The Ethical Ramifications of the Commodification of DNA

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Henrietta Lacks attended an appointment at Johns Hopkins in 1951 to address health concerns. Sample cells were taken from her cervix during a routine examination, and she was subsequently diagnosed with cervical cancer. These cells were studied and her DNA was sequenced without her knowledge. Studies conducted on her biospecimens demonstrated a unique quality of her cells which enabled them to grow and replicate in a culture outside the body. This phenomenon had not been witnessed prior to the study of her cells, commonly referred to as "HeLa cells", making them of particular interest to researchers.

For decades, her cells were widely distributed for study without her consent, and in 2013 her DNA was posted publicly. According to the US Department of Health and Human Services (HHS), 110,000 research articles have cited the use of HeLa cells between the years 1952 and 2018. The biomedical research conducted has ranged from studies on cancer therapeutics, drug discovery, and imaging to investigations of how human cells would respond to space travel. Some HeLa cells were even sent to space in 1964 (HHS, 2018). After her death, her family continued to live in poverty, experienced low access to healthcare, and never received financial benefits for the contributions of HeLa cells to modern medicine (Skloot, 2010).

The exceptional case of Henrietta Lacks has served as a basis for the discussion of equity in the use of human biospecimens in research in recent years (Beskow, 2016). Growing computing power in the past two decades has enabled vast amounts of data to be collected and stored. As DNA data being collected, stored, and analyzed increases so too does the potential for the abuse of power seen in the Henrietta Lacks case occurring on a mass scale. Through the lens of techno politics, I will analyze the collaboration of DNA testing companies and pharmaceutical

companies as DNA has become an increasingly powerful commodity in US markets. The work will also investigate the roles of biotechnology companies, governmental bodies, and consumers toward the commercialization and patenting of genetic material and related research. The idea of ownership of one's DNA as it relates to individual rights and research will be explored.

Patents on Genes: The Myriad Case

Tackling the issue of biospecimen utilization for research and commercial purposes has been a hot topic in the biotechnology sphere for some time now. The implications of recent court rulings as well as advances in contemporary technologies are continuously being assessed and still remain to be seen. Shobita Parthasarathy's extensive work with patents explores the way patents and biotechnologies coalesce. *Patent Politics* employs a technopolitical framework to analyze the influence of patent systems in the United States and Europe on their respective markets in biotechnology. She contends current U.S. court rulings have favored the patent system for altered ("not natural") genes which in turn has complicated the fight for legal rights surrounding genetic data initiated by the ACLU and other institutions (Parthasarathy, 2017).

The piece of Parthasarathy's work most relevant to the purpose of this paper is the section which breaks down the responses and actions of stakeholders in biotechnology to Myriad Genetics' patenting of BRCA-1 and BRCA-2 genes from the mid-1990s to the early 2000s. BRCA genes are genes that serve as markers for increased susceptibility to breast cancers and ovarian cancers. Myriad Genetics was the first entity to uncover the precise location of the BRCA genes in addition to their nucleotide sequence. From these findings, genetic tests were developed to detect mutations leading to higher risks of cancer, and the company became the supplier of these types of tests (Cartwright-Smith, 2014). Alarm bells were already going off

among certain groups about the patenting of human material; the ACLU, groups of scientists and researchers, healthcare professionals, and women's healthcare advocates among them. These groups claimed that such patents stifled innovation and enabled Myriad to obtain what was essentially a qualified monopoly over BRCA testing, jeopardizing access to affordable, accurate genetic tests (Parthasarathy, 2017). Both patent lawyers and biotech companies defended the patent.

After multiple court proceedings and rulings, the dilemma culminated in the 2013 Supreme Court ruling of *Molecular Pathology v. Myriad* which ruled against Myriad's right to patent the BRCA genes. Isolated human genes could not be patented as they were considered products of nature. Due to concerns about the validity of the case, the approach to the lawsuit against Myriad was primarily focused on arguing the violation of said doctrine rather than addressing any of the policy or monopolistic worries surrounding the patent. The ruling also notably left room for cloned DNA (cDNA) to be patented (Parthasarathy, 2017). Both of these details are crucial as they have colored the legal approach to patentability of genetic technologies in recent years.

Generally, critics of the patent system have pointed out its inability to account for distributive concerns; all of the moral, economic, and social arguments against a patent are essentially ignored. The patent system's approach to genetic material and research methodology is evolving and is a key factor in determining the future of ownership and control in genetics. Parthasarathy's work has guided my own work in examining DNA data's fate through the technopolitical structures that govern the genetic market.

Neoliberalism and the Bioeconomy

An inspection of the cultural and economic perspectives contributing to the rise of biotechnologies is prudent as they have ushered in a wave of powerful stakeholders in the genetic market today. The patterns in patenting lend themselves to these structures. Neoliberalism is defined as a political approach with an emphasis on the deregulation and minimization of governmental bodies that allows for a partially free-market system. As the dominant political ideology in the US, neoliberalism has resulted in a dynamic wherein the government generally prioritizes the interests of the private sector in lieu of communities. The United States' techno-positive culture and desire for global prestige only stands to exacerbate this phenomenon in the biotechnological sphere (Meghani, 2017). The bioeconomy refers to the sector of industry that depends on biological resources to generate goods and services. Birch (2006) attributes the expansion of the bioeconomy not to biological and genetic developments, but instead to neoliberalist ideologies. The small biotech firm is more capable of receiving attention and funds than other firms because their technological discoveries generate higher returns for investors. Drugs and other medicinal discoveries are a matter of life and death and are thus valued much higher than progress in other areas.

Understanding the dynamics of the bioeconomy lays the groundwork for analyzing the business models of emergent genomic testing companies. Biotech start-ups centered on genomics have been sprouting up all over Silicon Valley in the past decade. The specification of Silicon Valley here is important as the business models of emergent firms follow the archetype of tech start-ups in the area which are heavily funded by venture capitalists (Hogarth, 2017). The majority of these start-ups make promissory claims and have far-reaching projections for their technologies, establishing a high risk for either disappointment or failure. Even so, money is

continuously funneled into these start-ups by investors. The model only works in the context of the current bioeconomy and its neoliberalist underpinnings.

Money is transferred from venture capitalists to small biotechnology firms based on the pitches they present on their ideas. In some cases, the technologies haven't come into fruition yet when millions or billions of dollars are invested (Hogarth, 2017). A populace and a market that crave developments in preventative medicine allow for this to occur. When the initial ideas of the firms don't pan out, they have to scramble to tap in to market needs in new ways. The main takeaway from this is biotechnology firms, specifically direct-to-consumer (DTC) genetic testing firms, are based in speculative markets. Due to their nature, they are subject to great transformations in policy and implementation to remain financially viable and appease investors.

Regulations on Genetic Material

The patenting of the human genome and other biospecimens is a mere portion of the regulatory practices in genomics dictated by both culture and widely held economic values. With the rise of genomic sequencing services in the past decade, several regulations have been enacted. The Common Rule set by the HHS dictates protocol for human subject research receiving funding from US federal departments. Beginning in 2017, it was revised to adjust its definition of biospecimens for determining whether they count as human research subjects, which changes the informed consent requirements (Koch et al., 2018, pp. 101-107). The reworking of the Common Rule notably green-lights the use of biospecimens that have been de-identified and thus do not require informed consent (Koch et al., 2018). The policy leaves room for a significant gray area since whether de-identification of DNA is actually possible is contested. It instead calls on researchers and other agencies to review the extent to which information can be de-identified every four years. Companies that are not receiving funding from

federal departments do not need to follow these guidelines, though it is still good practice to adhere to them. Regulations pertaining to the storage of biospecimens and research using them are seemingly insufficient.

Along with concerns about obtaining consent for research, the issue of data privacy is a main concern in the rise of DTC genetic testing services. Currently, there is no overarching regulation in the US concerning data privacy. Corporations are free to collect data on consumers as they please and sell said data to third parties. States have decreed their own limits on data sharing (Klosowski, 2021). The majority of these legislative actions still allow for data sharing, but have caveats about obtaining consent from individuals. Disjointed legislation prompts confusion from both corporations and consumers. Having to check a box of consent to utilize services becomes tedious for the consumer, and they are unlikely to research deeper into the practices of the company (Phillips, 2017). Corporations can count on individuals not doing their due diligence to protect their privacy. Legislative bodies have failed to account for this factor, and in general have struggled to keep up with the expanding market for data.

Essentially, DTC genetic testing companies are free to sell individual's data to third parties at their whims and, so long as they have checked a box giving consent, research can be conducted on the individual's data. A key to addressing ethical dilemmas in genomics, is acknowledging how the same red flags being raised in privacy and security for general big data in technology are present in these firms. In popular Silicon Valley tech trends, information collected and stored on individuals serves as the main source of revenue in exchange for the use of services by the consumer. The impetus is placed on the individual to protect themselves from exploitation. With a complex, expensive healthcare system, the US individual is placed in a

precarious position against powerful biotechnology corporations bolstered by national economic desires and inadequate governmental regulation.

Current Trends in Genetic Testing

The premise for this paper's analysis rests on the notion that pharmaceutical companies are currently purchasing DNA data from private companies that offer genome sequencing services. The growing allegiances between DNA data collectors and the pharmaceutical companies that bid on them can be visualized in the graphic of Figure 1 (Roland, 2019).

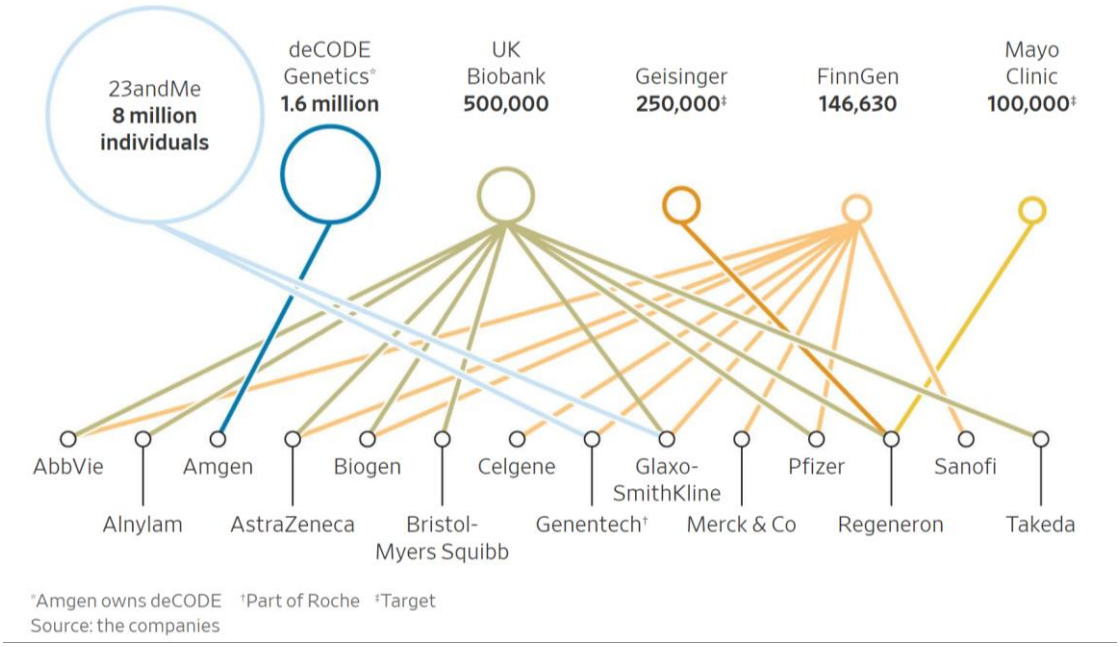


Figure 1. Selected genetic databases and their industry partners.

These partnerships are a natural progression as companies with stores of consumer DNA data are incentivized to profit off of the DNA data they collect while pharmaceutical companies are compelled to purchase DNA data for drug research.

The shift in DTC genetic testing companies' business models to include distributing data for research is due in part to lower participation than anticipated from the public in buying DTC tests. The nature of the firms as investments of venture capitalists explains the need for these corporations to quickly pivot their attention toward other revenue streams (Hogarth, 2017). The businesses are subject to the whims of the market, and once they own someone's data, it is difficult to determine exactly where that data may go in the future.

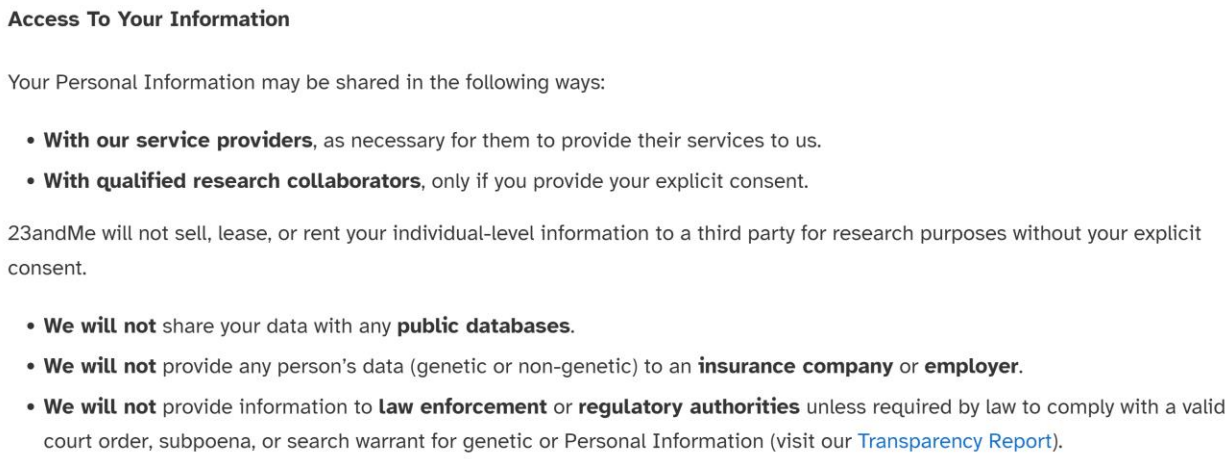
Still, there are certainly potential benefits from these connections. There has been a paradigm shift in drug development in the past fifteen years thanks to the employment of a big data approach capitalizing on the enrichment of several electronic databases (Kim, 2016). The interest in drug development demonstrated by DTC genetic testing companies stands to accelerate the rapid growth in databases being witnessed. The increased volume of data for research indicates great strides in precision medicine are on the horizon.

While this news is promising for the future of medical care, the potential sources of new research and breakthroughs in the field warrant some hesitation. For starters, the patent system and its regulation are lagging behind the progress being made in research. It is nearly impossible for the court systems and legislative bodies to keep up with the ever-expanding reach of big data. Additionally, based on the patent case regarding Myriad Genetics, a similar legal battle could ensue with patents submitted by pharmaceutical companies for drug therapies created with DNA from genetic sequencing companies. It is highly likely that opponents of the prospective patent would have a difficult time arguing against it in terms of the adverse effects to healthcare or other moral quandaries. This sort of trouble building a legal case against a patent on moral principles is common in the US.

As such, pharmaceutical companies could have their patents approved, capitalizing on the cDNA loophole, and legally become the sole providers for their novel drug therapy. Consumers could then struggle to pay the price for the therapies set by pharmaceutical companies. Lower income individuals or those without insurance are the most vulnerable to limited access to life saving drug therapies.

Consumer Awareness and Informed Consent

Returning to the Henrietta Lacks case, the equity in the utilization of DNA collected by private companies and destined for inclusion in research projects to develop medicines must be discussed. Taken from the Privacy Policy of the well-known DNA sequencing company 23andMe, Figure 2 illustrates how the company offers some transparency to consumers about where their DNA may end up (23andMe, 2022).



Access To Your Information

Your Personal Information may be shared in the following ways:

- **With our service providers**, as necessary for them to provide their services to us.
- **With qualified research collaborators**, only if you provide your explicit consent.

23andMe will not sell, lease, or rent your individual-level information to a third party for research purposes without your explicit consent.

- **We will not** share your data with any **public databases**.
- **We will not** provide any person's data (genetic or non-genetic) to an **insurance company** or **employer**.
- **We will not** provide information to **law enforcement** or **regulatory authorities** unless required by law to comply with a valid court order, subpoena, or search warrant for genetic or Personal Information (visit our Transparency Report).

Figure 2. Excerpt from the 23andMe Privacy Policy

Further exploration of comparable companies revealed privacy policies with almost identical messages. Transparency about the sale of DNA to pharmaceutical companies or third parties is certainly a step in the right direction for DTC genetic sequencing companies. However,

policies like this one provide consumers with a false sense of ownership and control over their DNA.

A wall of fine print accompanies the broad policies outlined by 23andMe and other DTC genetic testing companies. For example, 23andMe's terms of service is an astounding 9081 words long, and it accompanies a 15,807-word privacy statement (Phillips, 2017). With lengthy terms and conditions, actually reading the fine print would be an onerous task for consumers. The alternative option for consumers is to not consent. However, the majority of consumers are obliged to agree as they would rather have their biospecimens contribute to a burgeoning field of study than protect their privacy. This phenomenon also lends itself to the culture surrounding neoliberalism as well as the hype around the biotechnological sphere. Overall, the methods for garnering consent for data usage by DTC genetic testing companies has been found to be unsatisfactory (Koch et al., 2018, pp. 114-117). The practically automatic engagement with contracts described previously is at play in this situation. The lack of transparency resulting from these types of contracts is worrisome for consumer knowledge of where their DNA has gone. The biotechnological framework with changing market needs and speculative investments increases the likelihood that DNA will be shared with unexpected agencies. A consumer will never be informed of these transactions.

DTC genetic testing providers are the gatekeepers to insurmountable amounts of genetic data. They have elected to share data with pharmaceutical companies and, on occasion, public researchers. In both cases, research incentives are able to bypass traditional patient consent schemas by receiving data from DTC genetic testers. Pharmaceutical companies are entities whose main incentive is increasing the profit margin. This calls into question the altruism of their research efforts surrounding the human genome. In the research being conducted, profit

incentives could take precedence over universally beneficial outcomes. Monopolistic desires could lead to price increases capitalizing on the urgent needs of patients.

Discussion

The dynamics of a neoliberal economy, patents, regulatory practices, and current industry trends culminate in a new and exciting market for genomic sequencing and testing that is difficult for consumers to navigate. In order to conceptualize what is currently at stake in the presiding sociotechnical system of the United States consider the following scenario:

John decides to submit his DNA to be sequenced by Company A out of sheer curiosity. Without thinking much about it, he checks yes on the form asking if he consents to his data being used in research. Company A then proceeds to sell his DNA in a dataset to a pharmaceutical company, Company B. In their research procedure, Company B makes a slight modification to John's DNA that enables them to find a viable gene therapy method in the treatment of cancer. Company B may patent and profit millions off of a slight change made to John's DNA. Meanwhile John gets his sequencing results back, discovering he is destined to get cancer. John may never know how influential his DNA has been and may pay hundreds of thousands of dollars on a treatment that only exists because of his miraculous DNA.

The practices of both Company A and Company B are particularly exploitative and should be concerning to everyone, not just those who willingly decide to submit their DNA to private entities.

This paper offers a broad overview of the ethical dilemmas in genomic data handling by DTC genetic testing companies. It is intended to be a concise summary of a convoluted area of

study to deliver a cautionary message to consumers. Discussions about genomic privacy and biospecimen patentability and use in research will continue to evolve as the market changes.

Considering current trends, individuals who submit their DNA to a company collaborating with a pharmaceutical company are more likely to be unbeknownst to any usage of their DNA, than they are to receiving any direct benefit for their contributions. A consumer's DNA could be employed to generate a drug therapy by a private company eventually receiving a patent for the therapy that contains parts of the consumer's DNA. A pharmaceutical company would then gain ownership over the DNA of an individual. Ultimately, the search for ways to produce genetically based knowledge that is collectively beneficial without being extractive must be pursued.

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