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23 and Me, We and You: direct-to-consumer genetics, intellectual property and informed consent.

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In May 2012, direct-to-consumer genetic testing company 23andMe announced that it had obtained a United States patent for a method of determining predisposition to Parkinson disease. (1) Although the company treated the announcement as a positive development it did not receive unqualified approval. Instead, 23andMe's venture into the world of protecting intellectual property derived from medical research stressed an increasing area of tension in the nexus of the clinical, the commercial and the exploratory. There has been considerable controversy in the past around the use of genetic samples in research; (2) while the format may have changed with 23andMe's foray into genetic research, the issues have not.

23andMe has been open about its research arm, 23andWe, which conducts research on genetic data derived from sequencing customer samples coupled with follow-on surveys about health and lifestyle. (3) However, the extent to which customers are aware of what this research entails - and how the results will be distributed - is unclear. "I had assumed that 23andMe was against patenting genes and felt in total cahoots all along with you guys," one user wrote on the company's blog. "If I'd known you might go that route with my data, I'm not sure I would have answered any surveys." "It seems the ethics of one company profiting from the knowledge of others because it patented a gene variant could do with some scrutiny," wrote another "especially if it turns out that patients, who provided samples for the original research, were not made aware that the results would be patented." (1)

23andMe has stated that its motivation in obtaining the patent is to encourage translation to the clinic. (1) Regardless, commercial test providers and hopeful for-profit research institutions may have lessons to learn from the experience of public institutions in genetic research. There is a history of individuals and groups objecting, both morally and legally, when their genetic information is used to enrich or benefit someone else, especially without their knowledge. In *Greenberg v. Miami Children's Hospital Research Institute, Inc*, for instance, the parents of children with Canavan's Disease sued the research institute after it used their children's tissue samples for research on the causes of Canavan's and patented the results. The successful claim on the intellectual property of the resulting genetic test

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included the ability to control the cost of the test and collect royalties from other entities that wished to conduct research or develop competing products. The understanding of the families had been that "any carrier and prenatal testing developed in connection with the research for which they were providing essential support would … remain in the public domain to promote the discovery of more effective prevention techniques and treatments." (4)

A key component of cases like *Greenberg* is knowledge: the knowledge of what researchers and their institutions intend to do with your genetic information, especially if what they intend to do is attempt to profit from it. Many people are genuinely in favor of medical progress, but biomedical research is heavily predicated on trust. Potential donors need to feel that scientists and doctors are capable of dealing fairly with those who entrust them with intimate physical and medical information about themselves. (5) Outrage and betrayal frequently result when expectations and reality do not mesh, particularly among patient populations with a strong stake in the outcome of the research in question, such as patient's families, (6) or historically disenfranchised populations who have experience with negative interactions with formal institutions.6 The concern, bolstered by falling research enrollment rates, is that this lack of trust translates into an avoidance of research participation. (7)

From the perspective of researchers, participant misunderstanding is rarely the result of willful deception. In the US, the passing of the Bayh-Dole act has created an atmosphere in which publicly-funded research institutions are pushed to commercialize inventions that originate from federally funded research. The Act also grants the intellectual property to the research institution rather than the funding agency. (8) The idea is that revenues from successful commercialization will, in turn, fund future lifesaving research. The fact that 23andMe is a for-profit institution increases the pressure to pursue the potentially revenue-generating course of patenting research discoveries. And from the perspective of the company, acquiring these patents prevents other companies from taking a more protective stance towards the same research.

In this environment, the obligation to obtain informed consent from participants has generally been reduced to disclosure. 23andMe's online consent form does inform customers that commercialization may occur, (1) but based on the reaction of its community members, simple disclosure does not appear to relieve the burden. At least from the perspective of some participants, it may appear that the company is trying to profit off its customers twice: once when it sells them a test and again when it patents information obtained from the results. 23andMe's site does not mention the word 'patent' nor how the company intends to defend its intellectual property rights against researchers or pharmaceutical companies. Nor does the consent make explicit that participants will not receive any benefit from the resulting intellectual property. Like the families in *Greenberg*, participants may reasonably figure that their participation in research, particularly disease-specific research, entitles them to a share in the results, whether in the form of financial compensation or special access to any treatments that may ultimately result. Lack of discussion of these issues means that if customers, like those above, have objections to the idea of gene patenting and exclusive licensing, they have no opportunity to make an informed refusal.

It seems clear that commercial genetics companies will need to devote more attention to ensuring that their customers are fully aware if the company intends to retain and to conduct research on the data from customer samples and claim intellectual property of the results. (3) This would start with being more forthcoming about their intentions towards research done with customer samples. Voluntary research participation is the cornerstone of modern bioethics and goes to the core of what we value of individual self-determination and respect. It is not enough to say that what participants don't know won't hurt them - it is unlikely that any direct benefit or harm will ever revert to a tissue donor based on the genetic research or intellectual property based on their samples. But from an ethical perspective, it is possible to violate someone's autonomy even if the individual doesn't know you are doing so. (9) If one is going to conduct human subjects research then one must follow the principles of ethical research conduct, including informed consent, whether the research is in an academic university, a hospital or a commercial testing facility.

Aside from the ethical, there are practical considerations. Companies like 23andMe are engaging in a trade: information about your genetic makeup in return for the use of your genetic material for research, publication and patenting. This is similar to the trade that academic researchers sometimes offer except that in the case of 23andMe, the research participant pays for the privilege. Indeed, 23andMe has recently announced expanded partnerships with biotech firm Genentech to enroll participants in clinical trials and it is highly likely that Genentech intends to patent any successful results. (10) But, like the academic research community before them, commercial entities that fail to ensure honest and open communication with their customers about their true intentions and motivations may find it increasingly hard to build up biobanks with the number of samples needed to do genuinely useful research. As evidenced by the ongoing litigation against Myriad Genetics, opinions differ on whether gene patenting is either legal or ethical. (11) But there is considerably less debate over the need to respect the individual rights and autonomy of those on whom the future of biomedical research depends. For profit, no less than non-profit, institutions should remember that.

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