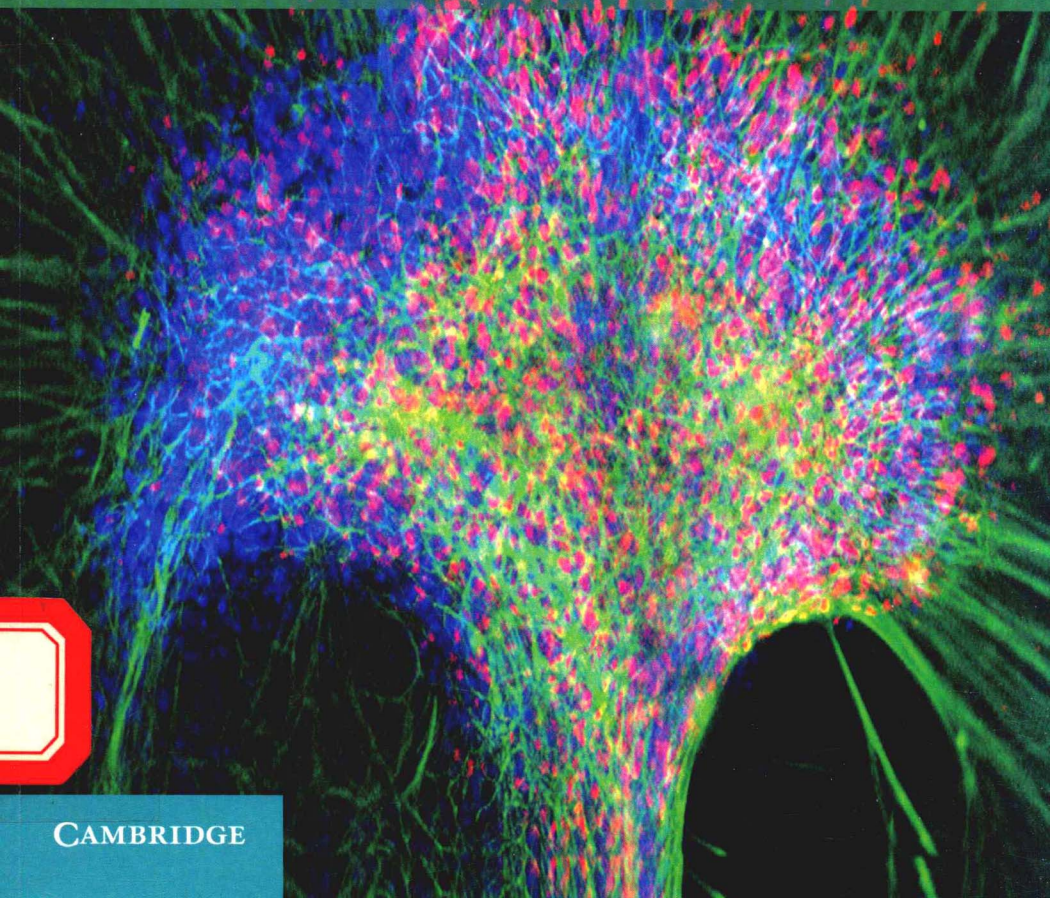


Identity, Invention, and the Culture of Personalized Medicine Patenting

Shubha Ghosh



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Preface

If I had to identify the Big Bang moment, the conception for this book was sparked by a 2005 news report about the FDA approval of BiDil, touted as the first drug specified for a particular racial or ethnic group. I have always been interested in issues of identity as a consumer of scholarship while pursuing studies of innovation, intellectual property, and the social and cultural contexts, as well as technical aspects, of markets as a producer. The BiDil news story struck me as interesting, and the topic as a bridge between my habits as a consumer and producer. But looking back over the manuscript and rereading, often painfully, the research I had brought together, I realized I owe a debt to many academic influences. Perhaps the yearning to acknowledge some of the influences reflects my misguided nostalgia. Nonetheless, acknowledge I feel I must.

First are the many teachers at St. Anselm's Abbey School and Amherst College who exposed me to the right balance of interdisciplinary thinking and rigorous questioning and analysis. Although I moved away from an engagement with the economics profession decades ago, moving toward economic analysis of the law and institutions, the graduate training at the University of Michigan formed my thinking about population studies, demography, and the commons that find expression in these pages. Thanks to the Population Studies Center of the University of Michigan, which celebrated its golden anniversary in 2011, for the positive influences. Finally, starting from my time as a student at Stanford Law School and continuing through the various schools at which I have taught, there are many legal scholars and educators from whom I have learned and still learn and whose ideas are reflected with a combination of admiration and detachment in this book. I believe in always paying back my debts in full, but I may have fallen short here.

Second are seminar participants who sat through various presentations and early fumbblings as this research project developed. I particularly would like

to thank participants in workshops at the University of Wisconsin Business School, University of Wisconsin Law School, SMU Dedman School of Law, Howard University Law School, and sessions at the Annual Meeting of the Law & Society Association for their support. My colleague Anne Miner at the University of Wisconsin has been very supportive of this project and an encouraging colleague in general.

Third is the financial support I have received from the University of Wisconsin as a Vilas Research Fellow and from the Graduate Fellowship Committee. Recently, I had a discussion with a colleague as to whether, as professors, our teaching subsidizes our research or the other way around. I think of the job as a bundled package. But the financial backing from my university supported research trips and writing time that were not a break from teaching, but enhancements to what I do in the classroom. More important than the financial support is the assistance of Cheryl O'Connor and Bonnie Sucha of the University Wisconsin Law Library for tracking down materials and legal citations. Teresa Evans and Sue Sawatske provided guidance in the technical details of formatting the manuscript. Finally, preliminary work on this project when I was Professor of Law at Southern Methodist University's Dedman School of Law benefited from the research assistance of Ayse Guner (JD, class of 2008) and Ross Allen (JD, class of 2008).

Fourth is John Berger of Cambridge University Press, who was very patient in guiding me through the proposal process and with my questions about production. He and the many other editors and production staff at Cambridge have been a delight to work with.

Fifth, I would like to acknowledge the law journals in which preliminary versions of the ideas in this book were tested out. I would like thank the editors of the respective journals for giving me permission to reprint derivative works based on sections from the following articles:

"Why Intergenerational Equity," 2011 Wisc. L. Rev. 103–109 (2011).

"Patenting Games; or, *Baker v. Selden* Revisited," 11(4) Vanderbilt Journal of Entertainment and Technology Law 871–898 (2009).

"Race-Specific Patents, Commercialization, and Intellectual Property Policy," 56 Buffalo L. Rev. 101–187 (2008).

"The Fable of the Commons: Exclusivity and the Construction of Intellectual Property Markets," 40 U.C. Davis Law Review 855 (2007).

"Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After *Eldred*," 19 Berkeley Technology Law Journal 1315–1388 (2005).

Writing this book allowed me to revisit the ideas of these earlier works and to synthesize them.

Sixth is reflected in the dedication to Keith Aoki, *Wunderfreund*, who passed away unexpectedly in 2011. To describe Keith requires a neologism, a German one at that. Keith was a pathbreaking scholar and remarkable teacher as well as an incredible colleague globally, beyond the boundaries of his home institution. Keith was also the first academic I met after entering law school teaching in 1996. We shared a van ride from LAX to attend a conference at UCLA. His sincerity and inquisitiveness came through from that first encounter in which he was trying to figure me out. I will miss him.

Most importantly, Soma was a constant source of joy and our dog, Chewbacca, provided countless distractions especially when he tried to break me from the laptop with a lick to the hand, sometimes to an oddly appropriate key.

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Persons and Patents

... it is a story ... seared into my genetic makeup that this nation is more than the sum of its parts – that out of many, we are truly one.

Barack Obama, Philadelphia, PA, March 18, 2008

In April 2010, Judge Robert Sweet of the Southern District of New York ruled that gene sequences could not be patented.¹ The court also ruled that a medical diagnostic test requiring comparison of a patient's gene with an identified breast cancer gene sequence was not patentable because it was a mental process.² These controversial rulings shook the foundations of many global industries engaged in providing medical services based on genetic information. Biotechnological research at university and industry labs faced a paradigm change if Judge Sweet's ruling were upheld. The assumption guiding commercialization efforts and U.S. scientific policy was that patents on gene sequences provided a stable set of legal rights for the development of science and industry in biotechnology.

Although this assumption has been the subject of criticism before and after the U.S. Supreme Court's landmark 1980 ruling in *Diamond v. Chakrabarty*, holding that a genetically modified single-cell organism could be patented,³ the availability of patents for gene sequences had not been seriously challenged until 2010. There was an expected sigh of relief from the affected industry interests when in July 2011, the Court of Appeals for the Federal Circuit overruled Judge Sweet's ruling with respect to the patentability of a gene sequence.⁴ However, the Federal Circuit upheld Judge Sweet's ruling that the diagnostic

¹ *The Association for Molecular Pathology v. United States Patent Office & Myriad Genetics, Inc.*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

² *Idem.* at 235–236.

³ 447 U.S. 303 (1980).

⁴ *The Association for Molecular Pathology v. United States Patent Office & Myriad Genetics, Inc.*, 653 F.3d 1329 (Fed. Cir. 2011).

method involving comparing gene sequences was not patentable. On March 26, 2012, the Supreme Court vacated the Federal Circuit's ruling and sent the case back to the appeals court for review in light of the Supreme Court's decision in *Mayo v. Prometheus*.⁵ From the perspective of industry groups, scholars, and policy makers, we are living in interesting times for patents and biotechnology.

In 2002, eight years before Judge Sweet's ruling, a start-up company called Nitromed received an initial patent on a prescription drug called BiDil that was designed for treatment of hypertension in "black patients," to adopt the language from the granted patent.⁶ Like many pharmaceuticals aimed at hypertension, BiDil was a nitrogen dilator, controlling the amount of nitrogen in the blood. Nitromed obtained a patent on an earlier version of the hypertension drug in the late 1980s. During its clinical trials, testing the effectiveness of the drug on actual people, researchers at the company noticed that a certain combination of compounds was particularly effective on the African-American population. The researchers were not looking to target the African-American population in their trials; they were using a population of veterans. African Americans constituted a large proportion of the veteran population used in the clinical trials as compared to the U.S. population as a whole. The company decided to patent the findings of its researchers as a new compound that would be particularly effective in treating hypertension in the African-American population. In 2005, Nitromed received approval from the U.S. Food and Drug Administration (FDA) for BiDil as a hypertension treatment for African Americans, the first time the agency had approved a drug compound for a particular racial or ethnic group. Although the patent did

⁵ See 2012 WL 9861819. The Supreme Court ruled in *Mayo v. Prometheus* that a specific method of personalized medicine was not patentable because it only recited a law of nature without any applications. See *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012).

⁶ U.S. Patent No. 6465463 (issued Oct. 15, 2002). The first claim reads as follows: "1. A method of reducing mortality associated with heart failure, for improving the oxygen consumption, for improving the quality of life or for improving exercise tolerance in a black patient comprising administering to the black patient a therapeutically effective amount of at least one hydralazine compound of Formula (I) or a pharmaceutically acceptable salt thereof, and at least one of isosorbide dinitrate and isosorbide mononitrate, wherein the hydralazine compound of Formula (I) is wherein a, b and c are each independently a single or a double bond; R₁ and R₂ are each independently a hydrogen, an alkyl, an ester or a heterocyclic ring; R₃ and R₄ are each independently a lone pair of electrons or a hydrogen, with the proviso that at least one of R₁, R₂, R₃ and R₄ is not a hydrogen" (emphasis added). Claim 2 is a dependent claim that refers to claim 1 but limits it to the case "wherein the black patient has a less active rennin-angiotensin system relative to a white patient." Finally, claim 3 also depends on claim 1 but limits it to the case "wherein the black patient has hypertension." This patent was reissued in 2004 as U.S. Patent No. 6784177 (issued Aug. 31, 2004).

not receive much publicity, the decision of the FDA did, bringing the issue of personalized medicine to the forefront of policy debates.⁷

Judge Sweet's decision in 2010 and Nitromed's patenting and commercialization strategies with respect to BiDil more than half a decade earlier have much in common. They both bring to the forefront the challenging question of patent law's relationship to people who use and rely on patented inventions. This question is the central focus of this book. It may appear that juxtaposing an abstraction like a patent with something concrete and living like a person is just an academic exercise. But developments in the marketplace, society, and legal rules have mixed the realm of the abstract with that of the personal.

A patent is a grant from the government that allows the patent owner to keep others from making, using, selling, or importing the invention covered by the patent. With this grant, the owner can, in theory, commercialize and sell the invention to the public. Almost all products, from your car to your smartphone to your microwave, are currently covered by a patent or have been covered by a patent in the past. Through the gadgets we use or purchase, patents affect our personal lives. Patents also cover pharmaceuticals and in that way directly affect our health and our ability to live. One of the biggest controversies, still ongoing, is access to medicines in both the developed and the developing worlds. The access-to-medicine debate has many dimensions, and the existence of a patent on these medicines is one of them. A patent is most certainly an abstraction, but it is one that intervenes in the personal sphere in many direct and indirect ways.

The patent at issue in Judge Sweet's decision, owned by Myriad, covered diagnostic techniques to identify a specific genetic sequence linked with the proclivity to breast cancer in women. Anyone using this particular diagnostic and the genetic sequence identified by Myriad would have to deal with the patent. The lawsuit against Myriad that gave rise to Judge Sweet's opinion challenged the patentability of the genetic sequence that was the basis for the diagnostic test. The legal argument was that no one can own a gene, especially when it is part of a person. Myriad's argument was that it did not own a gene as it existed in a person, but a purified, extracted form of the gene as it existed in a laboratory for the purpose of making a medical diagnosis. The distinction would be analogous to distinguishing ownership of a lock of hair from someone's head from ownership of the purified chemical and material

⁷ See, e.g., "Getting to the Heart of the Matter," *U.S. News & World Report* 14 (June 15, 2005); "Color-Blind Drug Research Is Myopic; More, Not Less, Study Is Needed on Ways Different Races Respond," *Business Week* 44 (June 27, 2005); "FDA Approves Heart Drug for African-Americans," *The New York Times* C2 (June 24, 2005).

compounds that comprise the lock. Judge Sweet, however, did not entertain such hairsplitting. What Myriad claimed ownership of was not distinguishable from an actual gene as it existed in a human person.⁸ Therefore, the patent was invalid. The facts of the case illustrate how our understanding of a patent is related to our understanding of a person.

This point is underscored by the Federal Circuit's decision on appeal. The court held that the patented gene sequence (see Figure 1.1) was different from the one that exists in the person. The patented sequence was not in a natural state, but was rather in a purified state. It had been processed physically by a researcher in a lab to obtain a new composition that could be manipulated and studied. The patented gene sequence was in effect a representation of, and hence different from, the naturally occurring gene.⁹ Much like a tree differs from a photograph of a tree, the song of a bird differs from synthesized bird calls, or color and light differ from hues of paint, so the patented sequence is the product of human endeavor. In a similar vein, the Federal Circuit upheld Judge Sweet's ruling that the diagnostic method of comparing two gene sequences is not patentable because the act of comparison constitutes a mental process.¹⁰ The act of comparing occurs inside a person's brain. Processing information occurs inside a person. Allowing patents on mental processes would be tantamount to patenting thoughts. The reach of patent law seems to depend on the boundaries of a person's body and mind. The person so defined by these boundaries is impermeable to patent ownership.

There has been no legal challenge either in the U.S. Patent Office (USPTO) or in the courts to the Nitromed patent. My research has found no evidence that Nitromed has brought legal actions for infringement or has even sought to license the patent – the usual strategies for enforcing one's patent rights. It should also be made clear that there is no genetic component to Nitromed's patent (see Figure 1.2). The patent covers a pharmaceutical compound that is effective for the treatment of hypertension in "black patients." But blackness is not defined in genetic terms. And, of course, it really cannot be. Nitromed is basing its claim on epidemiological and statistical data. The company's researchers found that the compound at issue was effective in treating hypertension as a statistical matter when tested on a group of self-identified black patients. Blackness is a self-identified category, rooted in sociological understandings rather than genetic ones. Whereas the decisions in Myriad suggest that the physical and mental dimensions of a person are not subject to patent

⁸ See note 1 to this chapter at 222–227.

⁹ See note 3 to this chapter at 1349–1350.

¹⁰ See note 3 to this chapter at 1355–1356.

United States Patent [19]

Shattuck-Eidens et al.

[11] **Patent Number:** 5,693,473[45] **Date of Patent:** Dec. 2, 1997

- [54] **LINKED BREAST AND OVARIAN CANCER SUSCEPTIBILITY GENE**
- [75] **Inventors:** Donna M. Shattuck-Eidens, Salt Lake City, Utah; Jacques Simard, Quebec; Francine Durocher, Ste-Foy, both of Canada; Mitsuru Emi, Tokoyo; Yusuke Nakamura, Yokohama, both of Japan
- [73] **Assignees:** Myriad Genetics, Inc., Salt Lake City, Utah; Centre de Recherche du Chul, Sainte-Foy, Canada; Cancer Institute, Tokyo, Japan

[21] **Appl. No.:** 480,784[22] **Filed:** Jun. 7, 1995**Related U.S. Application Data**

- [63] Continuation-in-part of Ser. No. 409,305, Mar. 24, 1995, abandoned, which is a continuation-in-part of Ser. No. 348,824, Nov. 29, 1994, abandoned, which is a continuation-in-part of Ser. No. 308,104, Sep. 9, 1994, abandoned, which is a continuation-in-part of Ser. No. 300,266, Sep. 2, 1994, abandoned, which is a continuation-in-part of Ser. No. 289,221, Aug. 12, 1994, abandoned.
- [51] **Int. Cl.⁶** C12Q 1/68; C12P 19/34; C07H 21/04; C07H 21/02
- [52] **U.S. Cl.** 435/6; 435/91.2; 536/23.1; 536/24.3; 536/24.33
- [58] **Field of Search** 435/6, 91.2; 536/23.1, 536/24.3, 24.33

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(List continued on next page.)

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[57]

ABSTRACT

The present invention relates generally to the field of human genetics. Specifically, the present invention relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer. More specifically, the invention relates to germline mutations in the BRCA1 gene and their use in the diagnosis of predisposition to breast and ovarian cancer. The present invention further relates to somatic mutations in the BRCA1 gene in human breast and ovarian cancer and their use in the diagnosis and prognosis of human breast and ovarian cancer. Additionally, the invention relates to somatic mutations in the BRCA1 gene in other human cancers and their use in the diagnosis and prognosis of human cancers. The invention also relates to the therapy of human cancers which have a mutation in the BRCA1 gene, including gene therapy, protein replacement therapy and protein mimetics. The invention further relates to the screening of drugs for cancer therapy. Finally, the invention relates to the screening of the BRCA1 gene for mutations, which are useful for diagnosing the predisposition to breast and ovarian cancer.

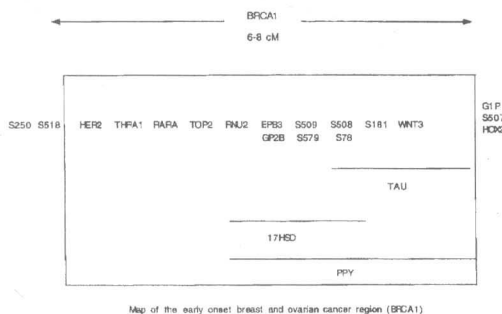
14 Claims, 18 Drawing Sheets

FIGURE 1.1. First page of one of Myriad's patents.

(57)

ABSTRACT

The present invention provides methods or treating and preventing mortality associated with heart failure in an African American patient with hypertension and improving oxygen consumption, quality of life and exercise tolerance by administering a therapeutically effective amount of at least one hydralazine compound and at least one of isosorbide dinitrate and isosorbide mononitrate, and, optionally, one or more compounds, such as, for example, a digitalis, a diuretic compound, or a compound used to treat cardiovascular diseases. In the present invention, the hydralazine compound is preferably hydralazine or a pharmaceutically acceptable salt thereof. Preferred methods of the invention comprise administering hydralazine or a pharmaceutically acceptable salt thereof and isosorbide dinitrate.

FIGURE 1.2. Abstract from the Nitromed patent.

ownership, the Nitromed patent on BiDil suggests that the sociological conception of a person is susceptible to patenting.

As I explain in Chapter 3 the use of the term “black patient” creates a tenuous foundation for the patent, certainly more tenuous than Myriad’s claim to the “breast cancer gene.” Nonetheless, the Nitromed patent, like the Myriad patent, illustrates how the abstraction of a patent is used to intersect with understandings of the human person. The motivation is one of commercialization, which opens up the salient question of the relationship between markets and persons – another focus of inquiry for this book. Furthermore, there have been nearly a thousand patents in the wake of the Nitromed patent that purport to cover inventions aimed at particular self-identified racial and ethnic groups, such as Asian Americans and Latinos. The Myriad and Nitromed patents are useful twins, one covering genetic understanding of the person, the other sociological. Of course these two understandings might intersect. In the European Union, for example, Myriad has a patent covering a special form of the breast cancer gene as it exists in Ashkenazi-Jewish women.¹¹

¹¹ Sabine Steimle, “Critics Question BRCA2 Patent Decision in Europe,” 97 (18) *Journal of the National Cancer Institute* 1326 (Sept. 21, 2005).

The quote by President Obama that begins this chapter shows how the genetic and sociological views of identity can easily be elided. When he refers to his “genetic makeup,” President Obama is not speaking literally. The quote is from his famous speech in which he distanced himself from the racist views of his minister, Reverend Jeremiah Wright. The brilliance of the speech was to highlight the historical and cultural contingencies of race. President Obama simultaneously questioned the use of race as a fixed, immutable category and emphasized the reality of race in framing the historical reality of race that shapes contemporary relations. His use of the phrase “genetic makeup” highlights this contingency. President Obama is not saying there is such a thing as a “black gene,” a phrase that confuses the sociological with the biological. Instead, the genetic makeup is a reference to a litany of contingencies. Who we are genetically depends on who our parents are, and their meeting and joining was not inevitable. Conception and fetal development are also subject to accidents, with the early stages of cellular division having several possible pathways. But the final accumulation of these contingencies produces an identity that we take as natural and, at some level, unchanging. The danger, of course, is that some may read a phrase like “genetic makeup” literally, and this book attempts, in part, to prevent dangerous conclusions like that.

My goal is to provide a more coherent framework for assessing the types of patents illustrated by my two starting examples of *Myriad* and *NitroMed*. I am not suggesting that such patents should be forbidden. In my opinion, Judge Sweet overstated the case in his decision. My concern is with the casual intrusion of patent law into the realm of personal identity. I am troubled by this intrusion partly because we do not fully understand it. For example, it is too easy conceptually to start reducing a person to one's genes. As history has shown, this conceptual move is particularly pernicious when a person's racial or ethnic identity is viewed as genetic.¹² At the same time, we are beginning to understand that the gene itself is not fixed and unchanging and can be shaped by environmental factors. Furthermore, certain diseases are more prevalent in certain groups. It is important that scientific and medical communities address these differences. Otherwise, disease prevention will focus solely on the majority. The goal of this project is to open options for improving the lives of persons in a responsible and thoughtful manner. With this goal in mind, this book should be read as the starting point for a discussion, rather than as the final word in it.

¹² Victoria F. Nourse, *In Reckless Hands: Skinner v. Oklahoma and the Near Triumph of American Eugenics* (New York: W.W.Norton & Co., 2008) 124–126.

WHY PATENTS?

I have described patents as an abstraction, but patents can have tangible and concrete effects. Under current usage, a patent is a grant from a national government to an individual or a group of individuals that allows the patent owner to prevent others from making, using, selling, or importing an invention. But patents have deep historical roots. Patents were at one point granted by the sovereign, namely the monarch, on any item. There were patents on different spices, on playing cards, on gaming devices. A grant of land was also referred to as a patent. The key meaning of the word “patent” follows from its Latin roots. A patent is and was an “open” grant, as opposed to a secret one.¹³ The sovereign made a pronouncement and the individual received this exclusive set of rights, protected by the crown. In 1624, with growing concern over the monopoly and market privileges bestowed by patents and general discontent with the power of the monarch, the English parliament enacted the Statute Against Monopolies, designed to limit the power of the crown to grant the privileges of patents for the manufacture and selling of particular products. The Statute limited these grants to those covering inventions and grants related to copyrights, or the printing privilege. It is from the Statute of Monopolies that the relationship between patents and inventions originates in the Anglo-American legal tradition.¹⁴ As this brief history suggests, patents are abstractions, essentially sovereign pronouncements, but they have economic and political implications.

With the formation of nation-states and the development of democratic market economies, the understanding of patent law changed from a strict grant from the sovereign to a property right for which an inventor would apply with a respective government agency that had the responsibility to ensure that property rights were granted to appropriate inventions.¹⁵ The agency, or the patent office, would enforce the patent statute that provided the legal requirements for an invention. While there are slight differences across countries in these legal requirements, they generally reduce to five:¹⁶ (1) patentable subject matter, or the product of some useful art or industry; (2) utility, or having some practical application; (3) novelty, or not previously existing; (4) nonobviousness,

¹³ Erich Kaufer, *Economics of the Patent System* 1 (1989).

¹⁴ *Idem.* at 8–9.

¹⁵ Suzanne Scotchmer, *Innovation and Incentives* (Cambridge, MA: The MIT Press, 2004) 11–14.

¹⁶ Shubha Ghosh et al., *Intellectual Property: Private Rights, the Public Interest, and the Regulation of Creative Activity* (St. Paul: Thomson West, 2010) 258–260.