2018). Unconstitutional application of 35 U.S.C. §101 by the U.S. Supreme Court. *John Marshall Review of Intellectual Property Law, 18*, 144–168. This argues that the Supreme Court overstepped and ignored important precedents in the 1952 Patent Act.
- Holman, C. M. (2014). *Mayo, Myriad*, and the future of innovation in molecular diagnostics and personalized medicine. *North Carolina Journal of Law and Technology, 15*, 639–678.
- Holman, C. M. (2016). The *Mayo* framework is bad for your health. *George Mason Law Review, 23*, 901–940.
- Aboy, M., Liddell, K., Crespo, C., Cohen, I. G., Liddicoat, J., Gerke, S., & Minssen, T. (2019). How does emerging patent case law in the US and Europe affect precision medicine. *Nature Biotechnology, 37*, 1118–1125.
- Liddicoat, J., Liddell, K., & Aboy, M. (2020). The effects of Myriad and Mayo on molecular-test development in the United States and Europe: Interviews from the frontline. *Vanderbilt Journal of Entertainment and Technology Law, 22*, 785–837.
- Aboy, M., Crespo, C., Liddell, K., Liddicoat, J., & Jordan, M. (2018). Was the *Myriad* decision a 'surgical strike,' on isolated DNA patents, or does it have wider impacts? *Nature Biotechnology, 36*, 1146–1149. This points to effects on patent-eligibility well beyond naturally occurring DNA sequences and diagnostics.
- Taylor, D. O. (2019). The Supreme Court's revolution in patent eligibility law: Alternative protections for biotechnology. *Nature Biotechnology, 37*, 227–30.
- Taylor, D. O. (2017). Amending patent eligibility. *UC Davis Law Review, 50*, 2149–2213.
- Duan, C., & Sarnoff, J. (2025). Certainly uncertain: An analysis of the Patent Eligibility Restoration Act of 2023. *American University Business Law Review*. Advance online publication. (Forthcoming, available through SSRN). This paper argues that limits to patent-eligibility are long-standing and justified.

- Duan, C. (2023). Examining patent eligibility. *St. John's Law Review, 97*, 47–114. This article is not directly about DNA patents, but relevant in that it argues that recent, permissive interpretation of patent eligibility is the anomaly, and the Supreme Court decisions a step towards restoring the historical balance.
- Gregory, H. (2015). Patent eligibility: Should Congress overrule the Supreme Court's recent decisions? Would the Court overrule the overrule? *Landslide, 7*(6), 1–8.
- Berg, J. (2019). DNA patents revisited. *Science, 364*, 1113. This paper calls for a National Academies' study of patent eligibility before passing a law to restore patent-eligibilty.

And finally, on the 10th Anniversary of the Myriad decision, in a dramatic turnabout, Myriad Genetics announced it would share data on variants that it had begun to protect as trade secrets in 2004, and stated that Myriad the company now opposed patents on naturally occurring sequences, while acknowledging the value of patents as incentives for innovation in general. This announcement was also reported in Forbes by genetic counselor, Ellen Matloff.

## Different Rules in Different Places

The rules about what can be patented differ between the United States and Australia—where the highest courts have invalidated patent claims to DNA sequences corresponding to human genes—and other patent jurisdictions, where such sequences can be patented if they meet other patent criteria. That is, patents claiming naturally occurring DNA sequences are patent-eligible in Europe (under a European Union [EU] Biotechnology Patent Directive, which is respected by signatories of the European Patent Convention) and in most other jurisdictions. Several authors have addressed international differences, including how different national governments have procedures to force licensing of diagnostic patents to override the patent-holder rights.

The BRCA patent controversies provoked several European nations to take action to prevent patent-based diagnostic service monopolies from developing. The EU Biotechnology Directive explicitly allowed patents on sequences. The policy approach was not to challenge the patent-eligibility in EU countries, but instead some national governments conferred authority to force "compulsory licensing" of diagnostic patents to promote public health. Proposals for pooling of patent rights, clearinghouses, and other policy approaches also emerged. These policies were reviewed in two books edited by Geertrui van Overwalle.

- van Overwalle, G. (Ed.). (2007). *Gene patents and public health*. Bruylant. This is particularly strong on different approaches to compulsory licensing in France, Belgium, and Switzerland.
- van Overwalle, G. (Ed.). (2009). *Gene patents and collaborative licensing models: Patent pools, clearinghouses, open source models and liability regimes*. Cambridge University Press.

The scholarship of Shobita Parthasarathy is distinctive in that it draws on social science and looks beyond purely legal or economic analysis to address the contexts in which patent law plays out. The BRCA patent controversies are a recurrent theme. Her 2017 book, *Patent Politics*, compares the U.S. and Europe; and her 2012 book, *Building Genetic Medicine*, centered on breast cancer and how genetic testing was managed by health systems in the United States compared to the United Kingdom.

Other comparative analyses include:

- Hopkins, M., & Nightingale, P. (2006). Strategic risk management using complementary assets: Organizational capabilities and the commercialization of human genetic testing in the UK. *Research Policy, 35*, 355–374.

- Hawkins, N., Nicol, D., Chandrasekharan, S., and Cook-Deegan, R. (2019). The continuing saga of patents and non-invasive prenatal testing. *Prenatal Diagnosis, 39*, 441–447.
- van Zimmeren, E., Nicol, D., Gold, R., Carbone, J., Chandrasekharan, S., Baldwin, A. L., & Cook-Deegan, R. (2013). The BRCA patent controversies: An international review of patent disputes. In S. Gibbon, G. Joseph, J. Mozersky, A. zur Nieden, & S. Palfner (Eds.), *Breast cancer gene research and medical practices: Transnational perspectives in the time of BRCA*. Routledge.

## Other aspects of gene patents that may be of interest

Several aspects of intellectual property that are not directly centered on access to clinical genetic testing but may nonetheless be of interest.

*Did the Bermuda Principles for open science matter?*

One of the most beautiful papers in genomics and intellectual property is not about patents at all. As part of her Ph.D. in economics at Harvard, Heidi Williams compared the use of sequences first made public by the International Human Genome Sequencing Consortium (the high-throughput centers that were part of the Human Genome Project funded by the U.S., France, Germany, Japan, and China, plus the Wellcome Trust in the UK) to those first sequenced by Celera Genomics and available under subscription or restricted public access. The publicly funded project operated under the Bermuda Principles of daily sequence disclosure, whereas full access to the Celera sequence database required a subscription. Most Celera sequences were not patented, but the use restrictions—a form of intellectual property—created a natural experiment that could be evaluated years later. Williams found a 20-30 percent boost in use of the sequences made immediately available compared to the Celera sequences, both in publications and in development of diagnostics.

In a follow-up study, she and Bhaven Sampat found little difference in follow-on innovation when comparing sequences that were patented versus not patented. These findings—a significant effect of non-patent constraints inhibiting innovation while the effects of patents are hard to discern—starkly illustrate how nuanced the effects of intellectual property are in genomics.

*Is "the anticommons" a thing?*

One cluster of papers centered on the idea of "the anticommons"—a notion proposed by Michael Heller and Rebecca Eisenberg in a 1998 *Science* Policy Forum article. This article turned the tragedy of the commons on its head. The "tragedy" stems from overuse of a "commons" that depletes its value for everyone—typically, an exhaustible resource. An "anticommons," in contrast, might arise when otherwise public resources were protected by patents or other legal means, leading to under-utilization and loss of social value because it would be difficult to aggregate the necessary bundle of rights to innovate. It remains a contested topic in patent research.

*What's the fuss about 20% of human genes being patented?*

Another group of articles surrounded a mêlée that followed the 2005 publication of another *Science* Policy Forum by Kyle Jensen and Fiona Murray. They used informatic methods to link sequences to patents, and startled the field by claiming 20% of human genes were associated with patents. This set off a controversy.

- Michael Crichton asserted in the New York Times that "one-fifth of the genes in your body are privately owned," and made patents a theme of the last best-selling novel he published in his lifetime, *Next*.
- Rosenfeld and Mason raised a similar concern in their 2013 article, asserting that 41 percent of human genes had a claim on them.

In several articles, Christopher Holman countered that the patent claims did not constrain freedom to do research or use sequences nearly as seriously as the rhetoric about "patented genes" implied.

- Holman, C. M. (2011). Will gene patents impede whole genome sequencing?: Deconstructing the myth that 20% of the human genome is patented. *IP Theory, 2*, 1–16.
- Holman, C. M. (2012). Will gene patents derail the next generation of genetic technologies?: A reassessment of the evidence suggests not. *University of Missouri Kansas City Law Review, 80*, 563–605.
- Holman, C. M. (2012). Debunking the myth that whole genome sequencing infringes thousands of gene patents. *Nature Biotechnology, 30*, 240–244.

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Several aspects of intellectual property that are not directly centered on access to clinical genetic testing but may nonetheless be of interest.

*Did the Bermuda Principles for open science matter?*

One of the most beautiful papers in genomics and intellectual property is not about patents at all. As part of her Ph.D. in economics at Harvard, Heidi Williams compared the use of sequences first made public by the International Human Genome Sequencing Consortium (the high-throughput centers that were part of the Human Genome Project funded by the U.S., France, Germany, Japan, and China, plus the Wellcome Trust in the UK) to those first sequenced by Celera Genomics and available under subscription or restricted public access. The publicly funded project operated under the Bermuda Principles of daily sequence disclosure, whereas full access to the Celera sequence database required a subscription. Most Celera sequences were not patented, but the use restrictions—a form of intellectual property—created a natural experiment that could be evaluated years later. Williams found a 20-30 percent boost in use of the sequences made immediately available compared to the Celera sequences, both in publications and in development of diagnostics.

In a follow-up study, she and Bhaven Sampat found little difference in follow-on innovation when comparing sequences that were patented versus not patented. These findings—a significant effect of non-patent constraints inhibiting innovation while the effects of patents are hard to discern—starkly illustrate how nuanced the effects of intellectual property are in genomics.

*Is "the anticommons" a thing?*

One cluster of papers centered on the idea of "the anticommons"—a notion proposed by Michael Heller and Rebecca Eisenberg in a 1998 *Science* Policy Forum article. This article turned the tragedy of the commons on its head. The "tragedy" stems from overuse of a "commons" that depletes its value for everyone—typically, an exhaustible resource. An "anticommons," in contrast, might arise when otherwise public resources were protected by patents or other legal means, leading to under-utilization and loss of social value because it would be difficult to aggregate the necessary bundle of rights to innovate. It remains a contested topic in patent research.

*What's the fuss about 20% of human genes being patented?*

Another group of articles surrounded a mêlée that followed the 2005 publication of another *Science* Policy Forum by Kyle Jensen and Fiona Murray. They used informatic methods to link sequences to patents, and startled the field by claiming 20% of human genes were associated with patents. This set off a controversy.

- Michael Crichton asserted in the New York Times that "one-fifth of the genes in your body are privately owned," and made patents a theme of the last best-selling novel he published in his lifetime, *Next*.
- Rosenfeld and Mason raised a similar concern in their 2013 article, asserting that 41 percent of human genes had a claim on them.

In several articles, Christopher Holman countered that the patent claims did not constrain freedom to do research or use sequences nearly as seriously as the rhetoric about "patented genes" implied.

- Holman, C. M. (2011). Will gene patents impede whole genome sequencing?: Deconstructing the myth that 20% of the human genome is patented. *IP Theory, 2*, 1–16.
- Holman, C. M. (2012). Will gene patents derail the next generation of genetic technologies?: A reassessment of the evidence suggests not. *University of Missouri Kansas City Law Review, 80*, 563–605.
- Holman, C. M. (2012). Debunking the myth that whole genome sequencing infringes thousands of gene patents. *Nature Biotechnology, 30*, 240–244.

## Research and Clinical Use Exemptions from Infringement Liability

The foremost recommendation of the 2010 SACGHS report on patents and genetic testing was to permit patient care testing and research by exempting such uses from infringement liability (pp. 94-97 of the report). That is, Congress should pass a law creating a statutory exemption. Such use might infringe patent claims, but the usual remedy of litigation for damages would be foreclosed because the patents could not be enforced against such uses.

Rochelle Dreyfuss, who served on the SACGHS committee as well as two National Academies study committees on intellectual property policy, had long contemplated such policies. The SACGHS report renewed interest, although no bills were proposed to implement the recommendation, and it was strongly opposed by some.

- Dreyfuss, R. C. (2004). Protecting the public domain of science: Has the time for an experimental use defense arrived? *Arizona Law Review, 46*, 457–472.
- Dreyfuss, R. C. (2016). Reconsidering experimental use. *Akron Law Review, 50*, 699–723.

The idea of a research exemption has a long history.

- Eisenberg, R. (1989). Patents and the progress of science: Exclusive rights and experimental use. *University of Chicago Law Review, 56*, 1017–1086. This article, cited over 1,000 times, analyzed how patents could affect research and examined the judge-made U.S. case law, because the U.S. had no statutory research exemption.
- Nicholas Short addressed "The political economy of the research exemption in American patent law," and reviewed the history of a failed House bill to create a research exemption in 1990, proposing legislative language that could be adopted in: Short, N. (2016). A research exemption for the 21st century. *University of Michigan Journal of Law Reform, 50*, 1–17.

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