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Article

Prospect patents, data markets, and the commons in data-driven medicine: Openness and the political economy of intellectual property rights

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Abstract

Scholars who point to political influences and the regulatory function of patent courts in the USA have long questioned the courts' subjective interpretation of what 'things' can be claimed as inventions. The present article sheds light on a different but related facet: the role of the courts in regulating knowledge production. I argue that the recent cases decided by the US Supreme Court and the Federal Circuit, which made diagnostics and software very difficult to patent and which attracted criticism for a wealth of different reasons, are fine case studies of the current debate over the proper role of the state in regulating the marketplace and knowledge production in the emerging information economy. The article explains that these patents are prospect patents that may be used by a monopolist to collect data that everybody else needs in order to compete effectively. As such, they raise familiar concerns about failure of coordination emerging as a result of a monopolist controlling a resource such as datasets that others need and cannot replicate. In effect, the courts regulated the market, primarily focusing on ensuring the free flow of data in the emerging marketplace very much in the spirit of the 'free the data' language in various policy initiatives, yet at the same time with an eye to boost downstream innovation. In doing so, these decisions essentially endorse practices of personal information processing which constitute a new type of public domain: a source of raw materials which are there for the taking and which have become most important inputs to commercial activity. From this vantage point of view, the legal interpretation of the private and the shared legitimizes a model of data extraction from individuals, the raw material of information capitalism, that will fuel the next generation of data-intensive therapeutics in the field of data-driven medicine.

Key words: data-driven medicine, intellectual property

1. Introduction

The article discusses the troubled relationship between open datasets and proprietary inventions in the field of data-driven medicine. The analysis adopts the angle of critical scholarship enquiring into the function of data as a valuable resource in the emerging information economy (Benkler 2002; Castells 2000; Cohen 2017). One of the central characteristics of the information economy is that since information is easily reproducible it creates a variety of 'free information' versus 'exclusive control' problems which relate to the intellectual property rights and openness distinction. The vehicle to kick off my take on the problem is the recent cases decided by the US Supreme Court and the Federal Circuit, which made diagnostics and software very difficult to patent.[1] Courts in the USA have long ago developed caselaw exempting natural phenomena and laws of nature, mental acts, and abstract ideas from patent eligibility. These 'things' do not fall into the statutory categories of invention and as such belong to the public domain or the nuanced notion of the commons. Yet, any attempt by courts to mark the difference between what can be claimed as private property and what belongs to the public domain or the commons seems to invite a highly subjective inquiry, and for this reason these decisions have been harshly criticized (Sichelman 2014).[2] At the same time, as I will argue, the distinction between the private and the shared seems to be driven by explicit concerns about the value of data in the information economy.

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Although scholarship has discussed extensively the recent cases decided by the US Supreme Court and the Federal Circuit with respect to the patentability of diagnostics and software and has highlighted a wealth of different problems, one important facet has escaped attention: the current debate within patent law between what can be private property and what can be shared is largely a debate over the proper role of the state in regulating the marketplace and knowledge production in the emerging information economy. To come to grips with this assertion, it is important to highlight the particular function of private rights, patents, claiming inventions in the field of data-driven medicine. Patents claiming diagnostics and software are prospect patents. Kitch (1977) famously proposed that these patents can be justified on the basis of an economic rationale similar to the one justifying property rights to mineral resources. Rather than the traditional justification of patents as rewarding inventive activity (Ghosh 2004; Merges 2005; Yelderman 2015), prospect patents are important business assets and primarily serve the purposes of coordinating business transactions in the marketplace. Importantly, they are a tool for collecting and propertizing data, such as genotype–phenotype correlations, and for building private datasets that hold enormous value. In fact, it may be that the data acquired, analyzed, and aggregated through practicing the claimed invention may even be more valuable than the patent itself. The reason is that such private datasets are potentially perpetual monopolies, almost impossible to replicate and at the same time essential to interpreting the results of diagnostic testing. As I explain in detail, the ramifications are that a single inventor may control a key technology in the field of diagnostics. What is more, a single inventor may control valuable data that everybody else needs to compete effectively.

An important aspect of prospect, information, and business asset theories is that they imply a minimalist role for the state (Ghosh 2004). For the proponents of these patents, when the Supreme Court in *Mayo Collaborative Servs. v. Prometheus Labs* essentially put correlations between the occurrence of disease and genetic disposition in the public domain, it effectively interfered with private property rights which form the basis of exchange in markets. It has been argued for example that it is more efficient to have one private company controlling a database with mutations rather than multiple private companies controlling small and incomplete datasets (Burk 2015). Other more skeptical scholars suggest that we should not deny protection to all diagnostics but discipline market patent-based exchanges to those that represent genuine inventions and control any undesired effects after they have been granted (Simon and Sichelman 2017).

The Supreme Court took a different view. It appears to acknowledge the prospect function of patents, yet pointed to the problems inherent in failure of coordination emerging as a result of a monopolist controlling a resource such as datasets that others need and cannot replicate. In effect, the courts regulated the market, primarily focusing on ensuring the free flow of data in the emerging marketplace very much in the spirit of the 'free the data' language in various policy initiatives,[3] yet at the same time with an eye to boost downstream innovation. The last point is important. From this vantage point, the dichotomy between private property and natural phenomena and laws of nature, mental acts and abstract ideas becomes an important object of study. These decisions not only favored sharing the datasets (such as the correlations between genotypes and phenotypes of disease); but they also favored the development of specific industries relevant to the development and patenting of the Big Data analytics and artificial intelligence (AI) tools to mine the datasets, which are expected to fuel the next generation of data intensive inventions that will transform both the conduct of research and delivery of health care.

While historians (Beauchamp 2013; Dutfield 2009) and scholars who point to political influences and the regulatory function of patent courts (Duffy 2010) have long questioned the courts' subjective interpretation of patent eligibility requirements,[4] the present article sheds light on a different facet: the role of the state in regulating knowledge production. These decisions essentially endorse practices of personal information processing which constitute a new type of public domain: a source of raw materials which are there for the taking and have become most important inputs to commercial activity (Cohen 2017; Edelman 2015). From this vantage point of view, the legal interpretation of the private and the shared legitimizes a model of data extraction from individuals, the raw material of information capitalism, that will fuel the next generation of data-intensive therapeutics in the field of data-driven medicine. The rationale for intellectual property and shared resources is interconnected, they feed into each other and raise a set of concerns about personal data that are different from, yet link to the discussion over privacy or data protection. This set of concerns is often neglected and needs to be studied more extensively to better understand the workings of information capitalism.[5]

2. Patenting laws of nature: diagnostics and correlations

A patent is a species of property right that gives their owner a time-limited right to exclude others from practicing the invention and genetic inventions can be protected by patents if they fulfill certain legal requirements. Patents on diagnostic uses are often referred to as 'disease gene patents', and typically cover all known methods of testing for a mutation. The invention is based on statistical observation of a genetic difference and a phenotypic difference (such as the occurrence of disease), then the patent claims any method for testing for that genetic difference. A typical diagnostic patent is written in the following format: a method for diagnosing a predisposition for disease X in a human subject which comprises obtaining a sample from a patient, and determining the presence of biomarker Y, where the presence of biomarker Y in the sample indicates a predisposition for disease X. It follows that accurate interpretation of predisposition to disease X requires a big dataset with genotype–phenotype correlations with robust statistical observations.

In a series of recent decisions the US Supreme Court decided that diagnostics are non-eligible subject matter. In *Mayo Collaborative Services v. Prometheus Laboratories*,[6] a case decided in 2012, the court said that a patent covering a standard diagnostic method comprising of the steps of administering a drug, measuring the level of a metabolite, and knowing based on the result whether to increase or decrease the drug's dosage, was unpatentable, as essentially claiming, and thus preempting, a law of nature, the phenotype-genotype correlations.[7] It followed long established caselaw exempting natural phenomena and laws of nature, mental acts, and abstract ideas from the statutory categories of invention. Patents should allow inventors to control some 'things' that embody such natural phenomena and laws, acts, and ideas, but not the natural phenomena and laws, mental acts and ideas themselves (Collins 2008: 12). For Collins, the latter are a public domain resource that should be '"exacted from" the patentee and given to the public as a condition

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of the patentee's right to exclude from the patentable embodiments of an invention'.

How can a diagnostic test claim laws of nature such as correlations between disease and biomarkers to the extent that others cannot use the same scientific facts to come up with new diagnostics? Answering this question is not straightforward. To answer it, let us begin with the following observation: the court did not shy away from peering into the motivations of patent owners explicitly addressing the problem of opportunistic behavior. Right holders use patents strategically to block competition from rivals. The court explained that it declared Prometheus' process as non-patent eligible because the laws of nature recited by Prometheus' patent claims 'are not themselves patentable, the claimed processes are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations.'[8] Therefore, the court in *Mayo* decided that laws of nature (the phenotype–genotype correlations) are patentable only if 'enough' is added to the claim to ensure an *application* of the natural law is being claimed. A patent must limit its reach to a particular, inventive application of the law (Thambisetty 2016). Engaging in a typical utilitarian calculus, the court reasoned that because those laws and principles are 'the basic tools of scientific and technological work,' it may be that the patented process 'forecloses more future invention than the underlying discovery could reasonably justify. . .they threaten to inhibit the development of more refined treatment recommendations that combine Prometheus' correlations with later discoveries.'[9]

Mayo essentially put diagnostics outside the remit of patent protection in the USA (Eisenberg 2015). The Court in *Mayo* said that the problem with Prometheus' diagnostics test is that it attempts to monopolize the phenotype–genotype correlations, in other words the statistical observations upon which the invention is based. The Court thought the invention (the steps performing the diagnosis such as taking a sample and determining the presence of a biomarker) and the dataset (with statistical observations between genotypes and phenotypes of disease) as almost merging in one entity. The right holder used the patented technology to build datasets and it is the combined effect of control over both the diagnostic technology and the datasets used for interpretation that threatens to inhibit future invention in the field of diagnostics. This is an important point and I will explain its significance more by looking at a subsequent decision which applied the *Mayo* test, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*[10]

Ariosa is an important case that applied the Mayo test stirring again the debate over the question of non-patentability of diagnostics. The discovery in question, cell free foetal DNA (cffDNA), was a truly revolutionary medical test based on a non-invasive technique (without the need to perform amniocentesis) to test for abnormalities in the foetus. In late 1990s, the inventors, Dr Dennis Lo (Chinese University of Hong Kong) and Dr James Wainscoat (University of Oxford), discovered the presence of paternal DNA in mother's blood which had travelled from the foetus. Simply by taking blood from the mother they could reliably identify foetal DNA, which would in turn allow them to diagnose certain foetal genetic conditions such as Down Syndrome. The tech-transfer office of the University of Oxford patented the test and then licensed the patent exclusively to Sequenom. Ariosa, Sequenom's competitor, challenged the validity of the patent and the patent was invalidated twice in the US District Court in California, a decision affirmed by the Court of Appeals for the Federal Circuit and in 2016 the US Supreme Court denied a petition to review the case.

As in *Mayo*, the decision was heavily criticized. Many argued that non-invasive testing addresses a real medical problem involving considerable intervention and producing a useful product that considerably improves the quality of human life. Even the Court of Appeals for the Federal Circuit in *Ariosa* lamented that under Supreme Court precedent it *had no option other* than to affirm the decision of the district court 'The application of the natural phenomenon unfortunately obliged us to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.[11] 'The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.'[12] Researchers *already knew* how to accomplish the individual steps of (1) fractionating blood; (2) amplifying DNA; and (3) detecting characteristics in amplified DNA.[13] However, individual judges of the Federal Circuit expressed their deep concerns, for instance Justice Lourie explained that 'it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps.'[14] According to this view, as with Prometheus's diagnostic test, Sequenom's test involves considerable human intervention in manipulating natural phenomena to perform a useful task. Human intervention was needed to actually measure *cffDNA* for the specific purpose of detecting abnormalities in the fetus. The question of patentability should then be addressed by looking at whether the invention satisfies novelty and non-obviousness otherwise we may deny protection to meritorious inventions.[15] Clearly, this opinion follows a long strand of judicial thinking that reflects pragmatism in rewarding useful inventions and protecting a nascent industry. [16]

Yet, there is more a nuanced story to be told about these decisions, one that highlights the role of the court in regulating the market and indirectly promoting specific industries. An interesting picture emerges when looking at Justice Dyk's opinion (judge on the Federal Circuit) concurring in the denial of the petition for rehearing en banc in *Ariosa*. He explains that the non-obviousness requirement and breadth of claims should screen out undeserving patents (he too was skeptical about the Mayo test in that he thought that an inventive concept can come from discovering something new in nature even if it is applied in a conventional way). Yet, he recognizes that 'claims that extend far beyond the utility demonstrated by the patent applicant and reduced to practice should be invalid, as they too broadly preempt the use of the underlying idea by others.'[17] Justice Dyk's focus on preemption is important as it directly addresses the reason why these patents can potentially preempt use of the genotype-phenotype correlations. As the law allows applicants to include few representative embodiments of the invention and further permits the use of prophetic examples in the patent application,[18] it may 'prevent claims that preempt future applications of the law of nature by others,' . . . Sequenom claimed more than it taught: 'any diagnosis of any disease, disorder, or condition. . . impermissible attempts to capture the entire natural phenomenon of cffDNA rather than any particular applications thereof developed and actually reduced to practice by the inventors'.[19]

The language of capture and monopolization reflects a different type of concerns akin to 'market failure', where Adam Smith's invisible hand fails to guide privately owned resources to their socially optimal uses in cases that economists refer to as involving 'public goods', 'natural monopolies', and 'externalities'. The court thought that the diagnostic test at issue in *Mayo* and *Ariosa* claimed the

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correlations between disease and biomarkers to the extent that others cannot use the same scientific facts and invest in new diagnostics. The reason is that these patents by design generate valuable data through their operation or use and effectively create undesirable monopolies. In other words, the problem lied in the inherent capacity of the technologies to generate invaluable datasets with correlations that competitors cannot replicate. The following section will elaborate this point.

3. Coordination failure and data-generating patents: regulating markets and knowledge production

Recent literature has acknowledged the function of patents in data-driven medicine as data collection points (Burk 2015; Simon and Sichelman 2017).[20] They describe these patents as 'data-generating patents' or data aggregators, which refer to patents on inventions involving technologies that by design generate valuable data through their operation or use. For instance, genetic tests and medical devices produce data about patients. Internet search engines and social networking websites generate data about users' preferences. When data-generating inventions are patented, the patentee has a monopoly over the uses of an invention, but at the same time the patentee also effectively enjoys market power over the data generated by the invention. Trade secret law further protects the patentee's market power over the data, even where the data is in a market distinct from the patented invention and very importantly, the patentee will continue to have a monopoly in this market even after the expiration or invalidation of the patent.

Therefore, diagnostic patents are *data collection points:* they provide their owner with a competitive advantage in generating a database of mutations and other clinical information that will be difficult and costly for competitors to replicate (Simon and Sichelman 2017).[21] The more people use a patented diagnostic the better and more accurate the database. The textbook example is Myriad Genetics: The company had a long-term monopoly on BRCA1 and BRCA2 genetic testing, and thus compiled amounts of data on variants in the BRCA genes (a proprietary database containing information on 46,000 genetic variants), giving the company a competitive advantage in the evaluation of rare BRCA1 and BRCA2 variants for which the medical significance had not yet been documented in a public database. As Myriad Genetics has refused to contribute to public databases it has been criticized as essentially leveraging its power in the data market by keeping such a database proprietary (Conley et al. 2014).

Competitive advantage in the field of diagnostics depends, in part, on the quality of the genetic data that companies can access, thus retaining exclusive access to such information is a key business strategy. Exclusive control of a patent portfolio for a particular disease field is used strategically to block competitors in the market for genetic testing (Price 2015). In this respect, broad patent claims and exclusive control arguably prevents widespread genetic testing whose results could potentially enrich databases. Exclusivity also prevents the building of more accurate datasets, as the commercial standard of one company becomes the clinical standard, since other companies are prevented from offering more accurate tests (Kane 2008).

Broad patents claims in 'disease gene patents', which typically cover all known methods of testing for a mutation essentially give patent owners too much power and create a coordination failure problem: Reacting to a statement by *Brief* for *American College of Medical Genetics et al. Amici Curiae 7.* the court in *Mayo* agreed that patents on the one hand provide incentives to innovate, on the other hand, exclusive control can 'impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.'[22]

The problem is exacerbated as rebuilding datasets is not easy (Oliver 2015). Even if all competitors cooperated, contributing their data to a public database would not appear to be a viable alternative, which means that 'private ordering' solutions (using liability rules as in the case when a patent pool is formed) may not always be feasible (Simon and Sichelman 2017). Arguably, such barriers invite regulatory intervention (Williamson 1974).[23] Without a patent on the upstream technology the follow-on innovators can freely decide whether to invest in downstream innovation.

These considerations bring together diverse inventions such as software, diagnostic, and gene-related patents, all excluded from patent eligibility as natural phenomena, laws of nature and abstract ideas.[24] Software, diagnostic, and gene-related patents are tools to collect data and in this sense rely upon 'network effects', the benefits of having many users. Google's famous software patent on PageRank technology is a good example illustrating these benefits. The PageRank technology is an algorithm used by Google Search to rank web pages in their search engine results. To determine which pages are most important, PageRank counts link votes. The scores are then used together with many other factors to determine if a page will rank well in a search. Although PageRank is one part of Google's page ranking system, when Google made the metric visible[25] it fueled a whole market of link brokering, as people begun to put links in blog posts and forums to chase higher scores. At the same time, the popularity of PageRank gave the company early on the possibility to attract users and collect data that it could aggregate to improve its underlying product (the PageRank technology), as well as to expand into secondary markets such as targeted online advertisement (Simon and Sichelman 2017). Companies such as google effectively utilize the data to better understand what users want, and to this effect currently use artificial intelligence to mine data from multiple sources.

Diagnostic technologies function in the same way. To give another example illustrating their function as data collection points let us take the example of Stanford University patents for a method for assessing embryo development and viability in order to improve IVF success rates. US patent 7,963,906 B2 claims 'a method for assessing the potential for developmental competence of a human embryo utilising certain parameters'. The patent has been granted by the US patent office, with an equivalent granted by the European Patent Office. It describes a process whereby thousands of pictures are taken during the first few days of an IVF embryo's life and researchers use the patented method to pick the healthiest embryos to be implanted into the womb. The success rates of the diagnostic depend on the quality of the dataset used for interpreting results. At the same time, the more people are tested the more accurate the database. The database can be used to improve the product and as the product is improved it attracts more users and becomes the clinical and commercial standard. A different but important point concerns expansion in neighboring markets as a database with millions of images with embryos at various stages of development can be mined with artificial intelligence systems together with data from other

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sources for a variety of different medical purposes. I will return to discuss this last point later.

We are now in a position to appreciate the criticism of the decisions in a different light. The story about building datasets and using patents as a tool to this effect implicate the 'prospect theory' of patents (Burk 2015). Rather than reward inventors for their efforts, the prospect theory in economic thinking links to a very different set of justifications. Kitch (1977) famously proposed that patents can be justified on the basis of an economic rationale similar to the one justifying property rights to mineral resources. According to Kitch physical resources such as minerals can be exploited in a coordinated fashion by granting rights in mineral prospects and the same should be true for intangibles. A fundamental assumption of the theory is that prospect patents need to be broad and foundational, as they are granted early on in the discovery process and aim at ending rivalry by allowing one inventor to control a key technology. To take the example of Myriad's patent, proponents of the theory would argue that it is best to have one private company controlling a database with mutations rather than multiple private companies controlling small and incomplete datasets.

Kitch was inspired by the prospect theory of property in tangibles developed by Demsetz (1967), which is based on the fundamental utilitarian idea that private ownership creates a self-interested incentive to exploit and develop an exhaustible resource. If people are free to act in certain ways with respect to their property, they would be likely to better satisfy their preferences. Rights to possess and use property advances individual welfare and the net welfare created in society. Given that physical resources are exhaustible the theory offers a solution to the 'tragedy of the commons' which might occur as a result of over-exploiting the exhaustible resource in question. Kitch's theory is essentially a theory of management of intellectual resources: patents as coordination points prevent duplicative or haphazard development of the invention.

The prospect theory of patents is strongly criticized for a variety of reasons. To name a few, unlike physical resources, intellectual property is non-rivalrous and essentially inexhaustible; prospect patents do not leave room for redistribution; rivalry migrates in downstream markets (Sideri and Panagopoulos unpublished data). Here I would like to concentrate on Burk's analysis of the prospect theory of patents in precision medicine, which emphasizes the particular problems inherent in the data generating patents functioning as data collection points: Commenting on Myriad's BRCA patents Burk (2015: 249) notes:

> Kitch's pioneering intellectual property analyses, concerning the development of unpatented but valuable information patent is not so much the tool that allows a single entrepreneur to coordinate development of the patented technology itself as it is the tool that allows coordination of associated know-how. If patents are to be compared to mineral rights, the benefit in this case is perhaps not the facility of the property right in coordinating the orderly extraction and processing of the ore, so much as it is the ability of the property right to organize placement of outbuildings and systematic scheduling of the crew around the mine.

But this coordination of non-patent data creates problems: aggregation of proprietary information essentially allows the patent holder to extend exclusivity beyond the term of the patent. In fact, the data aggregated around the patent may be potentially kept proprietary as it can be protected as a trade secret. Trade secrets in datasets can be perpetual monopolies since independent discovery or reverse engineering are not available options to competitors. As already explained, aggregated data such as genotype–phenotype correlations are almost impossible to recreate. The result may be monopoly pricing or even using the data to extend one's monopolistic position in neighboring markets.

To summarize the above discussion, *Mayo* and *Prometheus* can be seen as examples of market regulation. This approach challenges the traditional dichotomy between human invention that society needs to reward and a 'sort of public library in the cosmos packed with "manifestations" of natural laws, marked by open access' (Simon 2008: 2189). Prospect patents serve the purposes of coordinating transfer of technology and securing financing and venture capitalist investment. Prospect patents epitomize the emphasis on commercial exchange and are justified as a tradable commodity, an important investment asset. They reflect the real world of patents as business assets, strategic weapons to strike deals, attract investment, or amass big patent portfolios for the purpose of cross-licensing.[26] Diagnostic patents claiming diagnostic methods have the additional capacity to aggregate genomic data which are essential to operating the claimed invention and very difficult to recreate. The court decisions discussed earlier effectively said that it is better not to have a patent on the upstream technology so that follow-on innovators can freely decide whether to invest in downstream innovation or not.

It follows that an important characteristic of prospect patents is that they provide for a baseline for contractual exchange and a mechanism for resolving disputes over conflicting uses of resources. From a market regulation perspective, this approach implies a minimalist role for government. If government intervenes it will destroy incentives to work. If government does not respect individual rights people will not produce utility and there will be very little sum of total utility in a society. From this vantage point, for those in favor of a minimal role for the government one way to criticize the decisions is that they implicate a role for the government in regulating the market. Remember that standard neoclassical economics recognizes only two property regimes: either ownership is vested in private parties or it resides with the state. The usual economic approach to property law suggests that productive efficiency will be enhanced when private property is the norm, but government intervenes in cases of market failure in the interests of aggregate efficiency. What this means for the diagnostics market is that for those in the 'minimalist government' camp denying patent protection automatically implies government intervention such as for example by means of forcing private companies to share the correlations in public datasets.

Yet, there are solutions outside the private property-government control dichotomy. In Anglo-American jurisprudence the concept of 'inherently public property' recognizes that property can be owned and managed by society at large (Rose 1986), an idea whose intellectual roots dates back to the Romans. In economics, the pioneering work of Elinor Ostrom (1990) shows a wealth of real world examples such as irrigation, where resources are owned and managed by social groups. In the latter case, property is both a legal institution and a human invention for solving practical problems (Fennell 2011). Exchange depends to a great extent on shared norms and reputation, and resonates with anthropologists' description of the mode of operation of gift economies.

Taking a cue from Ostrom's work, Evans (2014) discusses data-sharing activities after *Myriad*. She notes that voluntary cooperation emerges in examples of self-organized, self-governing collectives that have managed irrigation, meadowlands, and forests in the past and the same ethos can be seen in the efforts of the National Institutes of Health to promote data sharing. She argues that

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voluntary sharing coupled with compulsory disclosure and market-oriented approaches could address the coordination problem in creating a market for genetic data. Indeed, numerous online databases exist, which differ with respect to their size, accessibility, and type of data stored. An example is the Clinical Genome Resource (ClinGen) project funded by the National Institutes of Health (NIH) in the USA that created a centralized resource of clinically annotated genes to improve interpretation of genomic variation, and the GA4GH BRCA Challenge. Some argue that the human genetics community is adapting to a new paradigm of publicly sharing datasets (Brookes and Robinson 2015) At the same time, laboratories could also use market solutions and charge a cost-based fee for giving access (Evans 2014).

In fact, recent work on data-sharing initiatives by Villanueva et al. (2019: 7) shows that 'there are many sources of data, many users of data, and many research and health care institutions pursuing data-sharing functions that are only somewhat aligned... Disparate actors with different roles work to collect and manage the data and build the networks that make the data useful for biomedical research, clinical care, and public health'. The authors further explain that rather than a single global Medical Information Commons (MIC) 'MIC captures the goal of sharing and linking data so that it can be transformed into information, and ultimately knowledge...the MIC is a collection of many different health-related commonses (or common pool resources) that would benefit from the widespread adoption of a group of high-level but flexible principles'.

This is an insightful comment, and perhaps a way to visualize it is by using the metaphor of a highway connecting data structures (rather than the idea of a global commons) which requires some sort of common rules. Yet, the point relevant to the present analysis is to show the market regulation effects of *Mayo*. Recognizing the patents as data collection points and prospects, *Mayo* essentially implies the need for either government regulation or the existence of a commons (or plural commons) and the need to foster a sharing ethos. Yet, the discussion on openness often takes a far too optimistic perspective. A point that is often undeveloped in the current discussions on commons and sharing concerns the important synergies between intellectual property and the public domain. Chandler and Sunder (2004) eloquently name this approach as 'the romance of the commons', the belief that because a resource is open to all by operation of the law, it will be exploited by all on equal terms. The reality is that equality of opportunity is hampered by social circumstances and different levels of knowledge and wealth. The result is that some will be more able to take advantage of the opportunities offered by open access. Indeed, as the following section will explain, the ones that will take advantage of the new commercial opportunities afforded by sharing are the private actors that will develop the new diagnostics, medical devices, and AI powered data-mining platforms.

4. From diagnostics to therapeutics: data analytics and the reinvention of therapy

The analysis of the data collection function of patents leads to the following observation with regard to the policy implications of the decisions: datasets of genotypes and phenotypes may potentially belong to a commons or diverse commons(es). Yet at the same time, these sharing arrangements coexist with private rights, the new generation of data-generating patents: the Artificial Intelligence (AI) tools to mine the data to predict medical events and tailor treatments, and digital therapeutics to manage disease. Importantly, the nature of therapeutics and meaning of therapy is changing as healthcare and pharmaceutical companies are partnering with AI biotech companies, and AI companies partner with hospitals and universities (Brayne et al. 2018). Cook-Deegan et al. (2019, f/n 2) explain:

> The sources of data include databases created for many different purposes. In genomics, most were created to collect data for researchers, but many genomic databases are now used in health care. Some databases, such as cancer registries, were established for public health surveillance, but are highly useful for both research and clinical care. Testing laboratories are a direct source of many data—for example, genomic testing laboratories, clinical laboratories, and imaging facilities. Moreover, as medical records are increasingly digitized, unstructured data are being transformed into forms that enable analysis of health outcomes and for other purposes. Also, many efforts are underway to integrate social determinants of health, genomic, imaging and laboratory data into electronic health records. The users of data include scientists hoping to understand biology or disease, but also health professionals helping individuals make decisions about health care interventions, counseling them about the meaning of data. Increasingly, individuals are using health and genomic data themselves.

In the future complete genomes of populations with phenotype data will be stored in Electronic Health Records (EHRs) and will further be integrated with other multi-omics results and environmental information, at least in high-resource clinical settings (price forthcoming). Storing all this data in EHRs will allow their mining with the aid of powerful algorithms and applications linking together diverse datasets.[27] In this scenario, biomedicine meets Artificial Intelligence (AI) and together they will drive both discovery and health care interventions through high-dimensional analysis of deep genomes and deep phenomes (Frey 2019). Researchers will be able to study phenotypes at different levels such as drug-dose response versus longitudinal analyses, as EHRs will offer large amounts of data, the ability to analyze data over time, and the capacity to include diverse datasets such as pictures, radiological data, and biometric data collected from mobile applications (Wei and Denny 2015).

A good example is a Google patent application from early 2019 for a 'system and method for predicting and summarizing medical events from electronic health records'. The patent claims a deep learning system that aggregates EHR data from a variety of sources into a 'timeline' in order to predict adverse events.[28] The patent claims an electronic device that predicts future clinical events such as unplanned transfer to intensive care unit, length of stay in a hospital greater than 7 days, unplanned readmission within 30 days after discharge of the patient, inpatient mortality, primary diagnosis, a complete set of primary and secondary billing diagnoses, or atypical laboratory values, such as acute kidney injury, hypokalemia, hypoglycemia, and hyponeutrimia'.[29] The claimed system includes a 'computer memory' or database for storing aggregated structured and /or unstructured EHR data, a computer or processing unit to execute machine-learning models trained on the data, and an end-user device, such as a tablet or workstation, that shows healthcare providers the results. The patent also describes the friendly user interface and 'The system of claim 2, wherein at least one of the one or more deep learning models each contain an attention mechanism indicating how much attention the at least one of the one or more models gave to elements in the electronic health record to predict

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the one or more future clinical events and summarize pertinent past medical events related to the predicted one or more future clinical events, and wherein the display of the notes or excerpts thereof are displayed in a manner indicating results from the application of the attention mechanism'.[30]

The line between therapeutics, medical devices, and digital health is becoming blurred. Let us take the example of Verily, formerly the Google Life Sciences division, now Alphabet Inc., which is working at the intersection of data science and healthcare. Verily has a number of partnerships to develop tools to collect and organize health data, and make predictions and recommendations. It collaborates with Alcon, Biogen, Dexcom, Ethicon, GSK, Galvani, Nikon, Sanofi, Verb Surgical, 3 M, Bringham and Womens Hospital, NHS Hospitals, Duke University School of Medicine, Parkinson Net, Radbound University and Stanford Medicine.[31]

To give an example of products that these partnerships generate let us take the example of Onduo, a joint venture between Sanofi and Verily. The idea is to combine hardware (glucose sensors), software (AI), and digital impetuses (reminders) to help people with diabetes manage their condition. These are patents for method plus device, and claim AI powered medical devices. Another example is a newly granted Verily patent[32] that offers a non-invasive system for diagnosing a diverse array of medical conditions, including hormonal issues, infections, and even cancer. The system uses a wearable device to monitor and asses a substance that is inserted or ingested into body.

5. Redefining therapy: digital therapeutics

There has been an explosion of health mobile apps, designed to help improve health and patient self-care and manage disease, named Digital Therapeutics. They receive market authorization as medical devices by the Food and Drug Administration (FDA) and are prescribed by physicians in a way similar to medicines. Digital therapeutics often target chronic diseases and neurological disorders, cases where there is need for self-management and tailoring treatment to individual cases.

Looking at the patents protecting digital therapeutics reveals an interesting picture: What all these patents have in common is first, they claim AI-driven technologies and second the devices and platforms are protected by data-generating patents: they collect a variety of user physiological data (such as blood pressure, pulse rate, respiration rate, skin temperature) transmitted to a mobile device, computer, or the cloud, which can be accessed by a physician. The readings will then be compared to known normal parameters and, if abnormal, will generate recommendations for the user of the device. This is the new market for Digital Therapeutics, where diagnostics and treatment recommendations rely upon behavioral and lifestyle changes usually generated by collection of a variety of different data. Treatments are being developed for the prevention and management of a wide variety of diseases and conditions, including type II diabetes, Alzheimer's disease, substance abuse, ADHD, and depression.

Bryn Roberts, Global Head of Operations for Roche Pharmaceutical Research & Early Development, explains[33]:

> The data we collect with the digital biomarker apps fall into two classes: 1) active test data, where the subject performs specific tasks on a daily basis, and 2) continuous passive monitoring data, where the subject carries the device (e.g. smartphone) with them as they go about their daily lives and sensors, such as accelerometers and gyrometers, collect data continuously. ….. We apply Deep Learning to do this activity-performance classification, or Human Activity Recognition (HAR), using deep artificial neural networks that have been trained using well-annotated datasets.

Roche has a grand vision:

> I'm intrigued by the general trend towards empowering individuals to share their data in a secure and controlled environment. Democratization of data in this way has to be the future. Imagine what we will be able to do in decades to come, when individuals have access to their complete healthcare records in electronic form, paired with high-quality data from genomics, epigenetics, microbiome, imaging, activity and lifestyle profiles, etc., supported by a platform that enables individuals to share all or parts of their data with partners of their choice, for purposes they care about, in return for services they value—very exciting![34]

Sensors and AI platforms can potentially collect *physical biometrics*, such as facial images, iris patterns and heartbeat, and *behavioral biometric data* such as touch dynamics, *keystroke dynamics* and *gait* recognition, voice ID, mouse use characteristics, and signature analysis. These physical and behavioral biometric data can be further analyzed to reveal cognition and emotion (*cognitive biomarkers*). Cognitive biometrics is a novel approach to user authentication/identification and relies on the response of the subject when they are presented with a particular stimulus (for instance a sound) acquired through a variety of techniques such as eye trackers (pupillometry) and electrocardiograms (Palaniappan and Revett 2014). Ultimately quantifying a person's cognitive biometrics will serve the purpose of forming 'digital phenotypes' revealing cognitive and emotional states (Palaniappan and Revett 2014). We see that the dimensionality of data is bigger than it first appears. Data can be subject to multiple independent measurements and can be used for a variety of different purposes, a fact that confers enormous power and a commercial advantage to owners of big datasets and algorithms. The data-generating patents are even stronger than before, as companies not only own data but also the algorithms to mine them.

A potential market where power may be leveraged is drug repositioning, which refers to the discovery of new uses of previously approved drugs and vaccines. Let us take the example of IBM Watson Health. IBM Watson is being used at Memorial Sloan Kettering Cancer Center to support diagnosis and create management plans for patients. To come up with management plans, the algorithm mines medical reports, patient records, clinical trials, and medical journals. What is more, Johnson & Johnson and IBM are using AI to analyze scientific papers to find new connections for drug development.[35] IBM machine-learning algorithms work on vast amounts of observational real-world data accessed through IBM Watson Health, as well as on drug information from pharmacological knowledge bases, such as DrugBank, to test hundreds of candidates for repurposing in various disease domains.[36] Pharmaceutical companies will reinvent themselves and will need to develop IT capabilities or collaborate with the IT companies that will develop the AI tools.

6. Conclusions: from market regulation to the political economy of informational capitalism

The recent caselaw on the distinction between invention and unpatentable laws of nature and natural phenomena, mental acts, and abstract ideas offers a fascinating case study of the function of patents

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as prospects and the role of courts as market regulators. The public domain or commons and intellectual property are not independent realms, but rather intimately intertwined. The phenotype–genotype correlations not only become a shared resource; they also fuel the new inventions in the field of digital therapeutics and the companies offering Big Data and AI analytics are uniquely positioned to take advantage of the opportunities stemming from sharing and openness.

In this sense, there is a lot to be said about the function of patents as a property institution that plays a fundamental role in the political economy of data and knowledge production. Cohen notes that scholarship on the relationship between law and the collection and processing of personal information typically considers such activities as raising problems of privacy or data protection (Cohen 2017), and typically focuses on ways to regulate related activities after collection has taken place. Yet, this view disguises the processes for resource extraction mediated by patents and the ways in which the processing and sharing of personal information in data commons becomes a public domain resource that is there for the taking.

It follows that the division between patentable inventions and unpatenable laws of nature and natural phenomena, mental acts, and abstract ideas is an intriguing distinction showing how a particular society thinks about patterns of resource ownership: what is private and what is common and for what reason. In the case of diagnostics, we see culturally situated ideas about both resource ownership and availability. The cultural construct of a public domain designates data as a resource and suggests ways they can be used to advance data-driven medicine. The commons legitimizes the ensuing patterns of appropriation as patents become artifacts of datafication. At the same time, as a property institution firmly grounded on offering a mere baseline for contractual exchange, prospect patents have very little to say about distribution.

On a more general level, the analysis suggested that intellectual property is not something that follows from openness, a necessary evil or an element parasitically attached to it; it is there from the start and colors the nature of openness. At the same time, if we look inversely as through a mirror, openness may link with a variety of different theories justifying the proprietary. The last point is important: neither the idea of commons nor the idea of private property need to link necessarily to commercialization; private property may be justified according to theories of human flourishing or desert and the commons may link to democratic debate.[37] Our current idea of commons and private property is a particular historical construction reflecting ideas about a particular configuration between markets, data, and medicine. In light of the above, I hope the present analysis contributed to our understanding of the nature of openness and its relation to property arrangements.

Notes

1. *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 566 US (2012); *Alice Corp. v. CLS Bank International*, 573 US 208, 134 S. Ct. 2347 (2014), at 12 (quoting *Mayo*).
2. Since ***Diamond v.*** *Chakrabarty*, 447 US 303 (1980), where the US Supreme Court declared that Congress [US Patent Act §101 on Subject Matter Eligibility] had intended patentable subject matter to 'include *anything under the sun* that is made by man', the patent eligibility test has been given a very narrow interpretation.
3. A real-world example is President Obama's Precision Medicine Initiative in the USA. In 2016, the US Congress authorized $1.455 billion to fund the Initiative. Currently, the All of Us Research Program builds on the latter initiative and seeks to gather data from one million people living in the USA to accelerate research and improve health. Another example is the National Health Service (NHS) England,[3] which has announced that from October 2018 people will have wide access to DNA tests and the NHS will become the first health service in the world to routinely offer genomic medicine. Hospitals will be connected to specialist centres that interpret patient DNA to help diagnose rare diseases and determine best treatment, building on the 100,000 Genomes Project, the DNA sequencing project administered by Genomics England, see NHS England, 'Improving Outcomes through Personalised Medicine' available at https://www.england.nhs.uk/wp-content/uploads/2016/09/improving-outcomes-personalised-medicine.pdf website visited on 27 July 2018; Sample, I. 'Routine DNA tests will put NHS at the 'forefront of medicine' story published in the Guardian on 3 July 2018 available at https://www.theguardian.com/science/2018/jul/03/nhs-routine-dna-tests-precision-cancer-tumour-screening website visited on 27 July 2019.
4. Lemley and Burk (2003) also show how the Federal Circuit has tailored patent rules to boost specific industries such as biotechnology and software. The latter scholars even favor a more intrusive role for courts, suggesting the use of patent law as a policy lever.
5. The discussion on data protection and privacy falls outside the scope of the present discussion due to space limits. Note that one major limitation inherent in private and data protection law, such as the General Data Protection Regulation in the EU, concerns their focus on granting individuals control over inputs of personal data undergoing processing, and granting the right to rectify, block, or erase their data, yet Big Data analytics and artificial intelligence (AI) draw inferences about groups of individuals rather than use personal health information (Wachter and Mittelstadt 2019). For the limits of informed consent regimes, see Cohen (2013). For the problems inherent in granting individuals property rights to their data see Murphy (1996); Barrad (1992); Samuelson (2000).
6. *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012).
7. US Patent Act §101 on Subject Matter Eligibility states that the four statutory categories of invention are Process, Machine, Manufacture, or Composition of Matter and courts have developed caselaw exempting natural phenomena and laws of nature, mental acts, and abstract ideas/as not falling into the statutory categories of invention.
8. *Mayo Collaborative Servs. v. Prometheus Labs*., Inc., 566 US (2012) Opinion of the Supreme Court, on Writ of Certiorari to the US Court of Appeals For The Federal Circuit, at p. 12.
9. *Mayo Collaborative Servs. v. Prometheus Labs*., Inc., 566 US (2012) Opinion of the Supreme Court, on Writ of Certiorari to the US Court of Appeals For The Federal Circuit, at p. 68.
10. *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 788 F.3d 1371, 115 U.S.P.Q.2d 1152 (Fed. Cir. 2015).
11. *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 809 F.3d 1282, 1287 (Fed. Cir. 2015).
12. *Ibid*.
13. *Ariosa v. Sequenom* 788 F.3d 1371 (Fed. Cir. 2015).
14. *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 809 F.3d 1282, 1287 (Fed. Cir. 2015).

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15. Sichelman (2014) traces the 'inventive concept' approach of the *Mayo* test in *Funk Brothers Seed Co v. Kalo Inoculant Co* and warns against the possibility of its expansive application.
16. It is useful to draw an analogy with products of nature to understand the point about rewarding useful inventions. For example, Beauchamp (2013) notes that the doctrine of 'useful difference' in purified natural products essentially made isolated natural substances the subject matter of a valid patent and was established in *Parke-Davis & Co. v. H. K. Mulford Co.*, a century-old decision by Justice Learned Hand. It was decided that an isolated and purified natural substance could be patentable, *so long as the greater utility of the purified* version made it functionally a new thing. The doctrine reflected pragmatism in rewarding useful inventions. Graham Dutfield (2009) further explains that around the time of the decision, the US chemical sector was facing a crisis. Germany's competence was in synthesis while the US excelled at isolation and purification. But as any resulting substances could be very easily reverse engineered, patent protection was thought to be essential to protect from Germans free riding on the US industry's efforts. In other words, by holding that purified adrenaline was different from the natural product because it had new functionality, Judge Learned Hand essentially protected a nascent industry.
17. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, (Fed. Cir. 2015) (Justice Dyk.) at p. 1287.
18. The patent *enablement requirement* refers to the requirement of 35 U.S.C. §112 which requires that the patent specification describes the invention in sufficient detail so that other can make and use it.
19. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, (Fed. Cir. 2015) (Justice Dyk.) at p. 1287
20. This approach challenges the dominant position in the literature is to describe patents and trade secrets as substitutes (companies decide either to patent or protect by trade secrets; also see Sherkow and Scott, forthcoming, where the authors explain that since patent disclosure requirements are not always rigorous, inventors may keep certain aspects of an invention secret, yet still receive a patent to the invention as a whole).
21. The authors explain that traditional defenses in trade secrecy law such as reverse engineering are not applicable which means that trade secrets in data may function as perpetual monopolies.
22. *Mayo Collaborative Servs. v. Prometheus Labs.*, Inc., 566 US (2012) Opinion of the Supreme Court, on Writ of Certiorari to the US Court of Appeals For The Federal Circuit, at pp. 16–19.
23. A separate but related argument for regulatory intervention points to the considerable public financing of discovery of diagnostic technologies, as Universities were primarily the inventors (Ouellette and Weires, forthcoming).
24. Indeed, the similar rationale for denying patent protection to diagnostics can be found in *Alice Corp. v. CLS Bank International*, where the court applied the *Mayo* test to abstract ideas, and like Mayo, called into question the patentability of a large class of inventions, here software.
25. Since 2016, google confirmed that it is removing PageRank from its Toolbar, so people cannot see how their website scored (in a scale between 0 and 10). Ranking will no longer be visible to anyone except Google itself.
26. While *ex ante* justifications of patents are based on the idea that incentives are required for the creation of knowledge, pharmaceutical patents are often described in the economics literature as prospect patents and are justified as providing incentives for the management of knowledge goods *after* they have been created. Prospect or commercialization patents are justified on the basis of *ex post* justifications, see Sideri and Panagopoulos (unpublished data). As Lemley (2004) explains these *ex post* justifications stress the need for incentives to develop, improve, or control overuse of information.
27. Note that for this to happen there are considerable technical problems to be resolved first (Price, forthcoming).
28. System and Method for Predicting and Summarizing Medical Events from Electronic Health Records United States Patent Application 20190034591.
29. *Ibid.*
30. *Ibid.* After *Myriad, Prometheus, and Alice*, types of patents allowed are *Patents for methods plus system* (i.e. a memory and a processor) see https://www.uspto.gov/web/patents/classification/uspc706/defs706.htm
31. https://verily.com/projects/ website visited on 29 August 2019.
32. Patent US20150238636A1for 'Engineered particles with polarization contract and alignment control for enhanced imaging number'.
33. On using AI and Data Analytics in Pharmaceutical Research. Interview with Bryn Roberts by Roberto V. Zicari on 10 September 2018 available from ODBMS Industry Watch Trends and Information on Big Data, New Data Management Technologies, Data Science and Innovation at http://www.odbms.org/blog/2018/09/on-using-ai-and-data-analytics-in-pharmaceutical-research-interview-with-bryn-roberts/ website visited on 13 July 2019.
34. *Ibid.*
35. https://www.ibm.com/watson-health/learn/artificial-intelligence-medicine website visited on 13 July 2019.
36. https://www.research.ibm.com/haifa/dept/vst/mlhls_drugrep.shtml website visited on 13 July 2019.
37. For example, open source promotes a form of openness that is based on the motivation to improve one's coding skills and be part of a community (Benkler and Nissenbaum, 2006); Carol Rose (1986: 779) explains that the commons can be about recreational play: Like commerce, then, recreation has social and political overtones. The contemplation of nature elevates our minds above the workaday world, and thus helps us to cope with that very world; recreational play trains us in the democratic give-and-take that makes our regime function. Elizabeth and erson highlights the potential of democratic debate, see Elizabeth Anderson, 'The Ethical Limitations of the Market' Economics and Philosophy 6 (2):179 (1990); For a real-world experiment, see DECODE project in Europe https://decodeproject.eu/.

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