

# **A HIDDEN TECHNOLOGICAL ASSUMPTION IN PATENT LAW: THE CASE OF GENE PATENTS AND THE DISCLOSURE REQUIREMENT**

by

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## **Abstract**

The disclosure requirement in patent law is designed to reveal knowledge regarding a patented invention in order to allow proper understanding and utilization of that invention. Some fundamental challenges arise when applying the disclosure requirement to genetic inventions. The contention offered in the current study is the presence of an inherent incompatibility between patent law's disclosure requirement and genetic inventions. This incompatibility prevents patent law from fully accomplishing its intended purpose.

Genetic inventions are highly contingent on big genetic statistical data (GSD). GSD comprise information which is gathered during the commercial phase of a genetic invention and imparts better-quality and different abilities regarding understanding and utilizing of a genetic invention. GSD are essential for a variety of purposes, which at least some should be satisfied by the disclosure requirement. Importantly, however, since GSD can be gathered only at the post-application period, GSD are not disclosed through the disclosure requirement. Therefore, I contend that there is a disclosure-genetics incompatibility. This incompatibility has several ramifications, which can be classified in the context of four primary malfunctions of the patent system.

The origins of this incompatibility can be traced to the structure of the disclosure requirement, a consequence of a hidden technological assumption in patent law. According to the argument presented here, a technological mindset in patent law can

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be identified regarding the very perception of what is the essence of an invention, namely, how should an invention function. Patent law perceives all inventions as fully-revealed objects (i.e., inventions which are fully understood at the moment of their invention). Patent law does not think of inventions as semi-revealed objects (i.e., inventions which are only partially understood at the inventing moment and are fully clarified only after mass usage). This technological assumption creates a difficulty that may be more pervasive than for genetics alone. Thus, acknowledging this technological assumption facilitates the introduction of an insight regarding the fully-revealed/semi-revealed spectrum along with possible implications of this phenomenon regarding inventions in other, non-genetic technological fields. Recommendations aimed at resolving the problematics of the presented incompatibility and having relevance to patent law in general are discussed.

## **I. Introduction**

The disclosure requirement in patent law is designated to reveal knowledge regarding a patented invention in order to allow proper understanding and utilization of the invention.<sup>1</sup> I argue that there is an inherent incompatibility between patent law's disclosure requirement and genetic inventions, an incompatibility which prevents patent law from fully accomplishing its desired objectives. The incompatibility's origins lay in the architecture of the disclosure requirement; this architecture is the outcome of a hidden assumption in patent law regarding the very idea of what comprises an invention. Considering this technological assumption, it seems that the problem is more general and not limited to genetics. In light of the exposure of the technological assumption, I offer an insight regarding fully-revealed and semi-revealed environments.

The following illustration should help clarify the presented argument. When BRCA genetic testing was first marketed, Variants of Uncertain Significance (VUS)—genes' versions whose correlation with cancer is unknown—were found in 10-15% of the cases. As more patients were tested, more genetic statistical data (GSD) were collected. With a proprietary database of about 14,000 variants, the rate of VUS dramatically

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<sup>1</sup> The disclosure requirement has additional objectives, such as facilitating patents' examination, setting the legitimate borders of the scope, and supporting enforcement of patents.

plunged to 2.5%.<sup>2</sup> The patent rights granted Myriad the exclusive right to gather these data.<sup>3</sup> Other genetic laboratories that do not hold GSD are unable to use the invention in the same way, certainly not effectively, even after the patent expires or has been invalidated. Considering these facts, it is not surprising that Myriad dominated the market even after the patent period. The vast database Myriad has retrieved, owing to the patent monopoly, enables it to understand and utilize the very same genetic invention differently than others.<sup>4</sup>

The cited case reflects a more profound incompatibility between the disclosure requirement and genetic inventions. Disclosure is a means to disseminate adequate knowledge for properly understanding and utilizing an invention. Society pays for this precious knowledge with exclusive rights. However, unfortunately, as shown in the case of Myriad, the disclosure does not satisfy its objective. In fact, patent law assists the patentee to conceal pertinent knowledge from the public. Hence, the question remains: Does patent law truly serve society when applied to gene patents? Does patent law deliver on its promises?

The current study focuses on American patent law and examines whether the disclosure requirement reveals adequate knowledge regarding a patented genetic invention. The study refers to and scrutinizes the literature, principles, and practices in the field of genetics, especially regarding GSD. Integrating knowledge from the field of genetics allows this study to offer a more nuanced, accurate, and reality-based portrayal. Furthermore, the study harnesses the theories behind the disclosure requirement to conclude whether gene patents allow the absence of specific knowledge required for proper disclosure.

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<sup>2</sup> See Michelle D. Sluiter & Elizabeth J. van Rensburg, *Large Genomic Rearrangements of the BRCA1 and BRCA2 Genes Review of the Literature and Report of a Novel BRCA1 Mutation*, 125 BREAST CANCER RES. TREAT. 325 (2011); Cecelia A. Bellcross, *The Changing Landscape of Genetic Testing for Hereditary Breast and Ovarian Cancer*, 38 CURRENT PROBLEMS IN CANCER 209, 211 (2014); Sining Chen & Giovanni Parmigiani, *Meta-analysis of BRCA1 and BRCA2 Penetrance*, 25 J. CLIN. ONCOL. 1329 (2007).

<sup>3</sup> See Brenda M. Simon, *Patent Cover-Up*, 47 HOUS. L. REV. 1299, 1310-1311 (2011).

<sup>4</sup> See Turna Ray, COMPETITION COMING FOR MYRIAD'S BRCA TEST, WHETHER OR NOT GENE PATENTS HOLD UP, GENOMEWEB (2013), <https://www.genomeweb.com/clinical-genomics/competition-coming-myriads-brca-test-whether-or-not-gene-patents-hold>; Sharon Begley, AS REVENUE FALLS, STAT (2016), <https://www.statnews.com/2016/11/29/brca-cancer-myriad-genetic-tests/>; Myriad's Launch of riskScore™ (2017), [http://files.shareholder.com/downloads/MYGN/6127367332x0x955723/3E32F7EA-2FA3-40E6-8DE6-C8987D82AB50/riskScore\\_Presentation\\_Final.pdf](http://files.shareholder.com/downloads/MYGN/6127367332x0x955723/3E32F7EA-2FA3-40E6-8DE6-C8987D82AB50/riskScore_Presentation_Final.pdf).

## II. The Disclosure Requirement: History, Theory, and Policy

This section presents historical and theoretical aspects of the disclosure requirement in order to lay the foundation for subsequent discussion regarding patent disclosure. I describe the disclosure requirement and its doctrines in American patent law, focusing on its objectives. I address the primary justifications of the disclosure requirement as an obligation that is part of the social bargain and that is also based on economic efficiency perspectives. Tracing the essence of the disclosure requirement allows us to address the incompatibility between genetic inventions and the disclosure requirement, to be presented in Section III.

### A. Historical Background – The Patent System as an Evolving System

In this section, I briefly sketch the history of the disclosure requirement and emphasize the evolutionary progress it has undergone from the 17th century until today. I rely mostly on secondary sources and focus on the United States.

Originally, patents were a gift or a means of recognizing one's diligence rather than a social bargain.<sup>5</sup> Patents were granted for objects that had little to do with an invention as we currently define it. For instance, in 1641, a patent was conferred for the exclusive right of making salt in Massachusetts; another Massachusetts patent was granted in 1648 to operate a ferry between two zones of the state.<sup>6</sup> Then, the patent system did not compel any disclosure requirement in return for the patent. Patents were not perceived then as innovation promoters, and expanding the public's knowledge was not part of the game plan.<sup>7</sup>

Since the mid-seventeenth century, patents included a specification—a general description of the patented object.<sup>8</sup> This specification was a far cry from today's mode of disclosure. The pre-nineteenth century's specification was marginal, certainly

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<sup>5</sup> See Edward Wyndham Hulme, *History of the Patent System Under the Prerogative and at Common Law*, 12 L.Q. REV. 141, 145-47 (1900); Mario Biagioli, *Patent Specification and Political Representation: How Patents Became Rights*, in MAKING AND UNMAKING INTELLECTUAL PROPERTY: CREATIVE PRODUCTION IN LEGAL AND CULTURAL PERSPECTIVE 25, 25 (Mario Biagioli, Peter Jaszi, & Martha Woodmansee eds., 2011).

<sup>6</sup> See Oren Bracha, *Geniuses and Owners: The Construction of Inventors and the Emergence of American Intellectual Property*, in TRANSFORMATIONS IN AMERICAN LEGAL HISTORY: ESSAYS IN HONOR OF PROFESSOR MORTON J. HORWITZ 369, 372 (Daniel W. Hamilton & Alfred L. Brophy eds., 2009).

<sup>7</sup> See Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 3)*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 771, 777 (1995).

<sup>8</sup> See David Seaborne Davies, *The Early History of the Patent Specification (Parts I-II)*, 50 L.Q. REV. 86 (1934).

meager and improper in comparison with contemporary disclosure. This marginal specification was not intended for disseminating knowledge.<sup>9</sup> The specification was included to benefit the patentees:<sup>10</sup> a textual description of rights facilitates exercising them; therefore, even a basic specification underscores the monopoly obtained and aids in enforcing it. The language and style of such specifications reveal their purpose: warning others rather than teaching, limiting society rather than revealing.<sup>11</sup>

In the late 18th century, the American patent system adopted its modern character as a social bargain: An inventor receives a time-limited monopoly, and the public enjoys novel knowledge and the invention itself.<sup>12</sup> The transition of the patent system from a royal license to a social bargain was accompanied by the emergence of a renewed specification requirement, the ancestor of the current disclosure requirement. Sections 2-3 of the U.S. Patent Act of 1790 obliged applicants to deliver a specification with explanations in writing, including drafts or models of the invention. The act required that the explanations would enable a person having ordinary skill in the art (PHOSITA) to make, construct, or use the invention. The Secretary of State was obligated to furnish a copy of the specification to the public, thus reflecting the informational value of this document.<sup>13</sup>

As one can discern, this is a society-centered specification. From about 1790 onwards, the focus shifted to the public, possibly due to sociological-political changes at that time.<sup>14</sup> One of these changes is the replacement of a monarchical ruling system with a system calling for distributed, democratic power. That dramatically altered the status of the public. The patent system could not continue to primarily serve patentees and kingdoms; it needed to include the public's benefit as well. The second grand change is the introduction of new ideals regarding science, knowledge, and innovation introduced in the U.S. Constitution.<sup>15</sup> The new approach in the Constitution considered

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<sup>9</sup> See Biagioli, *Patent Specification*, supra note 5, at 32; Bracha, *Geniuses and Owners*, supra note 6, at 372-73.

<sup>10</sup> See Edward Wyndham Hulme, *The Early History of the English Patent System*, in 3 SELECT ESSAYS IN ANGLO-AMERICAN LEGAL HISTORY 117, 121-43 (Association of American Law Schools, 1909); Walterscheid, *The Early Evolution*, supra note 7, at 779-80.

<sup>11</sup> See WILLIAM MATHEWSON HINDMARCH, A TREATISE ON THE LAW RELATIVE TO PATENT PRIVILEGES FOR THE SOLE USE OF INVENTIONS, 1803-1866, 93-94 (1847); Hulme, *id.*, at 117, 122-47.

<sup>12</sup> See JOSEPH BARNES, TREATISE ON THE JUSTICE, POLICY, AND UTILITY OF ESTABLISHING AN EFFECTUAL SYSTEM OF PROMOTING THE PROGRESS OF USEFUL ARTS BY ASSURING PROPERTY IN THE PRODUCTS OF GENIUS, 25 (Philadelphia: Bailey, 1792).

<sup>13</sup> Patent Act of 1790, Ch. 7, 1 Stat. 109, §§2-3 (April 10, 1790).

<sup>14</sup> See Biagioli, *Patent Specification*, supra note 5, at 26-30.

<sup>15</sup> See Michael Birnhack, *The Idea of Progress in Copyright Law*, 1 BUFF. INTELL. PROP. L.J. 3, 16-17, 35-36 (2001).

IP rights as innovation and science accelerators. At this point, patents transformed into knowledge carriers

However, not only sociological-political changes influenced the disclosure requirement; the technological environment played a role as well. The most common inventions within the first decades of the American patent system were mechanical inventions. For instance, in 1790-1793, more than 55% of all patents granted in the U.S. were machine-type inventions.<sup>16</sup> The patent system was designed by this technological environment mainly through the Patent Act of 1793 and the Patent Act of 1836.<sup>17</sup>

The 1793 act supplemented to the disclosure requirement a specific reference to machines, steering applicants to explain both the principle and the modes of a machine, incorporating drawings and written references in addition to the basic written description.<sup>18</sup> The reason for this additional requirement is that limiting the disclosure of a machine-type invention to text might not fulfill the disclosure's objectives.<sup>19</sup> Describing the making and using of a machine in written form may provide essential knowledge of the machine itself, but does not necessarily provide the essential scientific knowledge regarding it. In that sense, a picture (or drawing) is worth not only a thousand words but could deliver knowledge which words could not deliver alone.

An additional change in the 1793 act was the requirement of specimens. When the invention is a composition of matter, applicants must attach specimens of the ingredients and compositions. This provision was set to prove the reduction to practice<sup>20</sup> and to bring more knowledge regarding chemical inventions.<sup>21</sup> This change is pursuant to the modern technological revolution in chemistry that took place then. Led by Lavoisier, Dalton, and Berzelius, this revolution made chemistry much more intricate, though more practically valuable, than ever before. As in the case of the

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<sup>16</sup> Out of 57 patents granted in the United States under the Patent Act of 1790, 32 patents were machine-type inventions. See: WILLIAM ELLIOT, A LIST OF PATENTS GRANTED BY THE UNITED STATES, FOR THE ENCOURAGEMENT OF ARTS AND SCIENCES, FROM 1790 TO 1820 (Washington: S. Alfred Elliot, 1823); EDMUND BURKE, INVENTIONS AND DESIGNS ISSUED BY THE UNITED STATES FROM 1790 TO 1847 (Washington: J. & G.S. Gideon, 1847); HistPat Dataset, HARVARD DATAVERSE, <https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi:10.7910/DVN/BPC15W>; USPTO Data Sets, REED TECH USPTO DATA PORTAL – PATENT CLASSIFICATION INFORMATION, <http://patents.reedtech.com/classdata.php>.

<sup>17</sup> Patent Act of 1793, Ch. 11, 1 Stat. 318 (February 21, 1793); Patent Act of 1836, Ch. 357, 5 Stat. 117 (July 4, 1836).

<sup>18</sup> Patent Act of 1793, *id.*, §3.

<sup>19</sup> See WILLARD PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS, 294-96 (Boston: American Stationers, 1837); GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA, 125 (Boston: Little, Brown, 1849); CHARLES SIDNEY WHITMAN, PATENTS LAWS AND PRACTICE OF OBTAINING LETTERS PATENT FOR INVENTIONS 285, 289, 310-11 (Washington: W.H. & O.H. Morrison, 1871).

<sup>20</sup> See IVER P. COOPER, BIOTECHNOLOGY AND THE LAW 5.02[8] (1982).

<sup>21</sup> See supportive evidence: Patent Act of 1870, Ch. 230, 16 Stat. 198, §27 (July 8, 1870); WILLARD PHILLIPS, THE INVENTOR'S GUIDE, 250, 288 (New York: Collins, Keese, & Co., 1837).

requirement of drawings, this further requirement of specimens again reflected the principle that words solely could not adequately disclose the invention.

In 1836, an additional amendment was instituted: “[an inventor] shall deliver a written description...*avoiding unnecessary prolixity*...” The purpose of this amendment was to make the disclosure clearer. Some inventors abused the natural complexity of emerging technologies and purposely prolonged their disclosure to make it harder to comprehend.<sup>22</sup> The amendment of 1836 created tools to cope with such insidious disclosures.<sup>23</sup>

A more recent example demonstrating how the technological environment influences the disclosure requirement is the case of biological materials. American patent law allows applicants to deposit biological materials as part of the disclosure.<sup>24</sup> This modification was made in order to deal with the changing technological environment.<sup>25</sup> In this case, words, drawings, and models combined were not enough to provide society with sufficient knowledge regarding biological inventions.<sup>26</sup>

The historical overview laid out here depicts evolving progress. Due to sociological, political, and legal trends, the patent system turned into a social bargain. Through the disclosure requirement, it transformed into a platform for knowledge dissemination. The technological environments have also influenced the patent system. The type of invention affects the capacity of certain types of disclosure to deliver knowledge. The evolution of patent law allows it to keep up with changes. The next section will examine contemporary patent law to define the current disclosure requirement.

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<sup>22</sup> See WHITMAN, PATENTS LAWS AND PRACTICE, *supra* note 19, at 299-300; PHILLIPS, THE INVENTOR’S GUIDE, *id.*, at 249-50, 288.

<sup>23</sup> See A. S. Collins *ex parte* (June 8, 1870), *in* DECISIONS OF THE COMMISSIONER OF PATENTS FOR THE YEAR 1870, 57 (Washington: Government Printing Office, 1871).

<sup>24</sup> 37 CFR 1.801-1.809, 1.821-1.825.

<sup>25</sup> See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY, 207, 221 (Washington, DC: U.S. Government Printing Office, October 1991); Berge Hampar, *Patenting Recombination DNA Technology: The Deposit Requirement*, 67 J. PAT. & TRADEMARK OFF. SOC’Y 569, 569, 574-79 (1985). United States Patent and Trademark Office, THE DEPOSIT RULES, USPTO GUIDELINES, *available at* <https://www.uspto.gov/web/offices/pac/mpep/s2402.html>.

<sup>26</sup> *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345-46 (Fed. Cir. 2000), *cert. denied*, 121 S.Ct. 1957 (2001); *In re Argoudelis*, 434 F.2d 666 (CCPA 1970).

## B. Policy and Theory of Disclosure

The disclosure requirement is codified in the United States Patent Act.<sup>27</sup> According to Section 112, a proper disclosure requires three elements, commonly referred to as the disclosure doctrines: written description, enablement, and best mode.<sup>28</sup> An improper disclosure, namely a disclosure that fails to accomplish these doctrines (with an odd exception regarding the best mode<sup>29</sup>), engenders rejection of an application or invalidation of a patent.

The *written description doctrine* is the ID card of the invention. It should provide sufficient knowledge so the public can discern what exactly is included within the invention, and not less importantly – what is not.<sup>30</sup> The second, the *enablement doctrine*, is the instruction manual. The enablement’s purpose is to tender practical knowledge and to instruct regarding two fundamental actions: making and using the invention without undue experimentation, i.e., based on the disclosure alone.<sup>31</sup> The third doctrine, the *best mode*, is designed to prevent applicants from outsmarting society with a devious disclosure. If there are several ways of deploying an invention, the inventor must disclose her best mode of utilizing it.

The final doctrinal issue to be discussed is the timing of the disclosure requirement. The disclosure occurs upon filing a patent application.<sup>32</sup> Indeed, one may ask why the knowledge is required to be disclosed at the filing date and not at the patent’s expiration date? The primary reason is that disclosing knowledge at the outset of the twenty-year monopoly allows society to use the knowledge during the patent period for non-infringing or permitted purposes.<sup>33</sup>

The contemporary disclosure requirement has two major objectives. The first is the historical function of limiting the patent’s scope.<sup>34</sup> The disclosure helps society

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<sup>27</sup> 35 U.S.C. §112.

<sup>28</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010).

<sup>29</sup> See Robert W. Bahr, MEMORANDUM: REQUIREMENT FOR A DISCLOSURE OF BEST MODE (September 20, 2011) available at [https://www.uspto.gov/sites/default/files/aia\\_implementation/best-mode-memo.pdf](https://www.uspto.gov/sites/default/files/aia_implementation/best-mode-memo.pdf).

<sup>30</sup> See Timothy R. Holbrook, *Possession in Patent Law*, 59 SMUL. REV. 123, 127 (2006).

<sup>31</sup> See Guang M. Whitley, *A Patent Doctrine without Bounds: The Extended Written Description Requirement*, 71 U. CHI. L. REV. 617, 618, 621-22 (2004); Simon, *Patent Cover-Up*, supra note 3, at 1318; Brian P. O’Shaughnessy, *The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure within the Unpredictable Arts*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 147, 159-60 (1996).

<sup>32</sup> 35 U.S.C. §111(a)(2)(A).

<sup>33</sup> See Ted Hagelin, *Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 489-512 (2006); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); 35 U.S.C. §271(e)(1).

<sup>34</sup> *Magsil Corp. v. Hitachi Global Storage Techs.*, 687 F.3d 1377, 1380-81 (2012). This role is also referred to as commensurability. See CRAIG A. NARD, *THE LAW OF PATENTS* 87 (2008).



understand what is forbidden and what is not. This knowledge carries value for users, but not only them. For competing inventors, the disclosure publishes what has already been achieved by the patentee so they will refrain from re-inventing the same invention and better allocate their resources.

The second purpose pertains to the principle of the patent system as a social bargain, functioning as knowledge carriers.<sup>35</sup> This function is much younger than the previous one and has two main contributions. First, the disclosure is a contextual-practical knowledge carrier which provides society with adequate knowledge for replicating the patentee's deeds.<sup>36</sup> This is a narrow observation of the disclosed knowledge since it focuses on the very specific contribution of the patent. Second, the disclosure distributes general theoretical knowledge, inducing others to research and invent, not necessarily in the same field of the invention.<sup>37</sup> The disclosure mediates between different researchers and inventors, whether competing or not.<sup>38</sup>

The disclosure requirement is all about fairness and efficiency. Modern society does not merely endow a monopoly; namely, the disclosure is the consideration on which society agrees and expects to receive when granting a patent. The public can study the disclosed knowledge during the patent period. After the patent expires, free use of the invention brings the advantages of the free competitive market. That naturally brings us to the economic efficiency justification of patent law, and specifically to the disclosure requirement.<sup>39</sup> The idea of the time-limited monopoly is an efficiency-oriented notion: Society relinquishes the benefits of competition for a set period in exchange for knowledge; however, when the authorized monopoly ends, the allocation of exclusive rights is rebooted, and the competitive market is back, this time with new knowledge in society's pool. Even though this strategy might sound, *prima facie*,

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<sup>35</sup> See Jason Rantanen, *Patent Law's Disclosure Requirement*, 45 LOY. U. CHI. L.J. 369, 370, 373 (2013); Holbrook, *Possession in Patent Law*, supra note 30, at 131; Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 622-23 (2009).

<sup>36</sup> See Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 267 (1994); Allain Pottage & Brad Sherman, *Kinds, Clones and Manufactures*, in MAKING AND UNMAKING INTELLECTUAL PROPERTY: CREATIVE PRODUCTION IN LEGAL AND CULTURAL PERSPECTIVE 269, 277 (Mario Biagioli, Peter Jaszi, & Martha Woodmansee eds., 2011).

<sup>37</sup> See Dam, *The Economic Underpinnings*, *id.*, at 264; Rantanen, *Patent Law's Disclosure Requirement*, supra note 35, at 373.

<sup>38</sup> See R. Polk Wagner, *Information Wants to Be Free: Intellectual Property and the Mythologies of Control*, 103 COLUM. L. REV. 995, 1033-34 (2003); JOEL MOKYR, THE LEVER OF RICHES: TECHNOLOGICAL CREATIVITY AND ECONOMIC PROGRESS 188-90 (1990); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29, 29 (1991).

<sup>39</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW, 294-333, 354-71 (2003).

inefficient, it is strongly supported with economic efficiency dictates.<sup>40</sup> In a sense, the disclosure is a restraint imposed on patentees to limit the power of patents.

### **III. The Disclosure-Genetics Incompatibility**

The argument presented here is that the current disclosure requirement does not deliver on its objectives when applied to genetic inventions, thus revealing an overlooked incompatibility of the patent system as it relates to genetics. The key element here is the importance of being cognizant of what society fails to obtain through the social bargain of gene patents. It may be posited that a modern technological field might not suit the architecture of patent law, ultimately causing the patent system to fall short of fulfilling its aims. After addressing the specific issue of gene patents, I apply this principle to a broader idea, the notion of fully-revealed and semi-revealed environments. This principle seeks to offer a more general point of view on the interplay of patent law and different technological environments.

#### **A. Genetic Inventions and Genetic Statistical Data (GSD)**

Genetic materials are biological molecules composed of nucleic acids, such as DNA and RNA. Organism's traits (or phenotypes) are held, at least partly, by the organism's genome—all genetic materials carried by an organism. The genome is divided into separated units called genes. Today's genetics reveals inter-relationships between genes and intra-relationships within gene groups that are much more complex than has been believed.<sup>41</sup>

*Genetic Inventions* refer to methods, processes, compositions, or tools that consist of genetic materials. Genetic inventions hold an immense potential for many fields, such as research, healthcare, and agriculture. To promote more innovation in genetics, society uses a well-known legal platform—patent law—to incentivize innovation and expedite knowledge dissemination.

*Gene Patents* are patents granted for genetic inventions. Earlier works discussed important questions concerning gene patents, such as patentability, research

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<sup>40</sup> In fact, economic efficiency as a justification for patent law is the most common justification in modern literature. See LANDES & POSNER, *THE ECONOMIC STRUCTURE*, *id.*, at 2-4, 37-70, 270-93.

<sup>41</sup> See Naomi R. Wray et al., *Common Disease Is More Complex Than Implied by the Core Gene Omnigenic Model*, 173 *CELL* 1573 (2018).

preemption, and access to health products.<sup>42</sup> Here, however, I tackle an additional aspect, which the relevant literature has yet to discuss: the incompatibility of the disclosure requirement and gene patents.

Despite enormous achievements in genetics over the last few decades, there are still many limitations on our understanding and capabilities. One limitation is our inability to comprehend the exact theoretical and practical meaning of information embedded in genetic materials. This contrasts with our experience with classical technologies like mechanics and electronics: The information concealed in a mechanical invention will most likely become comprehensible in the course of the inventing process itself. However, inventing a genetic invention does not necessarily reveal the full knowledge it holds, nor the theoretical, logical mechanism according to which the invention operates. Instead, the full knowledge hidden within the genetic invention is gradually revealed as more statistical data are gathered over time, when utilizing the invention.

Take, for example, a four-legged chair as a classical invention. From the disclosure document, one can learn the underlying scientific principles of the chair. It delivers a full understanding of the invention and allows others to use it correctly, with no further knowledge required. We can learn from a patent disclosure why a four-legged chair is more stable than a two-legged chair; this knowledge relies on law-based comprehension, such as gravity and friction. We encounter a different situation in the case of genetic inventions; the knowledge which is initially disclosed regarding a genetic invention is not sufficient to deliver a full understanding of the invention. Instead, big, genetic statistical data that are collected and analyzed in the course of commercial use fill this gap. Namely, big statistical data somehow substitute or offset the lack of logic, law-based premises which are common in classical technologies.<sup>43</sup>

GSD are a type of information that is equivalent to knowledge which is revealed in classical inventions disclosures. However, since GSD are not disclosed, some types of

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<sup>42</sup> See Isabelle Huys, Nele Berthels, Gert Matthijs & Geertrui Van Overwalle, *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 NATURE BIOTECHNOL. 903 (2009); Robert Cook-Deegan, Subhashini Chandrasekharan & Misha Angrist, *The Dangers of Diagnostic Monopolies*, 458 NATURE 405, 405-06 (2009); Julia Carbone et al., *DNA Patents and Diagnostic: Not a Pretty Picture*, 28 NATURE BIOTECHNOL. 784, 784-91 (2010); Ashwin Agarwal, Lauren C. Sayres, Mildred K. Cho, Robert Cook-Deegan & Subhashini Chandrasekharan, *Commercial Landscape of Noninvasive Prenatal Testing in the United States*, 33 PRENAT DIAGN. 521, 526-27 (2013).

<sup>43</sup> See Robert Stevens, Chris Wroe, Phillip Lord & Carole Goble, *Ontologies in Bioinformatics*, HANDBOOK ON ONTOLOGIES, 635-36 (Steffen Staab & Rudi Studer eds., 2004); Matteo Fumagalli, *Assessing the Effect of Sequencing Depth and Sample Size in Population Genetics Inferences*, 8 PLOS ONE 1, 1 (2013) (“The ability to sequence many individuals from one or multiple populations at a genomic scale has greatly enhanced population genetics studies and made it a data-driven discipline.”); Chris C. Spencer et al., *Designing Genome-Wide Association Studies: Sample Size, Power, Imputation, and the Choice of Genotyping Chip*, 5 PLOS GENET. 1, 1 (“Because of the complicated pattern of linkage disequilibrium ... power cannot be calculated analytically and must instead be assessed by simulation.”)

content that are revealed in classical invention disclosures are absent from genetic inventions' disclosures. The need for GSD can be clarified through explanations and examples.

Geneticists can read (or better, spell) genetic materials, but in most cases, they cannot discern their profound, biological meaning only by looking at them.<sup>44</sup> Geneticists can typically detect what the literal translation of a gene in protein language is, but they cannot necessarily discern the real-life, biological translation, nor its precise function or activity.<sup>45</sup> Not only are geneticists unable to identify the role of a random protein in advance, but they cannot even foresee whether a given protein will lead to normal biological activity, a non-harmful modification, or a disease.<sup>46</sup>

Technological applications in the field of genetics often rely heavily on correlations rather than causations, simply because correlations are easier to spot with the available technologies and tools.<sup>47</sup> According to the common scientific approach, correlations do not imply causality between two correlated variables. However, their presence can greatly contribute to tracing the causality.<sup>48</sup> Taking the TCF7L2 gene, for example, it was first associated with diabetes in 1999.<sup>49</sup> After more statistical data was gathered,<sup>50</sup> geneticists have a much better understanding of this gene, and it became more lucid, both in predicting its impact on one's risk of diabetes,<sup>51</sup> but also in the more profound,

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<sup>44</sup> See Robert Stevens & Phillip Lord, *Application of Ontologies in Bioinformatics*, 2 HANDBOOK ON ONTOLOGIES, 735, 735-36 (Steffen Staab & Rudi Studer eds., 2009) ("The lack of the laws or grand theories of physics means that much inference in bioinformatics is still reliant on the processing of factual data – the knowledge we have about the entities. ... The biological sciences ... currently lack the laws and mathematical support of sciences such as physics and chemistry.")

<sup>45</sup> See 2 DAVID W. MOUNT, BIOINFORMATICS: SEQUENCE AND GENOME ANALYSIS, 12-13, 338-42 (2004); U.S. National Library of Medicine, HTT GENE, available at <https://ghr.nlm.nih.gov/gene/HTT> ("the exact function of this protein is unknown, it appears to play an important role in nerve cells (neurons) in the brain and is essential for normal development before birth."). Although the exact function is still a mystery, genetic inventions already address this gene: Francis O. Walker, *Huntington's Disease*, 369 LANCET 218 (2007); uniQure, *uniQure has demonstrated preclinical proof-of-concept and is preparing to submit an IND in Huntington's disease in 2018*, UNIQUIRE WEBSITE, available at <http://www.uniquire.com/gene-therapy/huntingtons-disease.php>.

<sup>46</sup> Thus, we cannot (yet) look at a genome and know for sure what its implications are. Taking one gene and trying to figure out its significances might be an impossible mission without experiments.

<sup>47</sup> See Paul Martin & Jane Kaye, *The Use of Large Biological Sample Collections in Genetics Research: Issues for Public Policy*, 19 NEW GENET. SOC. 165, 166-67 (2000) (explaining the difficulty in 'reverse engineering' a disease phenotype, and why statistical correlations are so helpful.)

<sup>48</sup> See Sewall Wright, *Correlation and Causation*, 20 J. AGRICULTURAL RESEARCH 557 (1921); JUDEA PERAL, CAUSALITY: MODELS, REASONING, AND INFERENCE, 9-66 (2000).

<sup>49</sup> See Ravindranath Duggirala et al., *Linkage of Type 2 Diabetes Mellitus and of Age at Onset to a Genetic Location on Chromosome 10q in Mexican Americans*, 64 AM. J. HUM. GENET. 1127 (1999).

<sup>50</sup> See Struan F. Grant et al., *Variant of Transcription Factor 7-like 2 (TCF7L2) Gene Confers Risk of Type 2 Diabetes*, 38 NATURE GENET. 320 (2006); Christopher J. Groves et al., *Association Analysis of 6,736 U.K. Subjects Provides Replication and Confirms TCF7L2 as a Type 2 Diabetes Susceptibility Gene with a Substantial Effect on Individual Risk*, 55 DIABETES 2640 (2006).

<sup>51</sup> See Andre R. Vaquero et al., *Using Gene-Network Landscape to Dissect Genotype Effects of TCF7L2 Genetic Variant on Diabetes and Cardiovascular Risk*, 44 PHYSIOL. GENOMICS. 903 (2012).

biological and causation meaning, which gives us a whole different way to comprehend it.<sup>52</sup> Geneticists link these advancements in understanding the TCF7L2 gene to GSD that were gathered.<sup>53</sup> The TCF7L2 case provides only one example of a general concept of using correlations to overcome some of our limited abilities in genetics.<sup>54</sup>

But what is required to detect correlations in the first place and to improve them toward perfection? The answer lies in data, considerable data. Researchers must survey massive quantities of genetic data to substantiate a statistically significant correlation.<sup>55</sup> The more statistical data processed, the more accurate and precise the correlation becomes. Therefore, actions such as mining, collecting, analyzing, and using big statistical data are essential for initially finding correlations and for continuously adjusting them. Processing statistical data assists in bridging the comprehension gap, namely, the deep understanding and a precise, law-based prediction we have in classical technologies but lack in genetics.<sup>56</sup>

Put differently, genetic inventions are characterized by statistical dependency.<sup>57</sup> The understanding, utilization, quality, reliability, research, and development of genetic inventions are highly contingent on statistical data gathered during their use.<sup>58</sup> In fact, geneticists combine and use (when possible) statistical data from various sources as a matter of course in order to improve the biological understanding and scientific abilities.<sup>59</sup>

Indeed, statistical data may be useful in classical technologies as well. For example, statistical data regarding an engine can help one ascertain the engine's ideal working

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<sup>52</sup> See Marcelo A. Nobrega, *TCF7L2 and Glucose Metabolism: Time to Look Beyond the Pancreas*, 62 *DIABETES* 706 (2013); Tianru Jin, *Current Understanding on Role of the Wnt Signaling Pathway Effector TCF7L2 in Glucose Homeostasis*, 37 *ENDOCR. REV.* 254 (2016).

<sup>53</sup> See Eleftheria Zeggini & Mark I. McCarthy, *TCF7L2: The Biggest Story in Diabetes Genetics Since HLA?*, 50 *DIABETOLOGIA* 1 (2007).

<sup>54</sup> See CAVAN REILLY, *STATISTICS IN HUMAN GENETICS AND MOLECULAR BIOLOGY* 179-80 (2009).

<sup>55</sup> See Report of the Bioethics Advisory Committee of The Israel Academy of Sciences and Humanities, *Population-Based Large-Scale Collections of DNA Samples and Databases of Genetic Information*, 4 (2002), available at <https://www.academy.ac.il/SystemFiles/21655.pdf>; Moritz Gerstung et al., *Precision Oncology for Acute Myeloid Leukemia using a Knowledge Bank Approach*, 49 *NATURE. GENET.* 332 (2017).

<sup>56</sup> For instance, predicting orbitals without the need to measure it, calculating the actual electric potential difference or current between two bodies using theory alone, and so on. While statistical data may help, it is not necessary in order to understand phenomena or apply tools to predict or influence on such phenomena.

<sup>57</sup> See Kathleen Liddell et al., *Patents as Incentives for Translational and Evaluative Research: The Case of Genetic Tests and Their Improved Clinical Performance*, 3 *INTELL. PROP. Q.* 286, 286-90 (2008).

<sup>58</sup> See Patricia G. Baker, *An Ontology for Bioinformatics Applications*, 15 *BIOINFORMATICS* 510, 510 (1999).

<sup>59</sup> See Darlene R. Goldstein & Rudy Guerra, *Introductory Material*, in *META-ANALYSIS AND COMBINING INFORMATION IN GENETICS AND GENOMICS*, 3, 3-20 (R. Guerra & Darlene Renee Goldstein eds., 2010); MOUNT, *BIOINFORMATICS: SEQUENCE AND GENOME ANALYSIS*, supra note 45, at 4, 282-83; Stevens & Lord, *Ontologies in Bioinformatics*, supra note 44, at 735, 751-52.

temperature to achieve maximum efficiency; this knowledge is based upon many uses and records of using the engine in various room temperatures. However, the meaning, significance, and contributions of statistical data in the classical technology environment are different, by definition, than those characterizing statistical data in genetics. I address this issue in Section III(C).

A genetic invention can be understood and utilized without GSD, but in a very different way, with lower performance, reliability, and compatibility. In addition, GSD enable concluding and adjusting correlations of genetic material-phenomenon relations, and therefore the very understanding of the genetic invention is contingent upon the statistical data collected during the invention's use. Thus, different amounts of statistical data controlled by different users may affect the way users comprehend the invention, and, as a result, the prospect of their researching, developing and utilizing the pertinent invention. The same genetic invention may act differently under different circumstances, and statistical data are one of the primary instruments to decipher this unpredictability.<sup>60</sup>

To summarize, when devising a genetic invention, the inventor initially reveals some of the knowledge the invention holds, but some other knowledge remains latent. This latent knowledge becomes apparent to the patent holder only in later phases, through statistical data that are mined and processed during the commercial phase. This type of statistical data—GSD—carries a high value for many sorts of goals, specifically for R&D and commercial purposes.

## **B. The Incompatibility of the Disclosure Requirement and Genetics**

The assertion is quite simple: Patents are bargains between patentees and society. Society grants the patentee with powerful rights regarding an invention in exchange for a full, public disclosure of the patented invention. The architecture of the patent system limits the scope of the disclosed knowledge to what is known to the patentee at the time of application. The assumption is that at this point, a patentee holds full knowledge regarding the invention. While this paradigm suits the classical technology environment, it does not work for genetics. My assertion is that disclosure should incorporate the knowledge derived from GSD, an argument supported by patent law theory. However, in practice, GSD can be revealed only after the disclosure is already

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<sup>60</sup> See Jacob S. Sherkow, *Inventive Steps: the CRISPR Patent Dispute and Scientific Progress*, 18 EMBO 1047, 1048-49 (2017).

submitted, thus excluding GSD. I term this phenomenon *disclosure-genetics incompatibility*. Following a discussion of its consequences, I address the structural features that produce this incompatibility: the static dimension and the temporal dimension. I link these features to the history of patent law. Afterward, I take the specific case of gene patents and GSD, and uncover a hidden assumption in patent law regarding the very idea of what comprises an invention.

### 1. *The GSD Shortfall*

When an inventor applies for a gene patent, she publishes the disclosure documents, which contain substantial knowledge. As noted, however, gene patent applications do not (and cannot) include GSD simply because GSD are not available at the time of application. Nevertheless, the fact that GSD can be discovered only at a later phase does not mean that such data are less important. GSD play a crucial role regarding the genetic invention, both in the sense of understanding and utilizing it. The importance of GSD is manifest in their comprising an inherent part of the invention's usage and at times, becoming even more valuable than the initial invention.<sup>61</sup> Some examples can underscore GSD's critical role.

Some genetic inventions are used for prognosis and determination of preferred treatments. One such invention is used for Acute Myeloid Leukemia (AML).<sup>62</sup> This patented invention, assigned to Janssen Diagnostics, identifies the expression ratio of two genes and predicts patients' response to Tipifarnib, an AML treatment. When used correctly, this genetic invention can improve not only prognosis but also patients' survival. The disclosure requirement is met on the application date, and after this point, no further knowledge is to be disclosed. Indeed, whereas the disclosure delivers very useful knowledge, this knowledge may be insufficient for understanding and using the invention properly. The following study elucidates this contention.

A recent study sampled over 1,500 AML patients, and came up with much better prognosis and personally-tailored therapeutic decision support, as compared with the standard ones practiced by physicians.<sup>63</sup> The element that allowed the researchers to have such enhanced insights is not the recognized tools nor the knowledge of how to use them, but the GSD they collected: "From a database of 1540 patients, we can make

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<sup>61</sup> Such data can be protected even when a patent expires or invalidated. See also: Matthew Herper, *Surprise! With \$60 Million Genentech Deal, 23andMe Has A Business Plan*, FORBES, Jan 6, 2015, <https://www.forbes.com/sites/matthewherper/2015/01/06/surprise-with-60-million-genentech-deal-23andme-has-a-business-plan/#77fcb9fa2be9>.

<sup>62</sup> See US007932036B1 (Patent No. US 7,932,036 B1).

<sup>63</sup> See Gerstung et al., *Precision Oncology*, supra note 55, at 332.

considerably more informative and more accurate statements about an individual's likely journey through AML therapy than the current standards in clinical practice."<sup>64</sup> The tool or method alone is insufficient; GSD are necessary as well. The researchers stressed that sizable GSD are a critical factor, and that the prognostic ability is enhanced as GSD increase.<sup>65</sup> Such GSD are not disclosed under the current patent disclosure requirement, as can be observed in the Janssen's patent, so those for whom GSD are inaccessible are not in a position to understand or use the invention in the same way. The researchers go one step further and argue that this is not a particular case in which GSD function as an essential component, but it comprises a more general principle.<sup>66</sup>

Upon reconsidering the BRCA1/2 case, reviewed in Section I, VUS dropped from 15% to 2.5%. This means that the invention is now better comprehended since more variations are now ascribed to a known phenomenon, whereas beforehand, their impact was unclear. Clearly, GSD led to enhancing the understanding and usage of the invention. With a massive proprietary GSD-base, Myriad can better understand the genetic invention.

The improved understanding can be translated into practical measures. This is accomplished by utilizing the invention more effectively, both in the sense of doing the same things better and doing things with the invention that others cannot do without GSD. A hypothetical user that applies the knowledge disclosed in Myriad's patents would not be able to assess the risk of cancer in case of VUS. The user reports to the patient that it is not clear whether this genetic variation is harmful or not. However, if Myriad would have examined the same patient, the result would be very clear. Thus, even if the very same tool is used in these cases, the results would vary significantly. This above illustration is not a hypothetical example: a study found that approximately 27% of mutation interpretations in ClinVar differed from Myriad's interpretations and were, in Myriad's view (which has a much larger database than the ClinVar database), limited or wrong.<sup>67</sup> Moreover, while some genetic variations were held to imply a risk of 87% of breast cancer,<sup>68</sup> once adequate GSD were collected, this prediction changed

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<sup>64</sup> *Id.*, at 333.

<sup>65</sup> *Id.*, at 338-40 ("we found that prognostic accuracy steadily increases with larger sample sizes...")

<sup>66</sup> *Id.* ("we believe that the same logic applies to knowledge banks from other cancer types.")

<sup>67</sup> See William Gradishar et al., *Clinical Variant Classification: A Comparison of Public Databases and a Commercial Testing Laboratory*, 22 *THE ONCOLOGIST* 1 (2017).

<sup>68</sup> See Deborah Ford et al., *Risks of Cancer in BRCA1-Mutation Carriers*, 343 *LANCET* 692 (1994).



to 54% and even 10% in certain circumstances.<sup>69</sup> Thus, a genetic laboratory which does not have GSD may report a patient's risk at 87% while using the same genetic invention.

The discussed examples infer a deeper issue: Even when the patented genetic invention itself is freely available, the absence of GSD might cause severe consequences. I term this phenomenon a *GSD shortfall*. Both the understanding of the invention and its utilization are crucially affected by GSD. GSD grant abilities to GSD owners that others, lacking GSD, cannot achieve; the understanding becomes deeper and clearer, and the utilization becomes better and different.

Achieving a *deeper understanding* means that GSD reveal correlations that allow for the formulation of new principles and the adjustment of recognized principles regarding the genetic invention. *Better utilization* signifies that whereas the non-GSD owner can use the invention and obtain a result, a user that owns GSD can obtain a more accurate and efficient result using the same genetic invention. *Different utilization* denotes that whereas a non-GSD owner may not obtain any result, a GSD owner may obtain a result using the same genetic invention. These cases can lead to a quite bizarre situation: Two users using the same genetic invention can potentially obtain entirely different results.

Considerable efforts have been made by geneticists to surmount the GSD shortfall. The genetics community has instituted many initiatives of GSD sharing: The Cancer Genome Atlas; Genome-Wide Association Studies Policy; ClinGen and ClinVar; Human Gene Mutation Database; modENCODE; 1000Genomes; Gene Ontology; International Serious Adverse Events Consortium; and Personal Genome. The genetics community is cognizant of the fact that the necessary skills are highly contingent upon GSD and that GSD are not sufficiently disclosed to the public. The very existence of these initiatives is strong evidence for a GSD shortfall. In the absence of a GSD shortfall, these projects, all requiring money, time, and logistics, would be unnecessary. Importantly, there are no GSD-equivalent sharing initiatives in classical technologies; this fact fortifies the assertion that the role of GSD in genetic inventions is appreciably different, being much more critical than in classical inventions.

Due to the presence of a gene patent, mining and analyzing GSD are acts that are exclusive to the patentee solely during the patent period. This is not a formal, explicit right of the patentee, however, in practice, this right is indirectly granted to the patentee,

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<sup>69</sup> See Chen & Parmigiani, *Meta-analysis of BRCA1 and BRCA2*, supra note 2.

creating a double monopoly: one for the invention and one for the access to GSD.<sup>70</sup> Since the patentee is the only one that can commercially use the genetic invention, she is also the only one, de facto, that has access to GSD. When the patent expires, the original invention is free for use, but GSD remain a monopolized, proprietary database.

Legal exemptions or defenses do not resolve the GSD shortfall. Exemptions and defenses do not allow commercial use of the invention since such use seriously violates the patentee's rights. No current nor (reasonable) hypothetical exemption or defense is likely to permit commercial use of a patented invention. Thus, the GSD shortfall remains an extant problem.

Theoretically, when considering the rationale for disclosure, a patentee should disclose GSD. However, in practice, GSD are not disclosed, creating an incompatibility between the disclosure requirement and genetic inventions.

## *2. Failures Caused by the Disclosure-Genetics Incompatibility*

The consequences of this incompatibility can be depicted by four major failures:

**(a) The Commercial-Competitive Failure:** The enhanced abilities of a GSD owner can be translated into a commercial advantage. The seemingly same invention, when accompanied by GSD, can be practiced in better and different ways. Since GSD are not disclosed, the patentee enjoys unique commercial advantages, not only during the patent period but also afterward. Indeed, since the GSD owner is the only one that can exclusively understand and use some aspects of the invention the patent is essentially extended, even after its expiration. Acquiring sufficient GSD is time-consuming since a GSD-base should include at least several thousands of samples.<sup>71</sup> In the meantime, the advantageous status of a GSD owner remains valid. Extending the patent contradicts the social bargain, since the actual period of monopolized power is longer than agreed.

Returning to Myriad, its market share in hereditary cancer testing was 90% in mid-2015, more than two years after BRCA patents were invalidated.<sup>72</sup> According to another source, Myriad dominated 85% of the market for BRCA in 2016.<sup>73</sup> Thanks to its patents,

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<sup>70</sup> See Seth Shulman, *Upstream Without a Paddle: Gene Patenting and the Protection of the Infrastructure*, 84 CHI.-KENT L. REV. 91, 94 (2008).

<sup>71</sup> See Report of the Bioethics Advisory Committee, *Population-Based Large-Scale Collections*, supra note 55; Gerstung et al., *Precision Oncology*, supra note 55.

<sup>72</sup> SARA WOJDA, MYRIAD GENETICS (2015), [http://www.gabelli.com/Gab\\_pdf/Research/Reports/MYGN\\_20150721.pdf](http://www.gabelli.com/Gab_pdf/Research/Reports/MYGN_20150721.pdf).

<sup>73</sup> Begley, *As Revenue Falls*, supra note 4.

Myriad was able to collect tremendous GSD, making even public databases (certainly, those of private newcomers) pale next to it: As of 2013, the GSD regarding BRCA1/2 in ClinVar were about 1% of GSD in Myriad's database.<sup>74</sup> Myriad is proud of its massive GSD-base, reminding everyone that its product is not like that of any of its competitors.<sup>75</sup> The disturbing truth is that Myriad is right.<sup>76</sup> Indeed, Myriad was so determined to keep its GSD advantage that it required others that used its patented inventions to deposit mined GSD to Myriad's proprietary database (with no sharing of GSD the other way around).<sup>77</sup> Other companies also boast of their GSD to demonstrate superiority.<sup>78</sup>

One of the basics of patent law is that after a patent expires, competition is restored. The patent system was not meant to bestow a post-patent advantage, a fortiori, nor a dominant one such as provided through GSD.

**(b) The Research & Development Failure:** The disclosure requirement has immediate value for researchers, developers, competitors, and the wider public.<sup>79</sup> This is the essence of innovation—knowledge leads to further knowledge (and so forth), which ultimately transforms into other innovations, such as novel methods and products. The non-disclosure of GSD harms this process.

Since GSD are not disclosed, the public's understanding of genetic inventions is interrupted, leaving peculiarities that GSD would solve were they to be published. Thus, this knowledge remains hidden even after the patent expires. This requires researchers to repeat a massive number of uses to acquire the same or equivalent GSD. Indeed, at times, recollecting the same GSD is either extremely difficult or impossible, as the subjects may no longer be available, interested, or may be extremely rare. Thus, the data may become practically lost and will not be incorporated into other GSD-bases if not disclosed.

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<sup>74</sup> See Ray, *Competition Coming for Myriad's*, supra note 4.

<sup>75</sup> See Myriad Genetics, *Introducing riskScore™: A Groundbreaking Breast Cancer Risk-Prediction Tool*, MYRIAD GENETICS WEBSITE <https://myriadmyrisk.com/riskscore/>.

<sup>76</sup> See Myriad's Launch of riskScore™, supra note 4; Begley, *As Revenue Falls*, supra note 4 ("The truth is, Myriad probably does have a better database because they've done more than 2 million [BRCA] tests and they're a pretty good lab", citing Prof. Robert Cook-Deegan); Robert Cook-Deegan et al., *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?*, 21 EUR. J. HUMAN GENET. 585, 585 (2013) (stating that Myriad's has much less VUS than the competitors.)

<sup>77</sup> See Simon, *Patent Cover-Up*, supra note 3, at 1310.

<sup>78</sup> See AncestryDNA, *About Us*, ANCESTRY WEBSITE <https://www.ancestry.com/corporate/about-ancestry/our-brands> ("AncestryDNA is the world's largest consumer DNA database with millions genomes tested."); My Heritage, *Main Page*, MY HERITAGE WEBSITE, <https://www.myheritage.com/about-myheritage/>.

<sup>79</sup> See Craig A. Nard, *Legal Fictions and the Role of Information in Patent Law*, 69 VAND. L. REV. 1531-36 (2016).

Moreover, since GSD are not published, they are not being reviewed as well, and so might be misunderstood and misinterpreted. Whereas the knowledge disclosed in the patent document is subjected to criticism, GSD are secretly concealed from reviewers. That may harm the correct understanding of GSD and therefore, impede scientific progression.<sup>80</sup>

**(c) The Teaching Failure:** An examination of the current policy for gene patents' disclosure reveals that the teaching objective is not fully met. I contend that gene patents' disclosures cause a failure of a more focused issue – the enablement.

The enablement doctrine should guide the public, so it will obtain the skills to exploit the invention successfully.<sup>81</sup> Hence, the enablement doctrine implies conveying full technical knowledge to establish a document which teaches two basic actions: making and using the invention without undue experimentation. Namely, one should be able to manufacture and utilize the invention based solely on the disclosure.

The propriety of the enablement is examined as of the time of the application, but as has become clear, GSD are gathered during the commercial (post-application) phase. Thus, at these later phases of the patent period, the invention, now combined with GSD, reflects an invention that is different in certain aspects from the disclosed invention. However, the knowledge disclosed to the public will not be modified or updated. Thus, if a user wants to operate the invention which is held by the patentee, she cannot do it based on the disclosure documents alone, and so we encounter a failure of the enablement principle.<sup>82</sup>

To support this assertion, I apply the undue experimentation principle. Experiments are considered as *undue* according to their necessity: If experiments can be substituted with theoretical calculations, there is no duty to disclose them; however, when it is impossible to reach the conclusions with theory alone, and experiments are required, such experiments must be revealed.<sup>83</sup> In the case of genetic inventions, before acquiring the level of operating skills already achieved by the patentee, users must conduct many 'experiments' to gain equivalent GSD. No theoretical calculations can take the place of GSD, and therefore, these experiments can be considered as undue experimentation. Users are compelled to repeat test-runs, although that contradicts patent law's basic

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<sup>80</sup> See more in Simon, *Patent Cover-Up*, supra note 3, at 1316, 1355.

<sup>81</sup> See O'Shaughnessy, *The False Inventive Genus*, supra note 31, at 187.

<sup>82</sup> See Gradishar et al., *Clinical Variant Classification*, supra note 67. This study illustrates how the disclosure does not provide the public with full information.

<sup>83</sup> See supra, note 31.

principles. The fact that GSD are uncovered in subsequent phases should not release patentees from their fundamental disclosure duty.

**(d) The Irony of Trade Secrecy:** It is widely accepted that patent law should act as an alternative platform to trade secrets.<sup>84</sup> The patentee must concede secrecy to earn a patent. The main rationale is to prevent further proliferation of trade secrets, which contradicts the principle of knowledge disclosure, a factor that promotes innovation. Two questions arise: What if patent law does not prevent the emergence of trade secrets? And what if the patent system promotes the creation of trade secrets?

The patentee is the sole agent who can gather GSD during the patent period. That is the double monopoly notion noted earlier. The GSD can be, and in many cases are, maintained as a trade secret. Even after the patent expires, GSD remain a trade secret. It would seem reasonable to assume that GSD gathered throughout the patent period should not remain a trade secret but should be disclosed; this supposition derives from the fact that GSD were gathered due to the exclusive access to GSD that was indirectly granted by the patent.<sup>85</sup> Gathering GSD during and thanks to patent protection, and then protecting them as a trade secret when the patent expires is a cunning, abusive use of the patent system. The irony is that patent law, as a system whose underlying principles are disclosure and anti-secrecy, unintentionally supports the formation of trade secrets.

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Understanding that GSD remain beyond the public's reach despite the disclosure requirement unveils a specific incompatibility between the patent system and genetics. The contemporary architecture of the patent system does not enforce a sufficiently broad disclosure. If society does not receive its due according to the patent bargain, a reassessment of the bargain's conditions must be made. Following the above analysis, the question to be addressed is what is the reason for the disclosure-genetic inventions incompatibility?

## **C. On the Patent System's Architecture and the Concept of Invention**

### *1. The Static & Temporal Dimensions*

I link the noted incompatibility with two elementary features of the contemporary disclosure: the static dimension and the temporal dimension. The *static dimension* is

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<sup>84</sup> See Holbrook, *Possession in Patent Law*, supra note 30, at 126-27.

<sup>85</sup> See Shulman, *Upstream Without a Paddle*, supra note 70, at 94-96, 103-05; Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

the one-time, non-continuous character of the disclosure requirement. Namely, once the disclosure is carried out, the disclosure phase is over. No further steps of knowledge disclosure are required. The *temporal dimension* refers to the timing in which the disclosure transpires: at the outset of the process when a potential patentee applies for a patent.

At the interface of these two features, the disclosure turns into the early, one-time duty we know today. In the more specific context of genetic inventions, the primary implication of the static and temporal dimensions is that GSD are not disclosed. There is no duty to disclose knowledge which is beyond the static and temporal dimensions' grip, even if this knowledge is tightly related to the invention.

It would seem that the disclosure-genetics incompatibility does not emerge in classical technologies. This is an intriguing point; why a problem emerges in one case, but not in another? This phenomenon can be linked to the technological dissimilarity between the classical environment and the genetics environment.

The nature of classical inventions allows the inventor to hold full knowledge regarding the invention at the time of its invention. Therefore, considering the static and temporal dimensions, the current structure of disclosure enables the performance of a complete disclosure.<sup>86</sup> However, in genetics, some of the knowledge is still latent at the inventing moment, and therefore, the static and temporal features impede the possibility of disclosing full knowledge. To summarize, the structure of the disclosure requirement does not suit the environment of genetic inventions. It requires us to rethink whether the famous one-size-fits-all paradigm is still plausible.

## *2. A Hidden Assumption of the Concept of Invention: Fully-Revealed & Semi-Revealed Objects*

As discussed in Section II, the patent system was formulated in a classical technologies environment. The system's architecture and the disclosure requirement's structure were designed by this environment. The static and temporal dimension suit the classical environment: They enable an early disclosure which is preferable to the public, and mitigate the burden laid upon the patentee (requiring only one disclosure instead of multiple disclosures). At the same time, regarding classical inventions, the public does not lose necessary knowledge in the case of classical inventions since the timing and frequency of the disclosure do not leave concealed knowledge.

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<sup>86</sup> In fact, in the classical environment, the temporal feature leads to a better disclosure that benefits the public more than a disclosure that would be performed at the end of the patent period.

When the static and temporal dimensions were integrated into the patent system, the emergence of genetics was a faraway development.<sup>87</sup> Put differently, the hidden assumption embedded in patent law's architecture is that an invention is a *fully-revealed object*—namely, an invention that is fully understood at the time of its invention. Inventions were not perceived as a *semi-revealed object*—namely, an invention that is only partially understood at the time of its invention, becoming fully comprehended only through extensive use. As noted, extensive use reveals more bits of knowledge that are concealed under the material veil of the semi-revealed object. These bits of knowledge comprise inherent components of the original object itself.<sup>88</sup>

A fully-revealed object does not change its essence over time, and if it does, it is a new, separate invention. However, genetics brings out inventions that are semi-revealed objects, which are uncovered over their lifetime thanks to commercial utilization. Thus, the patent law paradigm of inventions as fully-revealed objects has a technology bias. This bias leads to an inherent incompatibility between patent law and semi-revealed environments and prevents the disclosure from functioning properly. The hidden assumption of what comprises an invention and how it should behave seems to have blinded the designers of patent law and obscured other possibilities, such as genetic inventions, that might not fit into this template of a fully-revealed object. This dogma leads to a situation in which GSD remain out of the disclosure requirement's scope despite strong justifications to publish GSD.

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<sup>87</sup> See Michael Birnhack, *Reverse Engineering Informational Privacy Law*, 15 YALE J.L. & TECH. 24 (2012).

<sup>88</sup> See resemble ideas in different contexts: Shulman, *Upstream without a Paddle*, supra note 70, at 95; Jeanne C. Fromer, *Dynamic Patent Disclosure*, 69 VAND. L. REV. 1715 (2016).

## IV. Conclusion and Discussion

The evident conclusion of this study is the exposure of a severe incompatibility of disclosure-genetics. The study brings us to contemplate the actual—and not the virtual—contribution of the patent system to our society. We conceive the patent system as a platform through which society receives knowledge about something for which it grants a patent. However, in practice, society obtains only part of the knowledge which is protected by a patent.

This study offers an additional contribution. Beyond the specific field of gene patents, the study holds broader implications for patent law. I revealed a technological assumption concerning the concept of what an invention is, according to patent law. This hidden technological assumption relies on historical events, primarily on the common technological environment in which patent law was designed. Thus, the incompatibility discussed in this study is not a random mistake, but a characteristic engendered by a technological assumption in patent law: the patent system conceives inventions as fully-revealed objects and not as semi-revealed objects. This mindset may lead to many ramifications and oddities that are not limited to the arena of gene patents or the disclosure requirement.

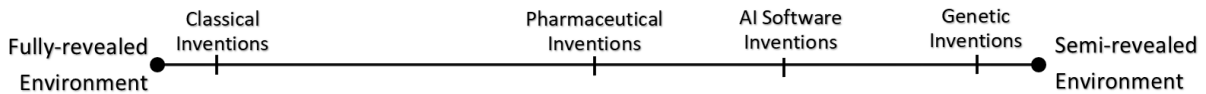
The study also suggests a broader conclusion for law in general. The study emphasizes the inevitable influence of technology and technological perceptions upon legal architecture. Society designs law based on certain expectations, but technology often exceeds these appraisals. Thus, the initial design may not fit other, unforeseen technological environments. The technological assumption in patent law is just a particular instance for a phenomenon that is likely to manifest itself in other fields of law regarding other technologies. Considering this notion, it seems that law is technology dependent.

The current study focused on the case of genetic inventions, but broadening its scope to other technologies (e.g., pharmaceuticals and software) will contribute much to deepen the understanding of the notion of fully-revealed and semi-revealed environments. The case of genetics in the current context may be assumed not to be unique. Namely, it is not that genetics is the only technology in which inventions act as semi-revealed objects. Inventions in other modern technologies may well behave in a similar way, albeit with some differences. This assumption offers a more profound outcome: Rather than implying a dichotomy between genetics and all other technologies, one may consider the presence of a spectrum ranging from fully-revealed



technologies to semi-revealed technologies. Thus, genetics comprises only a single case of a broader phenomenon. Whereas genetics might constitute an extreme case of a semi-revealed environment, this does not imply a unique status. Other technological fields may share its semi-revealed feature, though the intensity level may vary. The following axis demonstrates the hypothesis presented here regarding the possible broader phenomenon:

**Figure I: The Fully-Revealed to Semi-Revealed Axis Hypothesis**



Of course, examining this hypothesis and placing technologies on the axis requires conducting separate, comprehensive research regarding the pertinent technologies, their related inventions, patents, and the role of GSD-equivalent data, as does this study with regard to genetics. This extension clearly exceeds the scope of the current study; however, future research may address these issues, and the current study can be used as a basis for it.

Finally, to resolve the incompatibility caused by the technological assumption, I recommend considering imposing an obligation of *continuous disclosure*. Such a disclosure obligation would continue to require knowledge dissemination until the patent expires. Continuous disclosure may resolve the noted incompatibility and bring a solution to the GSD shortfall. Given this suggestion’s current rudimentary form, further research should be carried out before confirming its value. Any proposed solution must consider the perspective of both society and patentees. Of course, such a resolution may address not only the symptoms—an incompatibility and knowledge shortage—but the origin of the phenomenon itself, the technological assumption in patent law.