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# Economic Regulation of Next-Generation Sequencing

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## Introduction

The genetic testing industry is in a period of potentially major structural change driven by several factors. These include weaker patent protections after *Association for Molecular Pathology v. Myriad Genetics* (the “Myriad decision”)<sup>1</sup> and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*;<sup>2</sup> a continuing shift from single-gene tests to genome-scale sequencing; and a set of February 2014 amendments<sup>3</sup> to the Clinical Laboratory Improvement Amendments of 1988<sup>4</sup> (CLIA) regulations<sup>5</sup> and the Health Insurance Portability and Accountability Act<sup>6</sup> (HIPAA) Privacy Rule.<sup>7</sup> This article explores the nature of these changes and why they strain existing regulatory frameworks for protecting patients, research subjects, and other consumers who receive genetic testing.

Oversight of genetic testing has, at least to date, had two major thrusts: (1) privacy and ethical protections and (2) traditional consumer health and safety regulations. Examples of the first are the Genetic Information Nondiscrimination Act<sup>8</sup> and the HIPAA Privacy Rule, which after 2013 amendments expressly protects genetic privacy as well as other medical privacy.<sup>9</sup> Major health and safety regulations include the CLIA regulations and the U.S. Food and Drug Administration’s (FDA) medical device framework that covers genetic tests when FDA deems them to be *in vitro* diagnostic (IVD) devices.<sup>10</sup> Health and safety regulations aim to protect the public from low-quality, poorly substantiated genetic testing that may be unsafe or ineffective. To achieve this aim, however, policymakers need to

grapple with an additional concern: access to genomic data infrastructures.

Humans have just under 23,000 different genes, and every one of them can vary from one person to the next in a multitude of different ways.<sup>11</sup> Accurate, meaningful interpretation of genetic tests requires access to comprehensive data resources that clarify health impacts of the staggering number of possible gene variants that tests may detect. At present, there is no sector-specific legal framework to ensure that test providers will have access to these resources, which are scattered across many separate public and private data repositories. This article explores how data access problems can undermine the safety of people who undergo genetic testing.

Barriers to infrastructure access are a focus of regulatory concern in traditional industries like telecommunications and electric power, where it is understood that access barriers pose threats to consumer safety and well-being. Modern genomic data infrastructures support an array of new services that consumers increasingly rely on and, in the future, will come to expect — services such as predicting and preventing our impending cancers. This article discusses the problem of ensuring appropriate access to these infrastructures.

## Evolving Industry Structure

Several factors suggest that the genetic sequencing industry of the future will encompass three, and possibly more, vertically related markets: test administration, data operations, and genomic interpretation services. For purposes of this discussion, *test administration* is the process of studying a patient’s biospecimen to measure specific analytes, which are the chemicals or other properties that a test is designed to

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detect. In traditional genetic tests, the analytes may include one or more of a person's genes, or gene expression products that allow inferences about the person's genotype.<sup>12</sup> In whole genome sequencing (WGS), the analytes include essentially all of the patient's genomic DNA, whereas whole exome sequencing (WES) focuses on the exons (protein-coding regions) of the

testing techniques produce results that other laboratories would not be able to decipher.

Genetic test results have a significant potential for interoperability across different laboratories. Once a test reveals which gene variants a person carries, other laboratories may be equally able to decipher the meaning of those variants. This statement assumes, of course, that the labs share a consistent data format and that the other labs have access to genomic data resources that clarify the clinical significance of the variants in question. This latter assumption, unfortunately, is not always true. Still, the basic interoperability of genetic test results opens the door for the genetic testing industry to embrace novel industry structures that depart from the vertically integrated structure seen with some other types of diagnostic tests.

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WGS and WES involve a set of distinct but vertically related functions. First, the lab receives a biospecimen and extracts the portions of the individual's genome to be tested. This material is then sequenced and the raw sequencing data are processed using complex informatics filters and algorithms that convert the data into a format that lends itself to

interpretation.<sup>16</sup> The data processing filters the data and identifies a subset of the person's gene variants to receive additional inspection and interpretation by geneticists and other skilled workers.<sup>17</sup> One could debate where, precisely, the line between testing and interpretation should be drawn, but it is clear that the two functions are separable.

patient's genome.<sup>13</sup> Genetic test results reveal whether a person has particular gene variants, which are alterations that cause a gene to differ from its expected configuration. *Data operations* include developing and using data resources and information systems to support genomic interpretation as well as research and public health activities. *Genomic interpretation* is the process of assessing the clinical significance of test results, to clarify how people's gene variants affect their present or future health.

To date, the visibility of these three distinct markets has been somewhat masked. This reflects a legacy of past business practices in the clinical laboratory industry and the structural impact of gene patents. Diagnostic testing traditionally had a fairly high degree of vertical integration, with test administration and interpretation bundled together for many IVD tests. A vertically integrated firm operates in more than one segment of the chain of production and distribution of the goods or services it supplies.<sup>14</sup> Integration can be achieved in various ways, for example, by performing functions internally, through contracts (such as exclusive supply arrangements with outside entities), or by merging with suppliers or downstream processors.<sup>15</sup> A bundled test/interpretation service obviously makes sense if a lab's

Gene patents promoted vertical integration by conferring monopolies that allowed specific laboratories to administer tests for specific genes. This had the effect of giving those laboratories unique access to test results relating to those genes. Those results were a valuable data resource that enabled the laboratories to integrate downstream into data operations. With no competitors in the test administration segment of the business, there was neither a need nor a commercial opportunity to use these resources to support unbundled genomic interpretation services for consumers tested at competing labs. Instead, the labs used these data resources to aid their own genomic interpretation activities. In this way, gene patents fostered an industry structure dominated by vertically integrated incumbents engaged in test administration, data operations, and genomic interpretation for specific genes.

The Supreme Court's decision in the *Myriad* case invalidated some of Myriad's patents on the BRCA1

and BRCA2 genes. Right away, a number of laboratories pursued competitive entry into the business of testing those genes.<sup>18</sup> Myriad is seeking to block this entry based on other patents it holds, but this strategy can only delay competition temporarily. Existing patents will expire and, even though complementary DNA (cDNA) is still patent-eligible, it may not be novel and non-obvious enough to justify future issuance of new cDNA patents.<sup>19</sup> The end of gene patents — whether soon or a bit later — will foster competition in genetic testing.

Two additional factors support the unbundling of test administration and genomic interpretation. The first factor is that WGS and WES produce large amounts of by-product information in addition to their clinically relevant results.<sup>20</sup> WES is said to detect about 10,000 variants in a typical patient,<sup>21</sup> and WGS can generate 3–5 million.<sup>22</sup> Only a small portion of these variants will receive detailed scrutiny, with only a mere handful generating clinically significant findings that are relevant to the health condition that caused sequencing to be ordered. Many of the variants turn out to be variants of unknown significance (VUS) that defy interpretation because their clinical significance is not yet known. In 2013, the American College of Medical Genetics and Genomics (ACMG) published guidelines that identified just 57 gene variants (affecting 56 genes) that have sufficient clinical significance to warrant deliberate interpretation and reporting, even when they are not directly relevant to the condition for which sequencing was ordered.<sup>23</sup> All else — thousands of variants in each patient's genes — is unlikely to be interpreted and reported into the patient's medical record and simply may remain on file at the lab.

A second crucial force for unbundling is a growing acceptance of the proposition that test subjects should have direct access to information about themselves that is held by laboratories. Jeantine Lunshof, George Church, and Barbara Prainsack recently argued that there are ethical reasons to let people access raw (uninterpreted) data derived from specimens they contribute to biorepositories and noted that access to raw data is ethically distinct from the return of results.<sup>24</sup> Recent amendments<sup>25</sup> to the CLIA regulations and HIPAA Privacy Rule grant patients a right to request and receive copies of information held by CLIA-compliant, HIPAA-covered laboratories. A recent legal analysis concluded that these amendments empower patients to obtain most or all of the by-product genetic information produced during WES and WGS — including, potentially, raw sequencing data and information about uninterpreted variants.<sup>26</sup> If so, then these amendments are a game-changing development.

Placing large amounts of uninterpreted genetic information into the hands of consumers could stimulate market demand for unbundled genomic interpretation services as consumers seek to understand the variants that they have.

Some labs already offer unbundled, single-segment services, such as data-only sequencing services that identify a person's gene variants without interpreting them, or services that focus strictly on genomic interpretation.<sup>27</sup> Other labs continue to provide bundled services that span the full range of business functions. Which business model a company prefers depends on regulatory and economic factors and on the company's own skills and assets (including informational assets, as discussed further below). An FDA official recently signaled that the agency does not consider data-only test administration services to be medical devices, as long as the provider avoids making medical claims about the data.<sup>28</sup> This may cause some labs to favor a data-only business model in the hope that this model avoids falling under FDA's jurisdiction. Companies experienced in working with federal regulators may prefer a more integrated business model that carries greater regulatory compliance obligations in exchange for greater revenue potential.

In the genetic testing industry of the future, entities that provide unbundled, single-segment services will compete alongside incumbents that are vertically integrated through all layers of the business. Novel industry structures, in turn, will raise novel regulatory concerns.

### The Challenge of Genomic Interpretation

Interpreting genetic tests requires access to informational resources that relate specific gene variants to particular health conditions and clinical outcomes observed in earlier test subjects who had those same gene variants.<sup>29</sup> A particular gene has many conceivable variants, some known from past observations to be harmless while others have well-understood associations with bad health impacts such as susceptibility to a particular disease. If the test subject has one of these well-understood variants, interpreting a genetic test is fairly straightforward, but interpretation is more difficult when testing reveals a VUS.<sup>30</sup>

Figuring out the clinical significance of new gene variants requires access to genetic and clinical information for large numbers of patients — sometimes, for hundreds of thousands to millions of people.<sup>31</sup> Labs that conduct a high volume of testing may encounter many cases of a particular VUS in the course of doing business. Through data operations that correlate the VUS with clinical data for those same patients, such labs may fairly quickly be able to draw statistically sig-

nificant inferences about how the VUS affects health. At that point, the VUS ceases to have “unknown significance” because its clinical significance is now understood — at least by that particular laboratory. Myriad Genetics became a high-volume provider of tests for BRCA1 and BRCA2 because of its patents related to those genes. Myriad claims to have reduced its rate of VUS for those genes to below 3%,<sup>32</sup> whereas most labs testing those same genes in the European Union report a 20% VUS rate.<sup>33</sup>

In the U.S., there is no legal obligation for labs that discover the significance of VUS to share this information, and some laboratories keep these discoveries close to the chest as trade secrets.<sup>34</sup> Even if a lab publishes its discovery that a specific variant has a particular clinical significance, such discoveries are not scientifically verifiable without access to the underlying data used in reaching that conclusion. A variety of factors — such as commercial incentives and privacy laws — disfavor data sharing although, just for the record, the HIPAA Privacy Rule contains workable pathways to support data sharing when labs wish to do so.<sup>35</sup> The problem often is that labs do not wish to do so.

Various commentators have proposed ways to force the sharing of data that clarify the significance of VUS: for example, requiring free access to supporting data as a condition for publishing results in scientific journals,<sup>36</sup> linking reimbursement of clinical genetic testing to data disclosures,<sup>37</sup> or requiring data disclosure as a condition of CLIA laboratory certification<sup>38</sup> or of FDA clearance and approval of genetic tests.<sup>39</sup> Such proposals, unfortunately, have a potential to backfire if they reduce the incentives to develop new genomic data infrastructures at a time when much more investment is still needed to create data infrastructures for the future.<sup>40</sup> Compulsory access schemes have worked well in mature industries like telecommunications and electric power where crucial infrastructures already existed and the main concern was how to optimize utilization of those infrastructures. Compulsory access schemes may not work so well in industries where infrastructure still needs to be built, because it can damage the incentives to invest in new infrastructure.<sup>41</sup>

Because information is a critical input for genomic interpretation, firms that lack data access may be blocked from offering bundled test/interpretation or stand-alone interpretation services. If they do enter these segments of the business, their services may be ill-informed and dangerous for consumers. There have been various public and private efforts to support the creation of publicly accessible data commons.<sup>42</sup> The available data commons, however, are incomplete

because they lack some of the data related to VUS that reside in proprietary information systems.<sup>43</sup>

### Access Affects Safety

Next-generation sequencing broadens the debate about appropriate oversight of genetic testing. It may force scholars to venture beyond familiar privacy and health and safety issues to address new problems with industry structure and economic regulation. The crucial point to understand is that the industry’s structural and economic problems are not cleanly separable from concerns about test quality, effectiveness, and patient safety.

Data access problems can undermine the quality of test interpretation consumers receive from data-poor labs that offer bundled test/interpretation services. The fact that a laboratory is CLIA-certified does nothing to ensure that its tests will be interpreted using state-of-the-art information about VUS. A lab can satisfy CLIA’s requirements for test administration yet still offer data-impoorished test interpretation services. Similarly, FDA requires data to support claims that a tested gene is related to a specific clinical condition, but a test can receive FDA clearance or approval for clinical use based on evidence that *some* variants of the gene have a well-understood clinical significance. FDA does not and indeed cannot ensure that claims made in the clinical setting are based on the best available information for all possible variants of the gene. The full range of gene variants may not even be discovered until after a test moves into wide clinical use — that is, after FDA clears or approves it.

Even when a test is FDA-cleared or approved and is administered by a CLIA-certified lab, the test still may be unsafe or ineffective for patients who have variants that, though known to some participants in the industry, are unknown to the lab that is interpreting that patient’s test. In this way, the economic issue of data access raises very real health and safety concerns. There presently is no regulatory framework that addresses problems with access to, or the quality of, data resources used in genomic interpretation. Data-poor firms have no regulator to which they can turn for help with access problems. If such firms hold themselves out as offering genomic interpretation services for which they lack the requisite data access, then consumers have no regulator to protect them from the stream of dubious interpretations they may receive. There is, of course, a remote possibility of prevailing in a negligent misrepresentation or deceit tort lawsuit against test providers that base genomic interpretation on inadequate data resources. Those suits, unfortunately, arise only after the consumer already has been harmed. Prospective protection is much to

be preferred. The genetic testing industry has a void where an economic regulatory framework needs to be.

There are many examples of industries that harbor a mix of integrated and single-segment companies. The telecommunications industry prior to AT&T's breakup saw independent long-distance companies such as MCI competing alongside the fully-integrated AT&T.<sup>44</sup> The natural gas industry of the 1980s endured an intense struggle as independent sellers of the natural gas commodity sought access to high-pressure pipelines operated by integrated utilities that offered bundled sales-and-transmission services.<sup>45</sup> Passage of the Public Utility Regulatory Policies Act

facilitates competitive entry into some segments of an industry that is dominated, to a significant degree, by vertically integrated incumbents that in the past enjoyed lawful monopolies over the testing of specific genes. Such transitions are rarely smooth and uneventful.

One obvious concern is whether the available single-segment offerings will complement each other and interface effectively, so that customers can piece together the complete package of services they actually need. Suppose, for example, that Mary purchases data-only genome sequencing services from *LabA* and the results suggest a rare variant in Mary's *Gene*

The *Myriad* decision thrust the genetic testing industry into a period of transition and structural change somewhat resembling what the power industry went through after PURPA. The Court's decision facilitates competitive entry into some segments of an industry that is dominated, to a significant degree, by vertically integrated incumbents that in the past enjoyed lawful monopolies over the testing of specific genes. Such transitions are rarely smooth and uneventful.

of 1978 (PURPA)<sup>46</sup> fostered growth of independent power generating companies that competed alongside traditional, integrated electric utilities that sold generation bundled with high-voltage power transmission services.<sup>47</sup>

Industries with a mix of single-segment and integrated companies raise concerns that often create a need for economic regulation. The existence of independent power generators after PURPA created a need for nondiscriminatory access to the utilities' transmission assets, lest the utilities use their control over transmission to confer unfair advantages on their own generating facilities.<sup>48</sup> The Energy Policy Act of 1992<sup>49</sup> gave the Federal Energy Regulatory Commission (FERC) authority to order utilities to "wheel" (that is, to transmit) power for third parties — including for independent generators that compete with utilities in the power-generation segment of the business. The FERC thereafter promulgated its epochal Orders 888 and 889 that reshaped the power industry by unbundling wholesale electricity sales from transmission and by requiring nondiscriminatory access to transmission services.<sup>50</sup>

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*Y*, but there is no service provider offering stand-alone services to interpret the clinical significance of *Gene Y* variants. An industry structure is said to have modularity when complementary products and services are able to "interoperate through public, non-discriminatory, and well-understood interfaces."<sup>51</sup> In Mary's example, complementarity and modularity have failed: she has purchased a data-only service but cannot purchase complementary interpretation services on a stand-alone basis. Mary ultimately may be forced to undergo retesting/resequencing at a fully integrated lab (*LabB*) that provides a bundled service that includes sequencing and interpretation of variations in *Gene Y*.

A possible solution would be to require integrated service providers like *LabB* to offer unbundled interpretation services, so that patients like Mary can avoid duplicative resequencing. But is it appropriate to force *LabB* to alter its business model and provide stand-alone services, when the problem arguably lies with *LabA* for selling Mary a data-only service for which needed complementary services were not actually available? *LabB* may have legitimate concerns about the analytical validity of *LabA's* findings and may be worried that *LabB* could face tort liability for advising a patient on the basis of a dubious test result. When is it appropriate, and when is it problematic, for an inte-

grated service provider like *LabB* to refuse to deal with people who wish to purchase stand-alone, segmented services from it? The genetic testing industry is facing tough questions like these as it restructures.

Unregulated market forces sometimes resolve such problems over time, for example, if entry by new service providers fills gaps in available services, or if customers learn to spurn services that take their money without meeting their needs. Various private-sector and government-led solutions also may be helpful, such as industry-developed interface standards that make it easier for consumers to link modular services into useful packages; advertising (or mandatory disclosure requirements) to warn customers about potential difficulties finding complementary services; or more forceful policies that set terms and conditions on which service providers *must* interact with each other to ensure adequate levels of service to consumers. Note that all of these solutions are in the nature of economic regulation: the question is not whether individual products and services are safe and effective, but how to order commercial relationships within the industry.

None of the sector-specific agencies that oversees genetic testing presently has authority to address the industry's emerging economic regulatory issues. In particular, none has the power to compel access to privately-controlled data resources. In contrast, the FERC has authority under the Natural Gas Act to order nondiscriminatory access to high-pressure natural gas transmission pipelines as a remedy for undue discrimination by integrated gas utilities,<sup>52</sup> and the FERC has analogous authority under sections 205 and 206 of the Federal Power Act to order integrated power utilities to allow nondiscriminatory, unbundled access to their electric power transmission facilities.<sup>53</sup> The Federal Communications Commission (FCC) was given authority under the Telecommunications Act of 1996<sup>54</sup> to require local exchange carriers that offer long-distance telephone service to share their local networks on an unbundled basis with competing long-distance providers.<sup>55</sup>

There is no equivalent access authority in the regulatory frameworks for genetic and other IVD testing. The HIPAA Privacy Rule contains only one provision requiring access to data held by HIPAA-covered entities, and that provision merely requires health care entities to grant *patients* a right of access to their own health information.<sup>56</sup> After the recent CLIA-HIPAA amendments, patients now have access to information about themselves that is held by CLIA-compliant, HIPAA-covered labs.<sup>57</sup> However, the present framework for regulating the genetic testing industry does not address the need for *competing providers of test-*

*related services* to have access to data resources to support state-of-the-art interpretation of genetic tests.

### Incentives Not to Share

Laboratories with high-quality information resources have strong commercial incentives not to share them. In a 2013 study, McKinsey & Company advised IVD diagnostics companies to:

Use data as a barrier for protection against competitors: The increasing complexity of data in diagnostics provides an edge to [diagnostics] players who have access to data, and the ability to utilize the data to better inform clinical decisions. This provides an edge to first movers and the advantage can build over time — similar to Google in the technology industry. For instance, if a lab that offers sequencing services is able to combine the genomic information with patient medical records, it can develop a treatment decision algorithm which will get stronger and smarter over time, providing a distinct advantage over new entrants.<sup>58</sup>

Recent amendments<sup>59</sup> to the HIPAA Privacy Rule further erode incentives to share. The 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act<sup>60</sup> required the HIPAA Privacy Rule to restrict sales of health data. The HITECH Act prevents HIPAA-covered laboratories from charging a price for protected health information that they hold,<sup>61</sup> but it does allow them to transfer the data, pursuant to a HIPAA waiver, for use in other entities' research. When making these transfers, a laboratory can charge the recipient a reasonable, cost-based fee for the services it provides to prepare and transmit the data.<sup>62</sup> HIPAA waivers are a mechanism that allows data to be supplied for research without first obtaining authorization from the individuals to whom the data pertain.<sup>63</sup> Although somewhat controversial, HIPAA waivers are a major pathway of access to extremely large samples of data like the ones used to study the clinical significance of novel gene variants.<sup>64</sup> Thus, HIPAA's cost-based fee for data preparation and transmittal sets the commercial terms for much of the data sharing that is needed to support genomic interpretation in the future.

The big question is whether this cost-based fee for data preparation and transmittal creates adequate incentives for labs that hold useful data resources to share them with competing labs. HIPAA's cost-based fee was, after all, developed as part of a privacy regulation that may have had the goal of blocking data sharing rather than promoting it. Harnessing pricing as a

tool of privacy protection was a questionable venture from the outset, resting as it does on unverified conjectures — bordering on superstitions — about how the price of data influences individual privacy.<sup>65</sup> The HIPAA Privacy Rule exemplifies the category of laws that Stacey Dogan and Mark Lemley have described as “regulatory systems that are either deliberately anti-competitive or, more likely, simply indifferent to their competitive effects.”<sup>66</sup> The same cannot be said of the HITECH Act, which authorized HIPAA’s data pricing structure. HITECH aspires to promote development and meaningful clinical use of health data infrastructure, suggesting that its framers recognized that data sharing has socially beneficial aspects.

HITECH’s chosen cost-based fee structure echoes the cost-of-service rates historically used in many different infrastructure industries such as railroads,<sup>67</sup> telecommunications,<sup>68</sup> electricity,<sup>69</sup> and natural gas pipelines.<sup>70</sup> Genetic data resources and information systems are, after all, infrastructure: they are “assets that are vital inputs to the production of wealth at later stages of production” and, when used, generate “significant positive externalities (‘spillovers’).”<sup>71</sup> In this case, the spillovers include scientific and biomedical discoveries and benefits to individual and public health. Cost-based fees for infrastructure services, when properly designed, have a long history of stimulating investments in infrastructure and fostering adequate availability of beneficial infrastructure services.

A common (and misplaced) concern about HIPAA’s cost-based fee is that the real economic value of genetic data lies in the data themselves: how can the fee promote data-sharing, when HIPAA does not even let data-holders charge a price for the *data* and only lets them charge for data preparation and transmittal *services*? This concern reflects a belief that raw health data, by themselves, are valuable resources. Generally speaking, however, raw health data only become useful when combined with skilled labor and infrastructure resources that transform the data into large samples of longitudinal records that can support biomedical research and discovery.<sup>72</sup> Moreover, this concern overlooks the conceptual equivalence between an asset (data) and the capital invested to create that asset.

Suppose, for example, that a lab invests capital to develop genome sequencing and clinical data for 100,000 people. Capital investments of this sort can be tracked and reflected in a cost-based fee, presumably as part of the capital costs of data preparation. It is true that if labs simply hoard raw data that falls into their laps for free as a by-product of providing paid testing services, they will have zero capital investments to recover. However, labs with scientifically valuable datasets typically have invested consid-

erable sums in information systems to organize the data, in research that correlates the genetic findings with clinical observations, and in other efforts (such as extending their datasets by offering free testing to close relatives of patients who display interesting gene variants).<sup>73</sup> These investments add value to the data received as a by-product of their commercial testing activities, and would be recoverable as part of a cost-based fee. It is a philosophical distinction whether this is characterized as a charge for the data or a charge to recover capital invested to prepare the data. The commercial reality is that money is money, regardless of what it is *for*.

Congress thus had a reasonable basis to believe that data sharing might flourish under a regulated, cost-based fee structure such as the one the HITECH Act imposed. Where things went wrong is that HHS implemented the fee structure in a way that denies data infrastructure investors any return on their invested capital — an approach that may well violate the U.S. Constitution, an issue destined for eventual litigation.<sup>74</sup> There obviously is little incentive to share data if doing so deploys assets in a way that produces no return. An additional problem is that *Mayo Collaborative Services v. Prometheus Laboratories*<sup>75</sup> prevents laboratories from seeking method patents to protect discoveries of the clinical significance of a VUS.

This situation gives vertically integrated laboratories strong incentives to hold their data and discoveries as trade secrets and use them to enhance earnings in the test-administration segment of its business, which is not subject to regulated, cost-based pricing. Laboratories do not have unfettered freedom to set the price of their bundled test/interpretation services. This was made clear recently when the Centers for Medicare and Medicaid Services proposed, but then partly reversed, a large reduction in the price at which Medicare reimburses Myriad Genetics’ BRCA testing services.<sup>76</sup> Although laboratories cannot control the price of their bundled test/interpretation services, the price is still market-oriented in the sense that providers that offer a superior service can negotiate for a price that reflects the added value of that service, as opposed to being limited to pricing their services on a cost-plus basis.

In lieu of sharing its data resources, a lab that holds large stores of data also has the option of harnessing them to offer stand-alone interpretation services to help patients understand the clinical significance of gene variants detected by tests run at competing labs. A nuance in the Privacy Rule would allow the lab to offer stand-alone genomic interpretation services and price them at negotiated, market rates.<sup>77</sup> These stand-alone interpretation services would not be subject to

HIPAA’s cost-based fee, because the Privacy Rule permits individuals’ health data to be used for treatment purposes without having to obtain individual authorizations or a HIPAA waiver. The Office for Civil Rights, which administers the Privacy Rule, interprets treatment purposes as including the treatment of patients other than the ones from whom the data were gathered.<sup>78</sup> Thus, a lab could use data it gathered from its past patients to render test-interpretation services to future patients and — because this is treatment rather than a research use of data that requires a HIPAA waiver — HIPAA’s cost-based fee would not apply.

In contrast, a lab seemingly would need a waiver in order to transfer its data to competing labs or to a central data commons. A bulk data transfer of this sort supports a variety of activities that produce generalizable knowledge about how to interpret gene variants. Such uses seem better characterized as “research”<sup>79</sup> than as treatment of individual patients. A bulk data transfer done pursuant to a HIPAA waiver seemingly would fall under HIPAA’s cost-based fee. Table 1 summarizes the commercial alternatives just described. Under these conditions, labs that hold dominant positions in data supply may be unwilling to share.

**Abuse of Dominant Data Holdings**

State-of-the-art genomic interpretation, in this discussion, means an interpretation based on the best information currently known not just to the entity that is interpreting the test but to anybody in the industry. None of the regulators that oversees genetic testing has the power to require open, nondiscriminatory access to stores of data that are needed to ensure state-of-the art interpretation of genetic tests. When an industry lacks sector-specific economic regulations, this fact does not

leave matters entirely unregulated. Instead, economic regulation is left to generally applicable laws, such as section 1 of the Sherman Act,<sup>80</sup> which prohibits anti-competitive activities by two or more firms acting in concert;<sup>81</sup> section 2 of the Sherman Act, which prohibits actions by a single firm to monopolize or attempt to monopolize a market;<sup>82</sup> the Clayton Act<sup>83</sup> (as amended by the Robinson-Patman Act<sup>84</sup>), which prohibits various activities such as acquisitions that substantially reduce competition<sup>85</sup> or the use of anticompetitive tying and exclusive dealing arrangements involving goods;<sup>86</sup> section 5 of the Federal Trade Commission (FTC) Act,<sup>87</sup> which prohibits unfair competition;<sup>88</sup> and state-level antitrust and consumer-protection laws. These laws are enforced by the Antitrust Division of the U.S. Department of Justice and state attorneys general, by the FTC, and through suits brought by victims of alleged antitrust violations.<sup>89</sup>

As a general matter, antitrust law regards vertical integration as pro-competitive and potentially conducive to economic efficiency.<sup>90</sup> The mere possession of monopoly power — that is, having a substantial degree of market power<sup>91</sup> — is not intrinsically problematic if it is “a consequence of a superior product, business acumen, or historic accident.”<sup>92</sup> To establish monopolization or attempted monopolization under section 2 of the Sherman Act, the plaintiff must show monopoly power and also must show “willful acquisition or maintenance”<sup>93</sup> of that power. It may simply be a sad historical accident that the U.S. Patent and Trademark Office pursued a policy of issuing now-repudiated gene patents that allowed some commercial laboratories to capture monopoly holdings of data pertinent to their then-patented genes. The resulting data monopolies, lawful at the time they were acquired, are not intrin-

Table 1

**Major Business Models for a Vertically Integrated Laboratory That Possesses Large Stores of Data and Discoveries Useful in Interpreting Genetic Tests**

| Business Model  | Economic Impact   |
|---|---|
| Provide bundled test/interpretation services only. Hold data and discoveries about the clinical significance of gene variants as trade secrets.                   | The lab can use its data resources to offer a high-quality bundled service and seek to recover the value of its data and discoveries through the price of its bundled test/interpretation services.                     |
| Provide bundled test/interpretation services. Also offer stand-alone genomic interpretation services to customers whose genomes were sequenced at competing labs. | Neither service is subject to HIPAA’s cost-based fee structure. The lab can seek negotiated, market rates for both services.  |
| Provide bundled test/interpretation services. Share data resources to help competing test providers interpret their own tests.                                    | Data sharing may erode competitive advantage of the lab’s own bundled test/interpretation service. Data preparation and transmittal services the lab provides while sharing data are subject to HIPAA’s cost-based fee. |

sically problematic. The plaintiff would also need to show that the lab is using its data holdings to engage in some sort of exclusionary (predatory) conduct.<sup>94</sup>

Refusals to deal with competitors, customers, or other industry participants are said to be the most frequently alleged type of predatory conduct in health care antitrust law.<sup>95</sup> Yet, “[a]s a general rule, businesses are free to choose the parties with whom they will deal, as well as the prices, terms, and conditions of that dealing.”<sup>96</sup> Suppose a vertically integrated laboratory holds a monopoly position in supply of data needed to interpret variants of *Gene X*, but faces competition in adjacent markets for genomic interpretation and/or administration of tests related to *Gene X*. There are various ways the lab might exploit its power over data supply to harm competitors in the adjacent markets. As the Supreme Court has stated, “[T]he means of illicit exclusion, like the means of legitimate competition, are myriad.”<sup>97</sup> Examples could include:

*Outright refusal to share data.* The lab could simply refuse to grant access to data that competing interpretation services need in order to offer state-of-the-art interpretation services for variants of *Gene X*. If the data actually are indispensable and if there is no other way to acquire or recreate the data, this could drive the competitors out of business. Whether this is predatory conduct, as opposed to legitimate business competition, is a fraught question discussed further below.

*Inappropriate data sharing behavior.* Even if the lab does share its data, there are various ways the lab could engage in anticompetitive conduct. For example, the lab could supply data to competitors under HIPAA waivers but manipulate its internal allocation of capital costs, so that costs of the lab’s information systems are disproportionately allocated to the data preparation services it provides to competitors, rather than to its own in-house genomic interpretation and testing services. Doing so would artificially raise the cost-based fees competitors must pay for data preparation and transmittal services pursuant to HIPAA’s cost-based fee structure, placing them at a competitive disadvantage. At the same time, the lab would be able to price its own testing and interpretation services attractively and still show a profit, because a portion of its true costs of providing those services has been shifted onto its data supply business. Cost allocation is rife with possibilities for anticompetitive conduct in situations where an integrated company operates assets (such as computer systems) that support multiple services (data operations, genomic interpretation, and genetic testing).<sup>98</sup> The Supreme Court noted in a 1945 natural gas pipeline case that when “several classes of services have a common use of the same property, difficulties of separation are obvi-

ous. Allocation of costs is not a matter for the slide-rule. It involves judgment on a myriad of facts. It has no claim to an exact science.”<sup>99</sup> This fact can make it hard for regulators to detect and control abusive cost allocation when it is occurring.

HIPAA’s cost-based pricing structure adds to this problem. By denying a profit margin on capital invested in data systems, it prevents labs that enjoy a monopoly position in data supply from charging a price that reflects the data’s real value.<sup>100</sup> This creates incentives for vertically integrated labs to incur costs in the price-regulated portion of their business (data supply), and reap profits in adjacent markets that are not price-regulated (testing and interpretation). A classic example of this behavior in the telecommunications industry gave rise to the “Bell Doctrine” (also called “Baxter’s Law”) that played a role in the breakup of AT&T.<sup>101</sup> The pre-breakup Bell System’s core monopoly over price-regulated local telephone services allegedly let it leverage its way to market power in related markets such as rental of telephone instruments, where it could charge inflated prices.<sup>102</sup> Moreover, the cost-based pricing scheme the FCC applied at that time encouraged games with cost allocation, because there was a benefit in shifting costs away from unregulated services and into the regulated services.<sup>103</sup> Skepticism that regulators could effectively police the various forms of predatory conduct by the integrated Bell System became a central rationale for requiring AT&T to divest its local exchange carriers in the early 1980s.<sup>104</sup>

*Inappropriate conduct with unbundled interpretation services.* There are many ways an integrated laboratory might offer a stand-alone genomic interpretation service, yet engage in discriminatory conduct that has the effect of conferring unfair advantages on its own test administration activities. For example, the lab could refuse to share information about the data formats competing testing services must use, if they want their test results to interface with its stand-alone interpretation service. By making it hard for competing testing services to interface with the lab’s unbundled interpretation service, the lab may be able to extend or maintain its “empire”<sup>105</sup> in the market for test administration.

As these examples suggest, there is a potential for predatory conduct when an integrated firm enjoys significant market power in one of the vertically related markets in its industry. The Supreme Court’s decision in the *Myriad* case hastens the end of gene patenting but cannot restore the industry structure that might have evolved, but for the distortions wrought by now-invalidated gene patents. Had the market for test administration been competitive from the outset,

it would have been difficult for any single laboratory to gain a sufficient market share to capture dominant control over data supplies relevant to specific genes. The various competitors testing a particular gene would have had at least some incentive to cooperate to assemble the large-scale data resources all of them needed, to be able to draw statistically significant inferences about the clinical significance of the gene variants they were detecting. This might have fostered collaborative core data infrastructures, not controlled by any single laboratory, and promoted organizational separation of data operations from testing and interpretation services. The industry structure might

address potential problems with its overall structure. To the extent that gene patenting has left the industry with lasting structural problems, antitrust law may be able to fill this gap, but only after proof that antitrust violations actually are occurring. Such proof may be possible if specific anticompetitive behaviors are detected, such as the cost misallocation or nontransparent interface standards described in the examples above. Pursuing specific violations of this sort, however, can only offer piecemeal solutions that miss the industry's more general problem, rooted in the reluctance of laboratories to share proprietary data to support state-of-the-art interpretation of the clinical sig-

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have evolved in directions that cannot now be recaptured simply by invalidating patents on isolated gene sequences.

The Supreme Court's *Myriad* decision leaves important questions that seem destined for contentious debate in coming years. A major one is whether data operations need greater structural separation from the adjacent activities of testing and genomic interpretation. Such a separation would not necessarily require actual divestiture of data assets (along the lines of the AT&T breakup). It could instead be a functional separation akin to the restructuring of the electric power and natural gas pipeline industries in the late 1980s and 1990s. There, integrated utilities were allowed to continue to own their transmission assets but were required to offer unbundled access to those assets on nondiscriminatory terms.

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#### **Refusal to Share Access to Data**

A commercial laboratory — even if it has monopoly control over data supplies — has no general duty “to cut its own throat”<sup>106</sup> by helping its business rivals compete against it. The Supreme Court respects the right of firms to refuse to deal with their competitors, but this “does not mean that the right is unqualified.”<sup>107</sup> The Court is “very cautious in recognizing such exceptions” because of concerns about the “uncertain virtue of forced sharing,” concerns about “false positives” that might punish firms that in fact have legitimate reasons for refusing to deal, and concerns that enforced sharing “requires antitrust courts to act as

central planners, identifying the proper price, quantity, and other terms of dealing — a role for which they are ill suited.<sup>108</sup>

Some past cases have found liability for refusals to deal. The 1973 case, *Otter Tail Power Co. v. United States*,<sup>109</sup> involved an integrated utility company that was using its strategic dominance in power transmission to harm competitors in the retail distribution segment of its business.<sup>110</sup> A federal district court fashioned an antitrust remedy that enjoined the company from refusing to provide unbundled transmission services to competitors.<sup>111</sup> On appeal, the Supreme Court noted that the use of monopoly power to destroy threatened competition violates section 2 of the Sherman Act<sup>112</sup> and affirmed the district court's decision.<sup>113</sup> A 1985 case, *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*,<sup>114</sup> found liability under section 2 when a company refused to deal with a competitor after they had had a long course of prior business dealings.

A 2004 case takes a very narrow view, however. In *Verizon Communications v. Law Offices of Curtis V. Trinko*,<sup>115</sup> the Court interpreted *Aspen Skiing* as providing only a “limited exception”<sup>116</sup> to the general rule that companies have no duty to cooperate with competitors. *Trinko* treats refusals to deal as potentially problematic under section 2 only if a defendant has engaged in a voluntary course of dealing with its rivals and then stops doing so.<sup>117</sup>

A clinical laboratory's refusal to share its VUS data would almost never fit in this exception. Incumbent providers of genetic testing services often have no prior history of supplying VUS data to their rivals. Before the *Myriad* decision, the vertically integrated incumbents that held rights to test particular genes usually had no competitors in the business of administering and interpreting tests for those genes. Thus, there typically were not any business rivals that needed access to VUS data as an input. Moreover, the HIPAA Privacy Rule only recently was amended to clarify that labs can charge fees for data preparation and transmittal. Because no market for VUS data previously existed, there cannot have been prior dealings in that market. *Trinko's* narrow reading of *Aspen Skiing* recognizes a limited exception that makes sense only in markets where competition has existed for some time — long enough for rivalry to have emerged and for rivals to have dealt with one another. It sheds little light on the exceptions that may be appropriate as competition emerges for the first time after a major change in an industry's ground rules. Nevertheless, *Trinko* expresses the current state of the law.

*Trinko* involved a claim that Verizon Communications, Inc., the incumbent local exchange carrier (LEC) serving New York, failed to provide nondis-

criminatory access to unbundled services that rival telephone service providers needed in order to serve their customers.<sup>118</sup> This behavior allegedly was “part of an anticompetitive scheme to discourage customers from becoming or remaining customers of competitive LECs, thus impeding the competitive LECs' ability to enter and compete in the market for local telephone service.”<sup>119</sup> The conflict in *Trinko* arose after Congress had passed legislation that sought to disrupt LECs' monopoly power and encourage entry by competitors. The Telecommunications Act of 1996<sup>120</sup> imposed various duties on incumbent LECs to facilitate entry by competitors and established a framework of regulatory monitoring and enforcement.<sup>121</sup> Verizon allegedly was not living up to obligations it undertook pursuant to that statute.

The Court held that Verizon's refusal to deal did not fit into the limited *Aspen Skiing* exception. The complaint did “not allege that Verizon voluntarily engaged in a course of dealing with its rivals, or ever would have done so absent statutory compulsion” and “therefore, the defendant's prior conduct sheds no light upon the motivation of its refusal to deal” or whether there was “anticompetitive malice.”<sup>122</sup> This first quoted passage hints that plaintiffs may be able to satisfy *Aspen Skiing's* exception in either of two ways: (1) by alleging that the defendant actually engaged in voluntary dealings with rivals in the past, or (2) by arguing that it “would have done so” had circumstances been different than they were. In *Trinko*, this second clause seems to suggest that a plaintiff could have established anticompetitive malice by proving Verizon had sound economic incentives to deal with its rivals, even if the Telecommunications Act of 1996 had not required Verizon to do so.

Justice Scalia, who wrote for the Court in *Trinko*, endorses the surplusage canon of legal textual interpretation — the view that “every word and every provision is to be given effect.”<sup>123</sup> He presumably would not have inserted the clause, “or ever would have done so absent statutory compulsion,” unless the Court intended to grant plaintiffs a second way to establish anticompetitive malice under *Aspen Skiing*. Turning to the problem of genomic data sharing, would the Court be receptive to arguments that rational, self-interested laboratories have sound economic reasons to share their VUS data, such that their failure to do so supports an inference of anticompetitive malice? There is no way to predict.

An argument could be made that genomic data resources lose value when they are fragmented among multiple data holders that refuse to share.<sup>124</sup> The challenge, in genomic interpretation, is to draw statistically significant conclusions about the impact a particular

gene variant has on health. Genomic data resources do not merely exhibit network effects; they exhibit profoundly nonlinear network effects: a genetic dataset that includes twice as much data may be far more than twice as useful, for purposes of interpreting the clinical significance of specific gene variants.<sup>125</sup> Genomic data resources are conceptually similar to common-pool resources in natural resource law and to the natural monopolies of public utility law: competitive operations can be inefficient and create waste.<sup>126</sup> Incumbent laboratories that refuse to embrace the give-and-take of data sharing arguably diminish the quality of their own future test interpretation services, irrationally inflicting economic injuries upon themselves. Yet this argument looks hard to win. Data sharing confronts labs with a classic prisoner's dilemma, pitting the long-term economic advantages of data sharing against the immediate commercial gains of refusing to deal.

*Trinko* makes another point that seems unhelpful to the cause of genomic data access: the Court indicated it will not infer anticompetitive intent from a company's refusal to supply services at the cost-based rates available under the Telecommunications Act of 1996.<sup>127</sup> Presumably, the Court would be even more reluctant to infer bad intent from a lab's refusal to supply data under HIPAA's confiscatory cost-based fee structure that denies any return on invested capital. Laboratories do, of course, have the alternative of supplying test interpretation services (as opposed to supplying data) at non-regulated prices. Antitrust law, however, hesitates to force companies to enter whole new lines of business. Supplying stand-alone interpretation services does not merely require data; it also requires commitment of skilled laboratory personnel and potentially could interfere with a lab's ability to serve its own customers. In *Otter Tail*, the Court stressed that antitrust principles would not have required the defendant to supply unbundled transmission services if doing threatened its ability to serve its own customers.<sup>128</sup>

Other dicta in *Trinko* may help distinguish its facts from the situation with VUS data sharing. The Court noted that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."<sup>129</sup> An especially important issue is whether an industry already has a regulatory framework in place to deter anticompetitive harm.<sup>130</sup> Expanding the contours of section 2 liability may not be justified when, as in *Trinko*, sector-specific laws already provide a framework for addressing access issues. "Where, by contrast, there is nothing built into the regulatory scheme which performs the antitrust function, the benefits of antitrust are worth its sometimes considerable disadvantages."<sup>131</sup> This dictum per-

fectly describes the present situation in genetic testing. Although heavily regulated, there is nothing in its regulatory scheme that performs the antitrust function. The case for antitrust oversight by courts is as strong as it seemingly can be. How strong that actually is after *Trinko* is a different question.

### The Essential Facilities Analogy

The essential facilities doctrine offers a useful conceptual framework for thinking about the problem of VUS data hoarding. This doctrine is really just a special case of refusals to deal. It treats a denial of access to an essential facility as conduct that triggers concerns under antitrust law. Remedies can include requiring the facility owner to allow nondiscriminatory access to the essential facility. This does not imply that access would be free, as researchers and commentators sometimes seem to desire with respect to VUS data. It merely means that access would have to be provided at a reasonable price.<sup>132</sup>

The Seventh Circuit's opinion in *MCI Communications Corp. v AT&T*<sup>133</sup> is often cited for its list of elements the plaintiff must prove to establish an antitrust violation under the essential facilities doctrine, although other courts sometimes embellish or refine the elements.<sup>134</sup> The nub of an essential facilities claim, for purposes of this discussion, is that a monopolist controls a facility that is essential in the sense that the plaintiff cannot reasonably or practically duplicate it; the plaintiff needs access to that facility in order to compete with the monopolist in a market to which the facility supplies an input; the monopolist has denied access to the facility in circumstances where it would be feasible for the monopolist to allow access; and this denial results in monopolization or an attempt to monopolize the market where the defendant and plaintiff compete against each other.<sup>135</sup> This aptly describes the situation in the genetic testing industry after the *Myriad* decision.

The essential facilities doctrine enjoys continued vitality in European antitrust law,<sup>136</sup> but it has a mixed reputation among American law scholars.<sup>137</sup> The Supreme Court also maintains distance from it, stating in *Trinko*: "We have never recognized such a doctrine... and we find no need either to recognize it or repudiate it here."<sup>138</sup> This express non-repudiation leaves the doctrine technically alive, albeit eviscerated, in Supreme Court jurisprudence. Other U.S. federal courts have been less grudging in applying the doctrine to address genuine instances of monopoly abuse,<sup>139</sup> and scholars point to a group of Supreme Court cases, including *Aspen Skiing* and *Otter Tail*, that reflect essential facilities principles.<sup>140</sup>

The doctrine originally was conceived with a view to tangible facilities like railroad bridges and gas pipelines, but it has been extended (amid some controversy) to intangible assets like intellectual property (IP) rights and informational resources.<sup>141</sup> This controversy reflects the obvious tension between IP rights (which exist for the very purpose of creating a right to exclude) and the essential facilities doctrine (which punishes exclusionary conduct).<sup>142</sup> Some commentators feel the doctrine should be applied, if at all, only when an IP right holder is attempting to leverage an IP right in one market (e.g., data operations) to gain monopoly power in a separate market (e.g., test administration).<sup>143</sup> The current situation in the genetic testing industry conforms precisely to this situation, where scholars find the strongest justification to apply the doctrine.<sup>144</sup> The concern is that data-rich laboratories may be able to exploit their control over VUS data supply to disadvantage competitors in related markets for test administration and/or genomic interpretation services.

Entities controlling essential facilities have no duty to share them if competitors have other ways to obtain the needed facility.<sup>145</sup> This is true even though it would be costly or difficult for competitors to construct alternative facilities of their own.<sup>146</sup> This implies that the essential facility needs to be defined very narrowly in cases involving access to genetic data. Laboratory-held data that are duplicated in publicly accessible datasets could not support an essential facilities claim. The essential facility only would encompass data that are uniquely available in the defendant's data holdings. If a laboratory has reported 80% of its VUS data into public datasets but holds the other 20% as trade secrets, the essential facility only would include the 20% for which no other source exists.

Courts tend to be strict about requiring plaintiffs to show that they really cannot develop their own duplicate version of the needed facility. Plaintiffs must show genuine legal or other barriers that prevent them from duplicating the facility. With respect to genetic databases, this would be rather easy to show. Duplicating a monopolist's VUS data in many instances would require re-testing all of the same patients whom the monopolist previously tested and correlating those test results with clinical information for the same patients. Until the cost of genetic sequencing drops much lower than it is today, most people who undergo whole genome or exome sequencing once are unlikely ever to undergo the procedure again,<sup>147</sup> so there is little chance that they will appear at the rival laboratories to be resequenced in the normal course of seeking medical care. Even if cost were no object and if all the past patients would consent to be retested, it would be

unethical and wasteful of scarce health care resources to subject patients to retesting by every laboratory that needs to duplicate the monopolist's data resources. Patients' rights are the factor that ultimately limits the use of duplicative testing to re-create essential genetic data resources.

The ultimate problem with the essential facilities doctrine is that it forces courts to act as economic regulators and grapple with details of pricing and access arrangements that courts are ill equipped to administer. Courts seem reluctant to intrude into the affairs of industries that already have economic regulators in place. The *Otter Tail* case, where a court ordered access to transmission lines, was decided at a time when the FERC lacked authority to compel *Otter Tail* to offer unbundled transmission services. The power industry's situation at that time was similar to what now exists in genetic testing, where no regulator has authority to compel access to VUS data. The dearth of similar cases after *Otter Tail* does not mean that the United States has ceased to protect access to essential facilities. The primary work of defending access simply shifted from courts to regulatory agencies. The FERC found authority under the Natural Gas Act to require nondiscriminatory access to high-pressure gas pipelines,<sup>148</sup> and Congress addressed access to essential power transmission facilities in the Energy Policy Act of 1992<sup>149</sup> and to essential local telecommunications facilities in the Telecommunications Act of 1996.<sup>150</sup>

The core principles of essential facilities doctrine have never been repudiated. Rather, in many industries, they are protected through sector-specific laws and regulations that, as a court once said of the Natural Gas Act, "fairly bristle[] with concern for undue discrimination" and prohibit "any undue preference and any unreasonable difference in rates, charges, service, facilities, or in any other respect."<sup>151</sup> The genetic testing industry, at present, has no sector-specific regulator to oversee its looming infrastructure access issues. Under these circumstances, is it possible that U.S. federal courts may rise to the occasion? One hopes so. If not, help may have to come from Europe with its stronger essential facilities doctrine.<sup>152</sup> Genomic interpretation, as a data-driven activity, is not necessarily confined by territorial boundaries. Consumers wishing to discover the meaning of their uninterpreted gene variants can easily transmit their sequencing data for interpretation in whatever jurisdiction establishes the best access framework to support state-of-the-art genomic interpretation services. The question is not whether state-of-the-art genomic interpretation will be commercially available in the future, but where.

## Conclusion

After the last surviving gene patent has expired, gene patenting still will have left its lasting mark on the genetic testing industry. Stores of genomic data remain sequestered in proprietary databases of vertically integrated incumbent laboratories. Nondiscriminatory access to these data is essential in order for new entrants to compete effectively and to protect the safety of consumers who receive genetic testing. Courts may have a role to play in addressing VUS data access issues, particularly in Europe and other jurisdictions if American clinical laboratories attempt to exploit their dominant data holdings to achieve global dominance in genetic testing. After *Trinko*, the role of U.S. federal courts is less certain. Congress has demonstrated willingness to address access issues as they emerged in other infrastructure industries in the recent past. It seems premature, however, to rule out a useful role for courts. Economic regulatory vacuums, if allowed to persist, endanger the public in ways that may bestir reluctant courts to intervene.

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55. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 402-03 (2004) [hereinafter *Trinko*]; G. O. Robinson, "On Refusing to Deal with Rivals," *Cornell Law Review* 87, no. 5 (2002): 1177-1232, at 1217-1223.
56. 45 C.F.R. § 164.524 (2013).
57. See U.S. Department of Health and Human Services, *supra* note 3.
58. L. Ekstrom, D. Flaherty, J. Henry, S. Kulkarni, K. Pattabiraman, and T. Rudolf, "Capturing Value for Dx in Personalized Medicine - Is There a Path?" in *Personalized Medicine: The Path Forward* (Palo Alto, CA: McKinsey and Company, 2013): at 34.
59. See U.S. Department of Health and Human Services, *supra* note 9.
60. Pub. L. 111-5, Div. A, Title XIII, Div. B, Title IV, 123 Stat. 226, 467 (2009) (codified as amended in scattered sections of 42 U.S.C.).
61. 42 U.S.C. § 17935(d)(1) (Supp. V 2012).
62. *Id.* § 17935(d)(2).
63. 45 C.F.R. § 164.512(i) (2013).
64. See Shirts et al., *supra* note 31.
65. B. J. Evans, "Sustainable Access to Data for Postmarketing Medical Product Safety Surveillance under the Amended HIPAA Privacy Rule," *Health Matrix* 24 (2014): 11-47, at 20-24.
66. S. L. Dogan and M. A. Lemley, "Antitrust Law and Regulatory Gaming," *Texas Law Review* 87, no. 4 (2009): 685-729, at 690.
67. Interstate Commerce Act, ch. 104, 24 Stat. 379 (1887) (codified as amended in scattered sections of 49 U.S.C.).
68. Communications Act of 1934, ch. 652, 48 Stat. 1064 (codified as amended at 47 U.S.C. §§ 151-620).
69. Public Utility Act of 1935, ch. 687, 49 Stat. 803 (codified as amended in scattered sections of 16 U.S.C.).
70. Natural Gas Act of 1938, ch. 556, 52 Stat. 821 (codified as amended at 15 U.S.C. §§ 717-717w).
71. B. Frischmann and S. W. Waller, "Revitalizing Essential Facilities," *Antitrust Law Journal* 75 (2008): 1-65, at 4.
72. See Evans, *supra* note 35, at 92.
73. See Cook-Deegan, *supra* note 29, at 586.
74. See Evans, *supra* note 19, at 508; Evans, *supra* note 65, at 26-27.
75. 132 S. Ct. 1289 (2012).
76. Zacks Equity Research, "Myriad Genetics Jumps on Medicare Decision," April 3, 2014, *available at* <[http://www.zacks.com/commentary\\_print.php?article\\_id=128671&type=BLOG](http://www.zacks.com/commentary_print.php?article_id=128671&type=BLOG)> (last visited July 1, 2014).
77. See Evans, *supra* note 19, at 5.
78. Office for Civil Rights, U.S. Department of Health and Human Services, "Health Information Privacy, Frequently Asked Questions: *available at* <[http://www.hhs.gov/ocr/privacy/hipaa/faq/right\\_to\\_request\\_a\\_restriction/512.html](http://www.hhs.gov/ocr/privacy/hipaa/faq/right_to_request_a_restriction/512.html)> (last visited August 22, 2013).
79. 45 C.F.R. § 164.501 (2013).
80. 15 U.S.C. §§ 1-7 (2012).
81. *Id.* § 1.
82. *Id.* § 2; Miles, *supra* note 14, at § 5:1.
83. 15 U.S.C. §§ 12-27 (2012); 29 U.S.C. § 52 (2012).
84. 15 U.S.C. §§ 13-13b, 21a (2012).
85. 15 U.S.C. § 18 (2012).
86. *Id.* § 14.
87. *Id.* §§ 41-58.
88. *Id.* § 45.
89. See Miles, *supra* note 14, at § 1:1.
90. See, e.g., *United States v. Columbia Steel Co.*, 334 U.S. 495, 525 (1948) (noting that vertical integration is not itself unlawful); *Byars v. Bluff City News Co.*, 609 F.2d 843, 861 (6th Cir. 1979) (observing that firms, in theory, will only pursue vertical integration when the firm is at least as efficient as other firms in the segment into which it integrates).
91. See, e.g., *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 480 (1992) (noting that monopoly power under § 2 of the Sherman Act demands something greater than the market power required for purposes of § 1); *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 886 (N.D. Cal. 2011) (stating "monopoly power is best understood to be the substantial degree of market power").
92. *United States v. Grinnell Corp.*, 384 U.S. 563, 571(1966); *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 447-48 (2009) ("Simply possessing monopoly power and charging monopoly prices does not violate § 2"); *Trinko*, 540 U.S. at 407 ("The mere possession of monopoly power. . . is not. . . unlawful").
93. *United States v. Grinnell Corp.*, 384 U.S. at 570-71.
94. *Trinko*, 540 U.S. at 407; *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).
95. See Miles, *supra* note 14, at § 5:7.
96. *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. at 448.
97. *Trinko*, 540 U.S. at 414 (citing *United States v. Microsoft Corp.*, 253 F.3d. 34, 58 (D.C. Cir. 2001)).
98. See Evans, *supra* note 65, at 30-32.
99. *Colorado Interstate Gas Co. v. Federal Power Comm'n*, 324 U.S. 581, 589 (1945).
100. See Evans, *supra* note 19, at 508.
101. D. F. Spulber and C. S. Yoo, "Mandating Access to Telecom and the Internet: The Hidden Side of *Trinko*," *Columbia Law Review* 107, no. 8 (2007): 1822-1907, at 1841-42; P. L. Joskow and R. G. Noll, "The Bell Doctrine: Applications in Telecommunications, Electricity, and Other Network Industries," *Stanford Law Review* 51, no. 5 (1999): 1249-1315, at 1250-1251.
102. See Joskow and Noll, *supra* note 101, at 1262-1263.
103. P. Margiotta, "Communications Law: The Local Exchange Carrier Price Cap Order," *George Washington University Law Review* 63, no. 5 (1995): 723-758, at 724-725.
104. See Farrell & Weiser, *supra* note 51, at 94.
105. See *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 480 (1992) (quoting *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 611 (1953)).
106. *Ill. ex rel. Hartigan v. Panhandle E. Pipe Line Co.*, 730 F. Supp. 826, 883 (C.D. Ill. 1990), *aff'd*, 935 F.2d 1469 (7th Cir. 1991).
107. *Trinko*, 540 U.S. at 408 (quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985)).
108. *Id.*, at 408, 414.
109. 410 U.S. 366 (1973).

110. *Id.*, at 377.
111. *Id.*, at 368-69.
112. *Id.*, at 377 (citing *Lorain Journal v. United States*, 342 U.S. 143, 154 (1951)).
113. *Id.*, at 381-82.
114. 472 U.S. 585 (1985).
115. 540 U.S. 398 (2004).
116. *Id.*, at 409.
117. *Id.*, at 409-10.
118. *Id.*, at 402-404.
119. *Id.*, at 404.
120. Pub. L. 104-104, 110 Stat. 56 (1996) (codified as amended in scattered sections of 15, 18, 47 U.S.C.).
121. *Trinko*, 540 U.S. at 401.
122. *Id.*, at 409.
123. A. Scalia and B. A. Garner, *Reading Law: The Interpretation of Legal Texts* (St. Paul, MN: ThomsonWest, 2012): at 174 (citing *United States v. Butler*, 297 U.S. 1, 65 (1936)).
124. See Evans, *supra* note 19, at 506-506.
125. *Id.*
126. *Id.*
127. *Trinko*, 540 U.S. at 409.
128. *Otter Tail Power Co. v. United States*, 410 U.S. 366, 381-82 (1973).
129. *Trinko*, 540 U.S. at 411.
130. *Id.*, at 412.
131. *Id.* (internal quotation and citation omitted).
132. See Mills, *supra* note 14, at § 5:8, n. 10 (noting that it is an unanswered question whether a “reasonable” price may need to include some measure of monopoly rent in situations where the facility in question is truly irreproducible and unique).
133. 708 F.2d 1081, 1132-33 (7th Cir. 1983).
134. See, e.g., *Loren Data Corp. v. GXS, Inc.*, 501 F. App’x 275, 284 (4th Cir. 2012), *cert. denied*, 133 S. Ct. 2835 (2013).
135. *MCI Commc’ns Corp. v. AT&T*, 708 F.2d at 1132-33.
136. S. W. Waller and W. Tasch, “Harmonizing Essential Facilities,” *Antitrust Law Journal* 76 (2010): 741-767, at 741; T. L. Cotter, *The Essential Facilities Doctrine* (University of Minnesota Law School Legal Studies Research Paper No. 08-18, 2008): 6-11, available at <<http://ssrn.com/abstract=1125368>> (last visited April 29, 2014).
137. See, e.g., P. Areeda, “Essential Facilities: An Epithet in Need of Limiting Principles,” *Antitrust Law Journal* 58, no. 4 (1989): 841- 853; Cotter, *supra* note 136, at 11.
138. *Trinko*, 540 U.S. at 411.
139. R. Pitofsky, D. Patterson, and J. Hooks, “The Essential Facilities Doctrine under U.S. Antitrust Law,” *Antitrust Law Journal* 70, no. 2 (2002): 443-462, at 443-444.
140. *United States v. Terminal R.R. Ass’n of St. Louis*, 224 U.S. 383 (1912); *Associated Press v. United States*, 326 U.S. 1 (1945); *Otter Tail Power Co. v. United States*, 410 U.S. 366 (1973); *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).
141. See Cotter, *supra* note 136, at 11.
142. *Id.*
143. See Cotter, *supra* note 136, at 14-15.
144. *Id.*
145. See Miles, *supra* note 14, at § 5:7.
146. *Id.* at § 5:8.
147. See Evans, *supra* note 19, at 508.
148. *Associated Gas Distribs. v. FERC*, 824 F.2d 981, 998 (D.C. Cir. 1987), *cert. denied*, 485 U.S. 1006 (1988)
149. See Federal Energy Regulatory Commission, *supra* note 53, at 21560-61.
150. *Trinko*, 540 U.S. at 402-03; Robinson, *supra* note 55, at 1217-23.
151. See *Associated Gas Distribs. v. FERC*, 824 F.2d at 998.
152. See Waller and Tasch, *supra* note 136, at 741.