



Constraints on gene patent protection fuel secrecy concerns: a qualitative study

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ABSTRACT

Concern is mounting that innovators are responding to recent changes in patent eligibility by increasingly choosing to protect their discoveries as trade secrets. Due to the clandestine nature of trade secrets, it is impossible to quantify the extent to which innovators actually elect to protect their inventions as trade secrets rather than patents. Nevertheless, interest in each strategy may be gauged through qualitative means. We conducted semi-structured interviews of legal and scientific experts ($n = 30$) to understand the effect of recent patent eligibility changes on interest in patenting and trade secrecy of genetic innovations. Interview data indicate that secrecy may have increased in strategic appeal relative to patent protection in some areas of genetic innovation, although the actual election of secrecy strategies is often limited as a practical matter. The data also suggest that the

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burden of navigating the new intellectual property landscape may be falling disproportionately on those who translate gene-based discoveries into clinical applications. Some interviewees expressed concern about the normative implications of secrecy on advancements in and access to genetic medicine. Our findings are potentially relevant to policy proposals intended to restore some of the legal protection that was lost as a result of recent changes to patent eligibility, including amending the federal patent statute and expanding regulatory exclusivities for some genetic technologies.

KEYWORDS: genetics, innovation, intellectual property, patents, qualitative research, trade secrets

I. BACKGROUND

On December 7, 2016, Congress authorized up to \$1.455 billion to fund the Precision Medicine Initiative (PMI), which supports investigation of an emerging approach for disease treatment and prevention that takes into account the variability of individuals.¹ Because of the genetic basis of some of this variability, critical objectives of the PMI include identifying the genetic drivers of disease and translating those findings to improve clinical care and public health.² Achieving these objectives will require innovation along the entire length of the genetic research and clinical pipeline.

Historically, patents have been an important policy lever to facilitate innovation. A patent provides its owner a time-limited right to exclude others from practicing her patented invention.³ In theory, this period of exclusivity provides the patent owner an opportunity to recoup her investment through monopoly pricing or licensing.⁴ In exchange for this opportunity, however, the patent owner must disclose how to make and use the invention.⁵ Genetic inventions are treated as forms of intellectual property that can be protected by patents.

Section 101 of the federal patent statute codifies a threshold issue in determining whether an invention may be patented.⁶ That issue concerns whether the invention covers eligible subject matter.⁷ According to traditional patent doctrine, ‘anything under the sun that is made by man’ is eligible subject matter unless the invention falls into one of a few prohibited categories, which include abstract ideas and natural phenomena.⁸ Patent examiners at the U.S. Patent and Trademark Office (the ‘Patent Office’) evaluate patent applications to determine if they comply with the legal requirements for patenting and must deny patents on inventions that do not describe eligible subject matter.⁹ However, even approved applications that issue as patents remain subject to scrutiny because courts may later invalidate them for failure to satisfy Section 101.

¹ 21st Century Cures Act, Pub. L. No. 114–255 (2016).

² Euan A. Ashley, *The Precision Medicine Initiative: A New National Effort*, 313 JAMA 2119, 2119 (2015).

³ 35 U.S.C. § 154 (2017) (defining patent term); *Id.* § 271 (defining patent infringement).

⁴ J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L. J. 917, 928 (2011).

⁵ See *Id.* at 928–29.

⁶ 35 U.S.C. § 101.

⁷ *Id.* (providing that a patent-eligible invention is any ‘new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof’).

⁸ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 82–1979, at 5, 82d Cong., 2d Sess. (1952); H.R. Rep. No. 82–1923, at 6, 82d Cong., 2d Sess. (1952)).

⁹ 37 C.F.R. § 1.104(a),(c) (2017).

For decades, biomedical patents were infrequently denied or invalidated on Section 101 grounds.¹⁰ This began to change in 2012, however, when the U.S. Supreme Court articulated a new eligibility test in *Mayo v Prometheus* that requires any invention directed to one of the prohibited categories to include ‘significantly more’ to qualify as eligible subject matter.¹¹ The following year, in *Association for Molecular Pathology v Myriad*, a high-profile challenge to Myriad Genetics’ BRCA 1/2 gene patents that had enabled the company to monopolize testing for certain cancer risks, the Court held that isolated genetic sequences identical to those found in nature cannot be patented.¹² The lower courts have since applied the new eligibility test and extended the logic of *Myriad* to invalidate patents on innovations that were historically considered patentable, including gene-based diagnostic methods.¹³

Concern is mounting that this change in jurisprudence has weakened patent protection and that innovators are responding by increasingly choosing to protect their discoveries as trade secrets, which could negatively impact clinical care and public health.¹⁴ Until recently, trade secrecy was governed largely by state law, where a trade secret is any information that derives independent economic value from not being generally known to or readily ascertainable by others and is the subject of efforts to maintain its secrecy.¹⁵ In May 2016, however, Congress expanded liability in this area and created a federal cause of action for trade secret misappropriation.¹⁶

Like the patent right, the trade secret right includes the potential to charge monopoly prices for products and services incorporating proprietary information. However, while the patent right is limited to 20 years, the trade secret right can last indefinitely.¹⁷ Further, unlike patents, trade secrets are not disclosed; in fact, they lose their legal status as trade secrets as soon as they are disclosed, whether by innocent or

¹⁰ Judith Kim & Scott Schaller, *After Alice: The Two-Step Rule*, LIFE SCIENCES IP REVIEW NEWSLETTER 10, at 11 (Jan. 2015), http://www.skgf.com/uploads/1378/doc/LSIPR_Jan15_AfterALice.pdf (explaining that the judicial exceptions to patent eligibility ‘arguably did not play a large role in U.S. prosecution or enforcement of biotechnology and pharmaceutical patents until recent years’).

¹¹ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1294, 1297 (2012).

¹² *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013).

¹³ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *reh’g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S.Ct. 2511 (2016).

¹⁴ Arti K. Rai & Jacob S. Sherkow, *The Changing Life Science Patent Landscape*, 34 NAT. BIOTECHNOL. 292, 294 (2016) (concluding that in part as a result of recent U.S. Supreme Court eligibility decisions, ‘diagnostic firms may rely even more heavily on secrecy’); Anna B. Laakmann, *The New Genomic Semicommons*, 5 U. CAL. IRVINE L. REV. 1001, 1013–15 (2015) (arguing that it ‘would be a mistake to uncritically assume that new § 101 restrictions applied to genes and diagnostic methods will expand the storehouse of knowledge by increasing the number of donations to the genomic commons’ because it may cause inventors to ‘rely more heavily on secrecy to protect their patent-ineligible discoveries’); Derek E. Bambauer, *Secrecy is Dead—Long Live Trade Secrets*, 93 DENV. L. REV. 833, 833 (2016) (predicting that ‘innovators will shift to using trade secret law to safeguard advances, rather than filing for patent protection or using contractual and technological self-help to keep inventions confidential’ in part in response to the narrowed scope of patentable subject matter); Kevin E. Noonan, *Will ‘Open Source’ Be the Future of Genetic Diagnostics?*, PATENTDOCS (Mar. 20, 2016), <http://www.patentdocs.org/2016/03/will-open-source-be-the-future-of-genetic-diagnostics.html> (questioning ‘whether the changing paradigm instituted by the Supreme Court’s *Myriad* and *Mayo* decisions will in fact ultimately promote or inhibit the goal of discovering genetic correlates to disease for the most people and the most diseases’ if genetic data is maintained in proprietary databases).

¹⁵ The Uniform Trade Secrets Act § 1(4) (amended 1985), 14 U.L.A. 437, 438 (Master Ed. 1990).

¹⁶ Defend Trade Secrets Act of 2016, Pub. L. No. 114–153, 130 Stat. 376 (2016).

¹⁷ Bambauer, *supra* note 14, at 835; Anderson, *supra* note 4, at 924.

improper means.¹⁸ It is for this reason that patents and trade secrets are mutually exclusive forms of legal protection. If an invention is disclosed in a patent, it cannot be a secret, and if an invention is maintained as a secret, it cannot be patented.

In theory, the patent disclosure helps others avoid wasting resources duplicating the patented invention while giving others the opportunity to improve on it. In this way, patents are said to both reduce inefficiencies and stimulate further innovation.¹⁹ With respect to biomedical innovations in particular, society is said to benefit from patenting in the form of more and faster health-related improvements.²⁰ If innovators elect instead to keep their inventions secret, those benefits are lost. Although the trade-offs are in fact more complex than this telling suggests, the conventional wisdom that trade secrecy is less socially beneficial than patenting appears to be driving concerns that new limits on patent eligibility are shifting interest away from patenting and toward trade secrecy.

The aim of this study was to assess the validity of these concerns as applied to genetic innovations. Due to the clandestine nature of trade secrets, it is impossible to quantify the extent to which innovators actually elect to protect their inventions as trade secrets rather than patents.²¹ Nevertheless, interest in each strategy may be gauged through qualitative means.

Other scholars have reported qualitative data regarding business strategies for appropriating returns on inventions and concluded that intellectual property protection is important to the health sector. Among several studies of large companies conducted in the 1980s and 1990s, Cohen et al. surveyed R&D managers and found that the effectiveness of patents was rated highest by health-related industries among 34 U.S. manufacturing industries.²² In 2008, Graham et al. surveyed early-stage technology companies across several sectors and reported that patents were most frequently held by biotechnology and medical device start-ups, which also ranked patenting among their top two strategies for appropriating returns on inventions, ahead of secrecy.²³

While providing important insights into the use and value of various protective strategies, these studies pre-date the major changes to the patent eligibility doctrine. Thus far, studies of the impact of this policy change have focused on application filing and rejection rates and patent invalidation rates.²⁴ The perceptions and experiences of

¹⁸ Anderson, *supra* note 4, at 926.

¹⁹ W. Nicholson Price II, *Big Data, Patents, and the Future of Medicine*, 37 CARDOZO L. REV. 1401, 1418–19 (2016); Bambauer, *supra* note 14, at 837.

²⁰ Price II, *supra* note 19, at 1419.

²¹ David S. Almeling et al., *A Statistical Analysis of Trade Secret Litigation in Federal Courts*, 45 GONZAGA L. REV. 291, 295 (2009–10) ('[B]ecause trade secrets must be kept secret to qualify for protection, there is little publicly available material to study.').

²² WESLEY M. COHEN, RICHARD R. NELSON & JOHN P. WALSH, PROTECTING THEIR INTELLECTUAL PROPERTY ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (National Bureau of Economic Research Working Paper No. 7552, Working Paper Series, at Tables 1–2, 2000) (drug and medical equipment industries reporting the two highest effectiveness ratings of product patents, and two of the three highest effectiveness ratings of process patents, as compared to other appropriation mechanisms).

²³ Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L. J. 1255, 1276–77, 1290–93 (2009).

²⁴ Mateo Aboy et al., *Myriad's Impact on Gene Patents*, 34 NAT. BIOTECHNOL. 1119, 1120–21 (2016) (reporting grant rates of gene-related patents); Bernard Chao & Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 10 PATENTLY-O PATENT L. J. 10, 12–13 (2016) (reporting Section

stakeholders have not yet been investigated, although they are critical to understanding the attitudes and intentions that drive disclosure practices.

II. METHODS

As part of a larger project focused on changes in U.S. patenting practices,²⁵ we conducted in-depth interviews with legal and scientific experts to understand the effect of recent patent eligibility changes on interest in patenting and trade secrecy of genetic innovations. For purposes of this study, ‘genetics’ is defined broadly as any investigation of the genome and related practical applications. Thus, ‘genetic innovation’ refers not only to basic discoveries related to the structure and function of genetic material but also to the application of that knowledge to develop diagnostic tests, therapies, and bioinformatics tools and algorithms.

We emphasize that this study does not purport to measure actual use of patenting and trade secrecy. Qualitative interviews, by design, cannot measure. Rather, they seek to understand a research question utilizing a naturalistic approach ‘from the perspectives of the local population it involves’.²⁶ Qualitative interviews are therefore particularly effective in obtaining complex, contradictory, counterintuitive, sensitive, or culturally specific information about the experiences, values, opinions, behaviors, and social contexts of individuals who share particular interests or are affected by the same phenomenon.²⁷ As methodologists have explained, ‘[i]nterviewing those involved in contending sides of a dispute or listening to different versions of the same incident leads to more thoughtful and nuanced conclusions’.²⁸ Moreover, qualitative interviews are especially useful with respect to previously unstudied attitudes and actions, which cannot adequately be understood in the first instance with a structured survey that presumes awareness of the range of possible answers respondents might give and provides limited opportunity to probe answers and explore meaning.²⁹ In this respect, qualitative interviews are hypothesis generating, rather than hypothesis testing. Finally, where the research question involves clandestine practices that cannot be measured as a practical matter, as is the case with trade secrets, qualitative studies may be the best direct way to obtain relevant information.³⁰

This study was designed, analysed, and reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies (COREQ) (interviews and focus

101 rejection rates); Robert R. Sachs, *Alicestorm Update for Fall 2016*, BILSKIBLOG (Oct. 19, 2016), <http://www.bilskiblog.com/blog/2016/10/alicestorm-update-turbulence-and-troubles.html> (reporting Section 101 rejection and invalidity rates).

²⁵ To triangulate the results of this qualitative study, the project team also examined the file histories of over 650 claims distributed among 330 gene-related patent applications to obtain evidence of the impact of legal changes to the patentable subject matter doctrine on patenting practices relevant to these innovations. The report of this study is under publication review.

²⁶ NATASHA MACK ET AL., *QUALITATIVE RESEARCH METHODS: A DATA COLLECTOR'S FIELD GUIDE 1* (2005).

²⁷ *Id.* at 1–2; HERBERT J. RUBIN & IRENE S. RUBIN, *QUALITATIVE INTERVIEWING: THE ART OF HEARING DATA 4* (3d ed. 2012).

²⁸ RUBIN & RUBIN, *supra* note 27, at 4.

²⁹ RUSSELL K. SCHUTT, *INVESTIGATING THE SOCIAL WORLD: THE PROCESS AND PRACTICE OF RESEARCH 316* (6th ed. 2009).

³⁰ RUBIN & RUBIN, *supra* note 27, at 5 (‘Qualitative interviewing projects are especially important when the processes being studied are nearly invisible.’).

Table 1. Candidate Contacts and Participation, by Primary Professional Occupation (n = 54).

	<i>Number contacted</i>	<i>Number accepted</i>	<i>Response rate (%)</i>	<i>Interview population (%)</i>
Patent practitioners	21	13	62	43
Legal academics	15	11	73	37
Scientists	18	6	33	20
Total	54	30	56	100

groups).³¹ A purposive sample of interviewees was constructed from a review of recent legal and scientific literature and public presentations, as well as snowball sampling. Conditions for inclusion as an interview candidate were current occupation as a U.S.-based patent practitioner (attorney or agent), legal academic, or scientist; expertise in U.S. patent law or genetic science, as established by the candidate's education, training, or experience; and strong familiarity with the U.S. doctrine of patent eligibility, as evidenced by the candidate's publications, presentations, public comments, or case work. Candidates who satisfied all conditions were preference-ranked by their credentials as well as demographic considerations intended to enhance the diversity of opinions. Candidates were then contacted by email in order of preference.

Patent practitioners and scientists were included in this study to understand on-the-ground experiences with patenting and trade secrecy. Legal academics were included to triangulate this data with a broader and less biased (in theory) understanding of the legal and political landscape in which any practice changes have occurred and any solutions will take effect. However, as discussed in the next section, a number of interviewees straddled multiple categories and so were able to provide relevant information on topics outside of their primary professional domain.

A total of 54 individuals were invited to participate in the study and 30 individuals completed an interview, for an overall participation rate of 56% (Table 1). Of the 24 non-participants, 17% (n = 4) actively declined. The other 20 non-participants did not respond to two email invitations to participate. Most legal academics (73%) and patent practitioners (62%) agreed to participate, whereas scientists (33%) were difficult to recruit.

Semi-structured interview guides were developed that consisted primarily of open-ended contextual and evaluative questions.³² Relevant questions included whether recent changes to patent eligibility have changed how patent practitioners are drafting and prosecuting patents or have changed how inventors and investors are choosing to protect their intellectual property and explored potential solutions to problems that were identified.

³¹ Allison Tong, Peter Sainsbury & Jonathan Craig, *Consolidated Criteria for Reporting Qualitative Research (COREQ): A 32-Item Checklist for Interviews and Focus Groups*, 19 INT'L J. QUALITY HEALTH CARE 349 (2007).

³² Jane Ritchie & Liz Spencer, *Qualitative Data Analysis for Applied Policy Research*, in ANALYZING QUALITATIVE DATA 173–94 (Alan Bryman & Robert G. Burgess eds., 1994).

Interviewees gave verbal consent to participate, and all interviews were conducted by telephone, tape-recorded with permission, professionally transcribed, and de-identified. Interviewees were offered a \$100 honorarium for participating.

Interviews were conducted between January and July 2016. The median interview time was 44 minutes, with a range of 31–106 minutes.

Data were analysed according to thematic content analysis.³³ Using NVivo 11 for Mac (Melbourne, Australia: QSR International), interview transcripts were double-coded by theme, and any disagreement among coders was resolved by consensus. One author (CG) determined summative information.

All procedures and materials were approved by the Institutional Review Board of Baylor College of Medicine. A Certificate of Confidentiality was also obtained from the National Institutes of Health.

III. RESULTS

Results are presented as follows: (1) interviewee characteristics; (2) concerns about patenting; (3) changes in interest in trade secrecy; (4) implications for genetic medicine and public health; and (5) potential solutions. Quoted information is attributed to interviewees using their assigned interview numbers.

A. Interviewee Characteristics

By professional role, the participants consisted of 43% patent practitioners ($n = 13$), 37% legal academics ($n = 11$), and 20% scientists ($n = 6$) (Table 1). Although interviewees were categorized by current primary occupation, some performed work spanning multiple occupations. For example, two patent practitioners taught patent law in law schools and nine legal academics and practitioners were former bench scientists. These observations underscore the broad knowledge base and experiences that interviewees brought to the study.

Interviewees were fairly evenly distributed across geographic regions (Table 2). The largest number ($n = 9$) resided in the South, which was defined to include Washington D.C., a known hub of patent practice. The majority of interviewees were male ($n = 24$),³⁴ and the dominant employers were academic institutions ($n = 13$) and law firms ($n = 10$). The for-profit firms represented in the population sample provide gene-related products or services for clinical use.

Focusing on patent practitioners (Table 3), the majority ($n = 10$) served as outside counsel employed by law firms; three served as inside counsel employed by non-profit or for-profit institutions. Outside counsel were almost evenly split among multi-practice firms ($n = 4$) and intellectual property boutiques ($n = 6$) as well as primary practice focus. Finally, most outside counsel represented diverse industries, including

³³ Hsiu-Fang Hsieh & Sarah E. Shannon, *Three Approaches to Qualitative Content Analysis*, 15 QUALITATIVE HEALTH RES. 1277 (2005).

³⁴ This result is consistent with the overrepresentation of males in the patenting and scientific professions and among patentees. See Saurabh Vishnubhakat, *Gender Diversity in the Patent Bar*, 14 J. MARSHALL REV. INTELL. PROP. L. 67, 76 (2014) (finding that the majority of registered patent attorneys and agents are male); Ann Bartow, *Patent Law, Copyright Law, and the Girl Germs Effect*, 90 ST. JOHN'S L. REV. 579, 583–84, 587–88 (2016) (describing the underrepresentation of women employed in science, technology, engineering, and math fields and among U.S. patentees).

Table 2. Interviewee Characteristics (n = 30)*.

	<i>Number</i>	<i>% Interview population</i>
Gender		
Male	24	80
Female	6	20
Geographic location**		
Northeast	7	23
Midwest	8	27
South	9	30
West	6	20
Employer		
Academic institution	13	43
Law firm	10	33
For-profit firm	4	13
Health care system	2	7
Other	1	3

*Percentages may not add up to 100% due to rounding.

**As defined by U.S. census region.³⁵

biotechnology and pharmaceutical companies, although one patent practitioner specialized in biotechnology and another specialized in software.

All participants were interviewed as individuals; none purported to speak on behalf of their employers, clients, or colleagues.

B. Concerns About Patenting

In response to probes concerning recent changes in patent law, interviewees identified common experiences that have increased the risks and costs of pursuing patent protection for genetic inventions. Every patent practitioner (n = 13) and legal academic (n = 11), and one-third of the scientists (n = 2), expressed opinions on this subject.

First, interviewees reported that examiners are more frequently rejecting patent applications on Section 101 grounds, which is consistent with reported quantitative data.³⁶ Patents related to biological compositions, software, and diagnostics were singled out as hardest hit by the recent changes to patentable subject matter. With respect

³⁵ U.S. Census Bureau, *Regions*, <https://www.census.gov/geo/reference/webatlas/regions.html> (accessed July 28, 2017).

³⁶ See eg Amanda B. Maslar & Prachi V. Mehta, *To Bilski, and Beyond: An Empirical Analysis of Judicial Opacity on Patent Law and the Modern Administrative State*, 3 UNIV. ILL. L. REV. 1157 (2016) (finding that 400 randomly selected patent applications were less likely to be rejected on Section 101 grounds if prosecuted between 2004 and 2008 than if prosecuted between 2008 and 2012); Chao & Mapes, *supra* note 24 (finding that 15.9% of

Table 3. Patent Practitioner Characteristics (n = 13).

	<i>Number</i>	<i>% Patent practitioner interview population</i>
Inside counsel	3	23
Outside counsel	10	77
Multi-practice firm	4	40
IP boutique firm	6	60
Patent prosecution	4	40
Patent litigation	3	30
Both patent prosecution and litigation	3	30

to diagnostics in particular, a patent practitioner explained that the situation had become so dire that ‘it’s like we should throw a parade every time an examiner allows a diagnostic claim’ (6).

As a strategy for addressing these rejections, many patent practitioners said that they had begun prolonging the back-and-forth communications between applicants and examiners about proposed patents—a process called prosecution—in an effort to ‘buy time’. Interviewees explained they accomplished this by pursuing narrow claims and then filing continuation or divisional applications for broader claims; filing requests to suspend prosecution up to six months³⁷; and responding to final rejections by ‘parking’ applications in appeal. ‘You’re just waiting for good case law that might clarify the picture better’, explained a patent practitioner, ‘and so you’re dragging things out’ (6). In addition, several interviewees described having more telephone and in-person discussions (called interviews) with examiners, and earlier in the prosecution process, in an attempt to understand examiners’ Section 101 objections and what changes to patent claims (if any) might overcome them. However, one patent practitioner explained that psychological barriers or immediate budget constraints forced many of her clients to abandon applications rather than take appeals, and that the costs of pursuing multiple applications were also sometimes prohibitive (29).

With respect to drafting strategies, interviewees reported that several non-substantive modifications showed promise in preempting or overcoming Section 101 rejections. These included providing more detailed disclosures in patent specifications; adding or lengthening ‘wherein’ clauses at the end of claims; and adding steps that describe activities that must be performed to practice the claim but that in the past would have been omitted because ‘they don’t really contribute anything’ (18). These changes are intended only to improve optics: ‘it’s the same scope that you would have gotten previously, but [now] it is being drafted to suggest that the claim is more complicated than it needs to be’ (1).

office actions for 294 patent applications covering personalized medicine inventions issued before the *Mayo* decision included Section 101 rejections, compared to 86.4% in the years following *Mayo*).

³⁷ 37 C.F.R. § 1.103(a) (2017) (providing for suspensions of action upon a ‘showing of good and sufficient cause’).

In contrast to the strategy of providing more detailed disclosures, another patent practitioner described a strategy of omitting background information to avoid the appearance that the invention itself is an unpatentable law of nature. For example, the practitioner explained, if an inventor discovers a compound that inhibits a natural biochemical pathway, thereby stopping a cancer from metastasizing, she might elect not to disclose the cellular mechanism in a patent application on the compound and method of treatment to avoid the appearance that either is impermissibly based on or linked to a law of nature. Again, this omission would not change the scope of the claims, although it would make the patent itself less useful in understanding how the invention actually works.

Half of interviewees asserted that examiners' high rate of Section 101 rejections has compelled practitioners to make substantive adjustments to claims. In genomics in particular, what might previously have been described as an isolated sequence is now being presented as genomic material captured and put into a new form, like a transformed bacterium. Labeling probes and recasting diagnostic processes as steps of treatment methods were also identified as substantive strategies for avoiding Section 101 rejections. Interviewees noted, however, that these modifications usually narrow the scope of the patent right and open up new opportunities for others to 'work around' the invention since infringement requires the practice of every step or element of what is patented.³⁸

Four interviewees acknowledged that new pressures to limit patent scope can serve 'a useful purpose in preventing over-claiming' (12)—that is, preventing patent owners from obtaining patents that are so broad that they inappropriately monopolize a field of discovery. Indeed, there was a general recognition that some patents are so broad or abstract that they are problematic for society.

Still, some interviewees complained that applicants are increasingly compelled to narrow their patents to such a degree that they retain little commercial value because the workaround becomes a simple matter of omitting an unimportant component or step. Moreover, with respect to patented processes, if claim steps are added that must be performed by a different entity than the entity performing the original steps—for example, gene sequencing steps are performed by a laboratory but treatment steps that must be performed by a clinician are added—the patent's value may diminish to zero as a practical matter. That is because under the 'divided infringement' doctrine, as noted by three interviewees, courts have traditionally been unlikely to find a process patent infringed where no single entity practices every step, although recent case law may have improved the chances of an infringement ruling where multiple actors are involved.³⁹

Interviewees also expressed substantial concern about the new patent eligibility test, which focuses on whether an invention is 'directed to' a prohibited category from the natural world. Indeed, every opinion expressed about the test was negative and included

³⁸ Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Corp., 520 U.S. 17 (1997) (holding that direct patent infringement requires a party to perform or use each and every step or element of a claimed method or product).

³⁹ Leland L. Black, Note, *Patenting and Protecting Personalized Medicine Innovation Post-Mayo, Myriad and Lime-light*, 95 N.C. L. REV. 493 (2017) (describing the history of the divided infringement doctrine and how application of the en banc opinion in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) and careful claim drafting might avoid findings of non-infringement where separate actors practice different steps of a patented method).

such characterizations as ‘painfully, painfully, painfully wrong’ (1) and ‘the stupidest thing ever’ (2). One patent practitioner elaborated that the test recasts inventions ‘in an entirely different light that we’ve never used to look at inventions’ so that they now appear ‘pithy, and small, and meaningless’ (19). In any event, every invention is in some way an application of the natural world:

There are no patent claims that don’t have natural laws and things like that in them. We can’t live on this planet and not have natural laws. They exist. They’re there. And just talking about them shouldn’t then make a claim suddenly become patent ineligible (18).

Putting the test in historical perspective, a legal academic concluded that it represents ‘a radical new experiment in restricting the scope of the patent system that’s not at all consistent with the way things have worked for the past 150 years’ (13).

Ten interviewees explained that issues with the new eligibility test have been exacerbated by its inconsistent application during prosecution. According to a patent practitioner, ‘it’s not like you can really apply what one has learned from one examiner, or what worked for one case, to another case’ (29). Rather, each examiner has a unique take on the new test, which can change mid-prosecution, so that in the end, navigating application of the test to particular cases can feel like ‘trying to throw darts on a dartboard where you’re moving all over and you have a blindfold on’ (29). While interviewees noted that the Patent Office has issued guidance to clarify how examiners should apply the test,⁴⁰ which can provide a clue as to drafting language that might be successful, there was consensus that predictability remains elusive. This is in part because the law remains unsettled, which means that the Patent Office is, according to another patent practitioner, ‘examining on a shifting slate’ (19).

The efforts required to address Section 101 rejections through arguments or amendments that maintain patent value have generally increased the perceived risks and costs of patenting. As explained by a patent practitioner,

Now there’s a lot more strategy that has to go into drafting these patents, so the cost of preparation is higher. The cost of prosecution is much higher because 101 was never an issue before. Now we’re arguing section 101 all the time, even in cases where we think we’re clear (2).

Nevertheless, six interviewees opined that net patent costs may decrease in the long run because innovators will pursue patent protection less frequently, or abandon patents more frequently, due to the ‘considerable uncertainty as to whether they’re going to

⁴⁰ See U.S. Patent & Trademark Office, *July 2015 Update: Subject Matter Eligibility* (July 2015), <https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf>; U.S. Patent & Trademark Office, *2014 Interim Guidance on Patent Subject Matter Eligibility*, 79 Fed. Reg. 74,618 (Dec. 16, 2014). Near the end of the interview period, the Patent Office released additional guidance to its examining corps. See Memorandum from Robert W. Bahr, Deputy Commissioner for Patent Examination Policy, to Patent Examining Corps (May 4, 2016), <https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf>. Finally, from December 2014 to December 2016, the Patent Office released example sets illustrating subject matter eligibility analyses of hypothetical claims and claims drawn from case law. See U.S. Patent & Trademark Office, *Examples*, <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility> (accessed Apr. 26, 2017).

get anything out of it' (10). One patent practitioner who serves as in-house counsel described this experience as follows:

[W]e've fought a lot of 101 battles and I think we're now giving up on some of them. So it cost us more at first, and now we're sort of waking up and saying, "Let's just forget about it because we're not going to get this patent," and reduce our expend[iture] (30).

Another patent practitioner confirmed this experience: 'I have seen with my clients and I've also heard from other practitioners that if one cannot obtain suitable patent protection, the clients are not pursuing their filing of applications, and they're not pursuing patent protection' (29). Instead, some interviewees asserted, innovators may be changing their innovation activities or relying on trade secrecy as an alternative to patent protection.

C. Interest in Trade Secrecy

Twenty-two participants expressed opinions regarding whether trade secrecy protection has increased in recent years. These conversations were dominated by patent practitioners ($n = 10$) and legal academics ($n = 8$), although scientists were also well represented ($n = 4$).

In general, patent practitioners and legal academics who currently practice law believed that interest in trade secrecy has increased based on their personal experience deliberating trade secrecy strategies for others. As one patent practitioner explained, 'clients say they're looking more to trade secrets for protecting some of their technologies' (15). Other patent practitioners concurred: 'In the last couple years, I have talked plenty about trade secrets. Clients are very interested in keeping things secret' (2); and '[Y]ou do hear more and more people talking about that they're not pursuing patents, that they are going to treat these things as trade secrets' (16). Some interviewees alluded to knowledge of trade secrecy activities of others or even identified entities that may maintain patient data as proprietary or have expanded their use of trade secrecy.

The majority of interviewees who perceived or predicted increase in trade secrecy explicitly linked that increase to changes in the patentable subject matter doctrine. One patent practitioner described this understanding as follows:

I do think a lot of these decisions make inventors and companies think about this a little more carefully because if you do have a process that you can keep a trade secret, it might be more worthwhile to do it that way because if you're less likely to get a patent on your process or whatever it is, then the downside is that you've now told the entire world the great thing that you have... I think that's really where you see a lot of the discussion occurring, trying to figure out with some of this technology, do we keep it a trade secret or do we get a patent on it? I think both in the genomics area and also in other areas, the four Supreme Court decisions and the other appellate decisions that follow those cases, are certainly making companies and investors and innovators reconsider that calculus (14).

One legal academic, however, was more cautious: 'I think there's been a contemporaneous shift from patents to trade secrets with the 101 cases, but it's hard for me to draw a causal link between the two' (1).

Several interviewees focused specifically on diagnostics as an area where there is now greater appreciation for trade secrets. One patent practitioner even concluded that in diagnostics, currently, ‘the only rational investment is one in which hiding the ball, keeping things secret, is part of your business plan’ (3). A legal academic who practices law confirmed that diagnostic clients are increasingly worried about whether they will see a return on investment and are asking: ‘Should we focus increasingly on trade secret protection? On collecting data for internal use, but not actually sharing that data with the world?’ (12).

However, one patent practitioner and every scientist who discussed the subject were skeptical of increased interest in trade secrecy, citing scientific norms that encourage openness and sharing. These interviewees generally focused their comments on the database maintained by Myriad Genetics, which consists of genetic sequencing data and associated phenotypic information that Myriad began acquiring when it was the exclusive provider of BRCA1/2 testing.⁴¹ Although some of the patents that supported its exclusivity were eventually invalidated, Myriad continued to dominate the testing market through its proprietary database.⁴² Summarizing the views of this subgroup, a scientist contrasted Myriad’s ‘hoarding and proprietary attitude about patent data’ with the broader scientific culture in which ‘data sharing is growing’ (24). One scientist claimed that this sharing ethos is spreading to even commercial efforts like some diagnostic development:

[W]e are developing a culture in genetic testing similar to the culture in other parts of medicine, and that is: you don’t compete using trade secrets. You compete by providing excellent service and being really, really good at what you do (20).

In addition to sharing norms that encourage disclosure, interviewees identified three other practical obstacles to protecting innovations as trade secrets that could limit the use of this legal strategy. The first is the ease of reverse engineering some inventions, where reverse engineering means reproducing a product or process by examining its construction, composition, operation, or outputs.⁴³ Interviewees explained that some innovations are easily reverse engineered by their nature, making it almost impossible to maintain them in secret. These easily copied innovations include basic research discoveries like gene sequences, some manufactured compositions like pharmaceutical compounds, and simple diagnostic tests.

Another obstacle arises when trade secrets must be maintained in global markets. Trade secrecy laws are generally country specific; there is no international trade secret law.⁴⁴ If products incorporating a trade secret are made abroad—for example, in China—the innovator may have to share the trade secret with Chinese contractors.

⁴¹ Robert Cook-Deegan et al., *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?*, 21 EUR. J. HUM. GENET. 585 (2013) (describing Myriad’s proprietary database of information related to its clinical testing for BRCA 1/2 genetic variants).

⁴² Sharon Begley, *As Revenue Falls, a Pioneer of Cancer Gene Testing Slams Rivals With Overblown Claims*, STAT NEWS (Nov. 29, 2016), <https://www.statnews.com/2016/11/29/brca-cancer-myrriad-genetic-tests/>

⁴³ See The Uniform Trade Secrets Act § 1, cmt. (amended 1985), 14 U.L.A. 437, 438 (Master Ed. 1990).

⁴⁴ Elizabeth A. Rowe & Daniel M. Mahfood, *Trade Secrets, Trade, and Extraterritoriality*, 66 ALA. L. REV. 63, 64 (2014).

But, as explained a patent practitioner:

The first question is, can you trust them to maintain it and protect it and not misappropriate it? And if it were to get misappropriated and you were able to pursue some kind of action in China, would you have any chance of winning that action given the perceived Chinese judicial bias in favor of domestic entities? (4)

The remaining practical obstacles to trade secrecy identified by interviewees relate to the practical need to disclose trade secrets to, eg insurance companies to convince them to reimburse users of the innovation, academic journals to comply with disclosure requirements, and clinicians and consumers to give them confidence that the innovation is safe and effective. According to a patent practitioner, some of these motivations are so strong in diagnostics in particular that ‘commercially, often you can’t rely on trade secrecy’ (19).

Yet, interviewees identified a non-trivial and perhaps growing space for trade secrecy in bioinformatics, which is increasingly important as scientists move beyond detecting specific genes to understanding complex and probabilistic combinations of gene effects. For example, if the invention is ‘measuring the expression level of 70 different genes with some sophisticated algorithm,’ explained a legal academic, the algorithm can potentially ‘be kept as a trade secret for a very long time’ (9). Biologics and epigenetics were also singled out as areas ripe for trade secrecy.

D. Implications

Our interview guide did not include specific probes related to the practical and ethical implications of protecting genetic innovations as trade secrets rather than patents. Nevertheless, 14 interviewees discussed possible consequences for medicine and public health. Although no interviewee was particularly bothered about the loss of the inability to patent natural genetic sequences—and many were quite glad with this result on grounds that these kinds of patents are too broad or their claimed inventions not particularly innovative—there was general appreciation for the patent system among all interviewees and consensus that patents are necessary to incentivize certain kinds of innovations, like medical therapeutics (especially pharmaceuticals), which are costly to develop.

But there was substantial disagreement, even among the scientists, as to whether patents are necessary to support innovation and commercialization in diagnostic testing other than platform development. Some dismissed the idea out of hand, while others argued that patents are at least necessary to protect tests based on sophisticated algorithms, which some asserted cost a million dollars or more to develop and validate to the satisfaction of insurers. Regardless of investment costs, however, one legal academic noted that diagnostics is generally a ‘very patent sensitive industry,’ which gives ‘some reason to worry about the Supreme Court, based on very vague guidance from its past decisions, concluding that this is an area where we shouldn’t have patents’ (10). A geneticist involved in academic and for-profit research echoed this sentiment, stating that patents ‘are usually the defining factor as to whether or not someone will invest in a company’ and are especially important in the diagnostics space (22). However, a legal

academic stressed that restrictions on patenting will not end innovation in the field:

I just don't believe people that say, "Oh man, now that we don't have patents for diagnostics we're not going to get any new diagnostic tests." It's not true. Clearly, we're going to get new diagnostic tests. On the margin, does patent law change this stuff? Yes. Certainly. That's why we care about it and why we study it. Are these changes going to totally screw everything up and destroy the industry and destroy the livelihood of patent lawyers? No. They'll figure out a way to deal with it and we'll keep moving forward somehow. That's not to say this is the best of all possible worlds, nor that I think that the doctrine, the way that it is now, should remain, nor that it doesn't bring any problems. But I don't think it's, "Woe is me. The sky is falling. Now we have these four cases and innovation is going to stop" (17).

Most expressed concern about a world where the go-to mechanism for protection of gene-related innovations is trade secrecy. With patents, explained a legal academic, 'at least it's published, enabled, and eventually the patents expire' (5). By contrast, trade secrets are not disclosed, which some interviewees found particularly troubling for medical research, where there are often not 'multiple paths to the same goal' as there is with respect to software but rather only 'one pathway that just is the right pathway' (12). Explained a legal academic, 'We might worry more about the consequences of keeping medical information secret if the result is that we don't have access to life-saving medicines or information' (12). Secrecy of patient data in diagnostics was singled out as an area of heightened ethical concern for the reason that it can result in lower quality or more expensive medical care.

Still, two scientists who strongly opposed trade secrecy of patient data commented that trade secrets can have a useful function in other commercial contexts, particularly during the start-up phase of development. Moreover, three interviewees cautioned against concluding that patents are always preferable to trade secrets from a societal perspective, even in health care. For one, explained a legal academic, '[p]atents, of themselves, frankly aren't wildly great at the disclosure function' (17). This shortcoming was emphasized by another legal academic: 'One thing that I think unfortunately people don't fully understand is the extent to which patents are often issued without the disclosure piece of the bargain being fulfilled in any way, shape, or form' (9). A third noted that trade secrecy strategies may not be worrisome to the extent that they are 'leaky,' meaning difficult to contain. But if a potential trade secret is perceived to be too leaky, a different strategy for appropriating returns on an invention will be pursued.

Ultimately, the most problematic situations may be those where neither trade secrecy nor patenting is legally or practically available to protect inventions requiring significant private investment to develop. If inventors and their investors conclude that an innovation target cannot be legally protected from copying, and if other appropriation mechanisms are inadequate, that target might not be pursued. As one patent practitioner explained:

Innovation costs a lot of money, so if you can't actually protect it and know that you have the exclusive rights to it, you can't pursue innovation that costs that order of magnitude. You have to pursue innovation that is much cheaper, and that means much less

dramatic—not paradigm shifting [innovation]. And the type of things that we say that we really want, we're not going to get' (16).

Interviewees agreed that research conducted by university scientists is least at risk because it is already incentivized by government funding and various professional benefits associated with discovery. Thus, the model of open science and collaboration may work well for initial discovery. By contrast, the translation of basic discoveries for clinical applications often requires private investment, and it is these efforts that are most affected by limits on protection mechanisms. As a litigator explained, 'The basic research isn't going to stop. What's going to stop, perhaps, or be diminished to some extent, is the commercialization of the research' (7). This view was echoed by another patent practitioner who described first-hand knowledge of a shift in innovation strategies among non-university researchers. For some, the focus is now on producing patentable compositions, the practitioner explained, 'rather than spending money on the personalized medicine solution where, under current Supreme Court decisions, it's not necessarily likely that there will be protection for significant investment' (15). Indeed, this was the experience of an entrepreneur, who had explained to a patent practitioner interviewee that significant patenting pressure from investors was having a direct impact on his research agenda: 'It's quite frustrating because I am systematically being directed to spend my money researching the compounds that have the best patent protection,' he told the practitioner, 'and not necessarily the compounds that are the best medicinal molecules' (19).

Some interviewees analogized Section 101 jurisprudence to a pendulum that may eventually swing back toward strengthening patent incentives to develop these solutions.⁴⁵ Others worried about the harm that might be inflicted in the meantime. 'I actually think if we don't get some kind of a fix, particularly in the bio side,' concluded a patent practitioner, 'we're going to hurt healthcare in this country long term,' and it will be 'in ways that we can't recover' (15).

E. Solutions

Interviewees discussed five potential mechanisms for addressing the problems they identified. Every patent practitioner (n = 13) and legal academic (n = 11), and two scientists, offered opinions on these solutions.

Three solutions were directed at the patent eligibility doctrine. Of these, most interviewees (n = 13) preferred congressional amendment of Section 101 to clarify the kinds of inventions that are patentable. These interviewees generally felt that Congress would be more responsive than the U.S. Supreme Court to their concerns and would adopt changes that made more practical sense (or were more favorable to their interests) than any the Court might adopt. However, many practical barriers to legislative change were identified, including general congressional dysfunction; long-standing congressional reluctance to alter basic patent doctrine, including during the most recent patent reforms⁴⁶; congressional preoccupation with other patent matters,

⁴⁵ Accord Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1 (2016) (lending empirical support to this perspective).

⁴⁶ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (changing, among other things, the U.S. patent system from a first-to-invent to a first-to-file system).

especially patent trolling; and conflicting stakeholder interests that would promote rent-seeking behavior and ultimately block consensus. Indeed, two interviewees felt that this last barrier was so significant that only amendments narrowly tailored to specific fields, like diagnostics, would be politically feasible, citing as precedent the successful carve-outs of tax strategies from patentable subject matter and the practice of patented medical treatment methods from liability.⁴⁷ A patent practitioner, however, warned against going down this road:

I think if we start trying to carve out or make exceptions to the statutory text of Section 101, then we start ourselves down the path of every time there's a court decision that affects a particular technology, then we're going to propose a different carve-out or a different exception. That's one of the problems. And the second problem, of course, is it doesn't really solve the problem ... [R]eally all that does is toss the issue of, OK, now the courts will have to actually construe the language of that carve-out. So you'll continue to have uncertainty because what will happen is patent owners and accused infringers will start fighting over whether a particular technology actually falls within or outside of that section (15).

A smaller group of interviewees ($n = 6$) viewed the U.S. Supreme Court, rather than Congress, as the preferred locus of change. These interviewees believed that the Court should do one or more of the following: clarify the two-step test; limit *Mayo* and other precedent to their facts; identify Section 101 precedent that is no longer good law; and recognize that Section 101 should not be used to do the work of other patentability doctrines, like the non-obviousness requirement. While one patent practitioner noted the logic of a judicial fix—'there's a certain amount of symmetry, right, because the courts is where the problem started' (27)—in general, these interviewees seemed not so much to endorse the Court than reject Congress. 'I would love to see a legislative solution to this,' commented a patent practitioner, 'but I have a hard time seeing [Congress] accomplishing anything that has any good in it' (18).

Legal academics in particular were pessimistic that the Court will revisit Section 101 again for quite some time. When it does, however, several interviewees stressed that any requests for doctrinal change must be responsive to the perceived problems of, eg overbroad patents and abusive litigation tactics that they believe motivated the Court's recent patentable subject matter decisions. '[I]f we're going to craft any change in the law,' explained a patent practitioner, 'it can't be to tell the Supreme Court you're wrong; it has to be to properly cabin and deal with their concerns' (3).

Looking beyond the legislative and judicial branches, a legal academic identified the Patent Office as a third potential agent of change. Unlike many administrative agencies, the Patent Office does not have rulemaking authority.⁴⁸ But if it did, she explained, 'I think that's the place where we would have the best opportunity to get some sensible decision making' (10) because the Patent Office has the technical expertise to develop

⁴⁷ See *Id.* § 14 (providing that 'any strategy for reducing, avoiding, or deferring tax liability' is included in the prior art and therefore not patentable); 35 U.S.C. § 287(c) (exempting medical practitioners from liability for infringing medical and surgical method patents).

⁴⁸ See Sarah Tran, *Administrative Law, Patents, and Distorted Rules*, 80 GEORGE WASH. L. REV. 831 (2012) (describing limits on the Patent Office's substantive rulemaking authority). Accord Sapna Kumar, *The Accidental Agency?*, 65 FL. L. REV. 229 (2013) (arguing that the Federal Circuit acts as a de facto administrator of the Patent Act by engaging in substantive rulemaking).

rules for patentable subject matter that account for diversity in innovation fields. In addition, Patent Office rulemaking would be easier to change than legislation, which she explained is especially useful when dealing with technologies that are rapidly evolving.

Five interviewees explored a different regulatory mechanism to address changes in patentable subject matter doctrine: expanding data and marketing exclusivities granted by the Food and Drug Administration (FDA). Current exclusivities apply to drugs, biologics, and medical devices regulated by the FDA,⁴⁹ and some interviewees discussed extending the periods of exclusivity for these compounds to compensate for shortfalls in patent protection. Others considered coupling new regulation of laboratory-developed tests (LDTs) with exclusivities in order to better protect investment in diagnostics. A patent practitioner who serves as in-house counsel discussed this proposal in the context of tensions in three policy domains: patent protection, test regulation, and third-party reimbursement. If insurers refuse to pay or set reimbursement rates that are adequate to cover costs, then the business might not be viable regardless of the robustness of its patent protection. By contrast, reimbursement usually follows regulatory approval. Historically, he explained, the trade-off for somewhat broad patent protection of diagnostics that excluded competitors was the absence of regulatory barriers to market entry and the difficulty convincing third-party payers to reimburse tests. Now, however, diagnostics patents are hard to obtain, yet the FDA has pulled back on plans to regulate diagnostic tests⁵⁰ and ‘the pressure from the third-party payers on reimbursement is worse than ever’ (27). A legal academic, however, noted that if the FDA regulates diagnostics, competition may narrow because ‘only certain well capitalized firms probably will be able to overcome that barrier to entry in the first instance’ (9). Further, while enhanced FDA exclusivities may provide an adequate substitute for patent protection, they will not necessarily discourage secrecy because the FDA generally does not compel public disclosure of trade secrets.⁵¹

Finally, three interviewees addressed the role of public funding of research vis-à-vis patenting. A patent practitioner suggested that public funding might be increased to

⁴⁹ See eg 21 U.S.C. § 355(c)(3)(E)(ii) (2017) (providing a 5-year marketing exclusivity for drugs containing an active ingredient that has not been previously approved); 21 U.S.C. § 360j(h)(4)(A) (providing a 6-year exclusivity in data submitted in connection with premarket approval applications for Class III medical devices); 42 U.S.C. § 262(k)(7) (providing a 12-year marketing exclusivity for original biologics and a 4-year exclusivity period for data submitted in support of applications for original biologics). For a helpful description of these exclusivities in the context of other regulatory competitive shelters, broadly defined as ‘competitive advantages resulting from statutory bars on regulatory action where such action is otherwise mandated and would have taken place but for the triggering of the bar’, see Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L. J. 299 (2015).

⁵⁰ The FDA has generally exercised enforcement discretion not to regulate LDTs, defined as in vitro diagnostic devices intended for clinical use and designed, manufactured, and used within a single laboratory. In 2014, the FDA announced plans to begin regulating LDTs under a risk-based framework. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, FOOD AND DRUG ADMINISTRATION STAFF, AND CLINICAL LABORATORIES: FRAMEWORK FOR REGULATORY OVERSIGHT OF LABORATORY DEVELOPED TESTS (LDTs) (Oct. 3, 2014), <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm416685.pdf>. However, in late 2016, it notified industry groups that it would not finalize the draft guidance in order to work with the new administration and Congress, as well as stakeholders, to update the LDT framework. See U.S. FOOD & DRUG ADMIN., DISCUSSION PAPER ON LABORATORY DEVELOPED TESTS (LDTs) (Jan. 13, 2017), <https://www.fda.gov/downloads/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/laboratorydevelopedtests/ucm536965.pdf>.

⁵¹ See 21 U.S.C. § 331(j) (prohibiting the disclosure of trade secrets).

offset the investment losses caused by restrictions on patenting. Meanwhile, a scientist arrived at the same conclusion from a different direction, asserting that patenting rights should be adjusted in response to the generosity of public funders because the social value of patents is inversely correlated with the level of funding. However, the relationship between public funding mechanisms and trade secrecy was not discussed.

IV. DISCUSSION

This is the first study to qualitatively investigate the potential impact of recent changes to the patent eligibility doctrine on patenting and trade secrecy of genetic innovations. These data support other empirical evidence that recent changes to patentable subject matter have constrained the ability to obtain patents on gene-related inventions.⁵² The data also contextualize that evidence through detailed accounts of the psychological and practical effects of recent legal changes on patent practitioners, innovators, and their professional practices. Consistent with other scholars' findings that a patent application's rejection reduces the likelihood that the underlying invention is commercialized,⁵³ the data further suggest that the burden of navigating the new intellectual property landscape may be falling disproportionately on entities that translate scientific discoveries into clinical applications, especially those whose work is not publicly funded. Patent practitioners and legal academics expressed mild to serious concern about the downstream impacts on investment and innovation, with practitioners most strongly ascribing to the view that patents are necessary to incentivize costly development activities, including not only drug development but also (and more controversially) some diagnostics. These data therefore align with other scholarly works describing the industry-specific nature of innovation and arguing for the greater need for robust patent protection in industries where research costs are high, the development process is long, and success is uncertain.⁵⁴ By contrast, all but one of the scientists viewed the recent restrictions on patenting as largely beneficial to science and society, although these opinions focused on *Myriad's* elimination of patents on gene sequences. This divergence in perspectives is consistent with opposing narratives in gene patenting identified in other patent scholarship: the innovator narrative generally embraced by patent practitioners and industry members, which focuses on the need for patents to incentivize research and commercialization, and the science and congestion narratives generally embraced by academic scientists, who worry that patents impede research and are unnecessary in light of public research funding.⁵⁵

The data further indicate that secrecy may have increased in strategic appeal relative to patent protection in some areas of genetic innovation. Although the actual election of secrecy strategies may be limited as a practical matter, our results support concerns that trade secrecy is replacing patent protection on the margins. To date, those concerns have been largely predictive and not explicitly tied to deliberation of appropriation strategies for specific innovations. This study endorses those concerns through the

⁵² See *supra* note 36.

⁵³ Elizabeth Webster & Paul H. Jensen, *Do Patents Matter for Commercialization?*, 54 J. L. ECON. 431, 443–44 (2011) (finding that rejection of a patent application decreases the probability of attempting market launch of the underlying invention by 12%–13% and mass production of the underlying invention by 12%–14%, as compared to inventions on which patents are granted or pending).

⁵⁴ See eg Dan L. Burk & Mark L. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1581–83 (2003).

⁵⁵ Jorge L. Contreras, *Narratives of Gene Patenting* 43 FL. ST. L. REV. 1133, 1152–60, 1169–71 (2016).

systematic collection and analysis of data reflecting the lived experiences and expertise of diverse stakeholders. Again, however, opinions were not homogenous. In general, patent practitioners and legal academics involved in appropriation strategies described an uptick in interest in secrecy, and based on their professional experiences or industry knowledge, considered increased use of trade secrecy to be likely, if not inevitable or already in progress. Scientists, however, tended to view scientific sharing norms as an effective check on this trend. Although scientists focused on secret collections of patient data, that could be an artifact of the significant attention that Myriad's activities have received in the scientific press⁵⁶ and not intended as a limit on their view of the reach of sharing norms.

We express no opinion as to whether the costs of the new landscape described by interviewees outweigh its benefits. Among other things, as noted by some interviewees and many patent scholars, there is a reason to question whether patents facilitate the spread of knowledge as a practical matter.⁵⁷ However, our findings are potentially relevant to policies that have been proposed for the purpose of restoring some of the legal protection that has been lost as a result of changes to the patentable eligibility doctrine. Consistent with the preference of most interviewees, one proposal now receiving serious attention is revision of Section 101 to acknowledge the patent eligibility of certain invention categories, such as physically implemented processes, or to clarify that patent eligibility does not include considerations addressed elsewhere in the Patent Act.⁵⁸ Given interviewees' concern about achieving consensus on statutory language, it is notable that the amendments proposed by two national intellectual property organizations are almost identical⁵⁹ and could suggest that cooperation and agreement are more feasible than many interviewees had supposed.

In addition, legal academics have begun to examine proposals to couple existing or new regulation by the FDA with enhanced exclusivities, possibly conditioned on

⁵⁶ See eg *HIPAA Complaint Alleges Myriad Genetics Withheld Variant Data From Patients*, 170 AM. J. MED. GENET. 2234 (2016); Roger D. Klein, *AMP v. Myriad: The Supreme Court Gives a Win to Personalized Medicine*, 15 J. MOL. DIAGN. 731 (2013); E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENET. MED. S39 (2010).

⁵⁷ See eg W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1043 (2016) (noting that 'the extent to which patents practically aid the spread of knowledge remains a contested empirical question', and '[a]lthough the answer likely varies across areas of scientific and technological inquiry, the majority view is that disclosure is often inadequate').

⁵⁸ Jorge A. Goldstein, Michelle K. Holoubek & Krishan Y. Thakker, *The Time Has Come to Amend 35 U.S.C. § 101*, 44 AIPLA Q. J. 171, 193–95 (2016) (proposing removal of inventiveness analyses from Section 101); Am. Intellectual Property Law Ass'n, *AIPLA Legislative Proposal and Report on Eligible Subject Matter* (May 12, 2017), <https://www.aipla.org/resources2/reports/2017AIPLADirect/Documents/AIPLA%20Report%20on%20101%20Reform-5-19-17-Errata.pdf> (proposing statutory specification that the only exceptions to eligibility are inventions that exist 'in nature independently of and prior to any human activity' or 'can be performed solely in the human mind', and requiring eligibility determinations to be independent of other conditions for patenting); Intellectual Property Owners Ass'n, *Proposed Amendments to Patent Eligible Subject Matter Under 35 U.S.C. § 101* (Feb. 7, 2017), <http://patentdocs.typepad.com/files/proposed-amendments-to-patent-eligible-subject-matter-under-35-u.s.c.-101.pdf> (proposing similar changes to the AIPLA proposal); Robert R. Sachs, *Twenty-Two Ways Congress Can Save Section 101*, BILSKIBLOG (Feb. 12, 2015), <http://www.bilskiblog.com/blog/2015/02/twenty-two-ways-congress-can-save-section-101.html> (considering, *inter alia*, Section 101's amendment to include categorical safe harbors, a narrow definition of judicial exceptions, and expansive definitions of 'machines' and 'processes').

⁵⁹ Dennis Crouch, *AIPLA on Board with Statutory Reform of 101*, PATENTLYO (May 16, 2017), <https://patentlyo.com/patent/2017/05/aipla-statutory-reform.html>.

sharing, and to expand disclosure requirements for publicly funded research.⁶⁰ Although these mechanisms may not reach all of the commercialization scenarios described by interviewees, our data provide a reason to explore how they might impact the use of trade secrecy as an appropriation strategy, assuming the federal government's general deference to proprietary interests can be overcome.⁶¹

Our findings are subject to several limitations. First, as noted above, this study cannot, and does not purport to, measure the extent of use of patent strategies or trade secrecy by genetic innovators. Rather, its purpose is to provide a textually rich description of the experiences and opinions of expert stakeholders regarding changes in interest in patenting vis-a-vis trade secrecy in the field of genetics broadly defined. These data might, in turn, provide a basis for additional empirical studies that focus on specific fields of interest, such as diagnostics.

Second, there may be selection bias in that the opinions of participants may be systematically different from the opinions of those who were contacted but did not participate. Nevertheless, interviewees were selected in part for their diversity of opinions.

Third, there is likely a systematic bias of patent practitioner opinions against any measures that have the effect of narrowing patent protection. Such bias, however, should not impact their reports of experiences discussing patenting and trade secret strategies with clients. In any event, patent practitioners are uniquely positioned to understand the impact of legal changes on their clients' business strategies and so we believed that it was imperative to include their perspectives and predictions, although we recommend caution in their evaluation.

Fourth, the number of scientists who participated in the study was approximately half the number of patent practitioners and legal academics. As a result, the data we obtained from scientists may be less diverse than data from the other interview populations. The pool of scientists satisfying inclusion criteria, however, was uniquely constrained by the requirement of public evidence of strong familiarity with a specific patent doctrine. Because activity in patent jurisprudence is outside the usual scope of scientific efforts, we had difficulty not only recruiting scientists for the study, but also identifying those whom to recruit.

Fifth, the interviews excluded some populations, including technology transfer officers and non-scientist corporate executives, who might have provided additional insight into the subjects probed. A key objective of the study, however, was to identify diverse experiences and opinions within each population selected for interviewing.

⁶⁰ Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 UNIV. CAL. DAVIS L. REV. 1881, 1932–34 (2016); Brenda M. Simon & Ted Sichelman, *Data-Generating Patents*, 111 NW. U. L. REV. 377, 433–34 (2017).

⁶¹ In addition to FDA regulation, see *supra* note 51, this deference also appears in the Health Insurance Portability and Accountability Act (HIPAA) and the 21st Century Cures Act. See Christi J. Guerrini, Amy L. McGuire & Mary A. Majumder, *Myriad Take Two: Can Genomic Databases Remain Secret?*, 356 SCIENCE 586, 587 (2017) (explaining that data access rights under HIPAA do not extend to trade secrets); Mary A. Majumder et al., *Sharing Data Under the 21st Century Cures Act*, GENET. MED. (2017), at 2 (epub ahead of print) (explaining that the 21st Century Cures Act 'seems to affirm that proprietary interests trump data-sharing interests through its recognition that the Director's authority to mandate data sharing remains limited by existing policies intended to protect award recipients' trade secrets, proprietary interests, confidential commercial information, and intellectual property rights').

Limited resources to accomplish this objective required us to narrow the number of interviewee populations.

Sixth, other changes to patent law occurred contemporaneously with the shift in interpretation of the patent eligibility doctrine. Most notably, the America Invents Act created new avenues for challenging issued patents before the Patent Office, and some of them permit challenges on Section 101 grounds.⁶² Although petitions for these kinds of proceedings comprise less than 10% of all post-grant review petitions,⁶³ patents can be invalidated on other grounds,⁶⁴ and the expansion of opportunities to do so may be responsible, wholly or in part, for any rise in interest in trade secrecy.

Finally, the data are a reflection of the legal landscape that existed when each interview was conducted. During and after the interview period, that landscape continued to shift in important ways. First, in May 2016, Congress passed the Defend Trade Secrets Act (DTSA), which for the first time recognizes a federal cause of action for trade secret misappropriation.⁶⁵ The DTSA strengthens the trade secret right by bringing uniformity to it and allowing trade secret holders to strategically bring both state and federal misappropriation claims, thereby increasing the chances of litigation success.⁶⁶ The law was enacted late in the study and so was not probed, but it seems fair to assume that if the DTSA has impacted the patent-trade secret calculus for genetic innovators, it has tipped the scales further in favor of trade secrecy.⁶⁷

Meanwhile, the courts have continued to grapple with application of the new eligibility test. In June 2016, the U.S. Supreme Court declined to hear *Ariosa v Sequenom*, in which a non-invasive method for detecting fetal abnormalities was held to be ineligible subject matter despite having transformed the field.⁶⁸ Many patent practitioner interviewees had hoped that the Court would take the case as an opportunity to clarify the eligibility test in a manner favorable to pro-patent interests. Its refusal to do so was surely met with disappointment.

On the other hand, beginning in May 2016, the federal appellate patent court has rejected Section 101 challenges in a series of precedential decisions.⁶⁹ If the U.S. Supreme

⁶² Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (establishing new post-grant review and covered business method patent review proceedings, both of which permit challenges on Section 101 grounds).

⁶³ U.S. PATENT & TRADEMARK OFFICE, PATENT TRIAL & APPEAL BOARD STATISTICS 10/31/2016 (2017), at 2, https://www.uspto.gov/sites/default/files/documents/aia_statistics_october2016.pdf (reporting that inter partes review proceedings that do not allow challenges on Section 101 grounds comprise 91% of post-grant petitions filed to date).

⁶⁴ 35 U.S.C. §§ 102, 103, 112 (2017) (describing patenting requirements of novelty, non-obviousness, and clear and sufficient description); 35 U.S.C. § 311 (authorizing inter partes review proceedings before the Patent Office for challenging issued patents on grounds of novelty or obviousness).

⁶⁵ Defend Trade Secrets Act of 2016, Pub. L. No. 114-153, 130 Stat. 376 (2016).

⁶⁶ Eric Goldman, *The New 'Defend Trade Secrets Act' is the Biggest IP Development in Years*, FORBES (Apr. 28, 2016), <https://www.forbes.com/sites/ericgoldman/2016/04/28/the-new-defend-trade-secrets-act-is-the-biggest-ip-development-in-years/#666e9b824261>.

⁶⁷ Tony Dutra, *New Trade Secret Law: More to Consider in Patent Trade-Off*, BNA PATENT, TRADEMARK & COPYRIGHT JOURNAL-DAILY ED., (June 3, 2016), <http://www.bna.com/new-trade-secret-n57982073569/> (stating the opinions of intellectual property attorneys that the DTSA's addition of federal court venue will cause industries that rely on patenting to 'look more closely at the trade secret option now').

⁶⁸ *Ariosa, Inc. v. Sequenom, Inc.*, 136 S.Ct. 2511 (2016).

⁶⁹ *Enfish LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016); *McRO, Inc. v. Bandai Namco Games America, Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Rapid Litigation Management, Ltd. v. Cellzdirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

Court continues to demur on patent eligibility questions, this latest development may well mark the beginning of the pendulum's return to more robust patent protection.

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