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"Trust is not something you can reclaim easily": patenting in the field of direct-to-consumer genetic testing

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Purpose: Recently, 23andMe announced that it had obtained its first patent, related to "polymorphisms associated with Parkinson's disease" (US-B-8187811). This announcement immediately sparked controversy in the community of 23andMe users and research participants, especially with regard to issues of transparency and trust. The purpose of this article was to analyze the patent portfolio of this prominent direct-to-consumer genetic testing company and discuss the potential ethical implications of patenting in this field for public participation in Web-based genetic research.

Methods: We searched the publicly accessible patent database Espacenet as well as the commercially available database Micropatent for published patents and patent applications of 23andMe.

Results: Six patent families were identified for 23andMe. These included patent applications related to: genetic comparisons between grandparents and grandchildren, family inheritance, genome sharing, processing data from genotyping chips, gamete donor selection based on genetic calculations, finding relatives in a database, and polymorphisms associated with Parkinson disease.

Conclusion: An important lesson to be drawn from this ongoing controversy seems to be that any (private or public) organization involved in research that relies on human participation, whether by providing information, body material, or both, needs to be transparent, not only about its research goals but also about its strategies and policies regarding commercialization.

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INTRODUCTION

In recent years, direct-to-consumer (DTC) genetic testing companies have been advertising and offering genetic tests directly to the public.[1] Some have sought to increase the value of their "biobanks" by asking customers to provide phenotypic information.[2] Various commentators have described participant-centric research initiatives, common features of which include voluntary and active participation, use of social media technology, active interaction between participants and researchers, and the appeal to promote public goods (e.g., scientific progress).[3–5]

23andMe is a DTC genetic testing company that provides its consumers with the opportunity to consent "to the use of their data for research."[6] Consumers are "given the option of contributing phenotype data via a series of Web-based surveys. The result is a single, continually expanding cohort, containing a self-selected set of individuals who participate in multiple studies in parallel."[6]

Within participant-centric research, 23andMe has focused on genetic and phenotypic correlations with Parkinson disease (PD), sarcoma, and myeloproliferative neoplasm.[7] 23andMe states on its website that letting consumers participate in research in this way "can produce revolutionary findings that will benefit us all," stimulating consumers to "direct research by participating in studies of conditions and traits you care about," and to "join an effort to translate basic research into improved health care for everyone."[7]

These encouragements to customers to advance research for the public good, however, stand in contrast with 23andMe's announcement on 28 May 2012 that it was to be granted a US patent—patent 8187811, for "polymorphisms associated with Parkinson's disease"[8]—the very next day. CEO Anne Wojcicki announced on the company website ("The Spittoon") that the goal of the patent was to ensure that the underlying research could lead "towards successful translation of this discovery."[8]

The announcement immediately sparked controversy on the Spittoon website among users and participants, with comments on many topics: the patentability of genes; the link between patents and medical advances; 23andMe's potential (ab)use of the patent, e.g., to charge royalties or block the performance of PD genetic tests; the lack of communication of 23andMe on its intention to patent discoveries; and the mismatch between applying for patents and the avowed mission of democratizing genomics.[8] These reactions suggest that the knowledge that 23andMe had sought a patent based on its participant-centric research could undermine trust in the company.

A major criticism concerned the lack of transparency regarding any intention to patent discoveries related to PD. Therefore, we aimed to study which patent applications have been filed by 23andMe. This article presents the results of an analysis of the company's patent portfolio and discusses some of the potential

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ethical implications of patenting in the context of public participation in Web-based genetic research.

MATERIALS AND METHODS

We searched the European Patent Office's database Espacenet and the commercial database Micropatent for published patents and applications that showed 23andMe as the applicant or patentee. Espacenet provides access to more than 70 million patent documents. Our search revealed patents and applications accessible on 1 September 2012. Applications filed less than 18 months before, or filed independently by other companies working with 23andMe, would not have been revealed. We examined patent "families," which contain patents and applications related to a single invention. For each family, we provide the following basic information: priority application filing date, patent or application publication numbers, and a summary of the broadest method claims.

RESULTS

Six patent families were identified (**Table 1**). Although our focus is on the PD patent family (family 6), this has not been 23andMe's only foray into patenting. Obviously, for a company involved in DTC genomic testing, it is reasonable that, without customer consent, they might seek to patent improvements in sample handling, sample testing, data analysis, and data presentation. Patent families 1, 2, 3, and 5 seem to fall in these categories. Family 4, which is concerned with a method of selecting a sperm or egg donor to maximize the chances of having a baby with desired phenotypic characteristics, raises many ethical questions but is not founded on participant-centric research and will not be commented on further here.

The international application in patent family 6 ("polymorphisms associated with Parkinson's disease") includes a claim directed to a method for screening a human subject for susceptibility to PD based on the determination of certain alleles. The nucleic acid primers or probes used in such analyses are claimed, as is a kit for assaying for PD susceptibility. In another claim (claim 10), however, we see 23andMe seeking to cover possible downstream inventions in PD therapy.

DISCUSSION

Intellectual property (IP) protection is a well-established practice that aims to promote technological progress and investment. Patenting is common practice for any technology-based industry, but in the (bio)pharmaceutical sector, patents are considered vital, for example, to raise venture capital or justify further investment and as a way to transfer results of publicly funded research to commercially viable applications.[9–11] Although in the context of genetic diagnostics, patent offices have granted several patents of doubtful and disputed validity,[9–12] the mere fact that 23andMe has participated in IP-protecting activities since 2007, shortly after it was formed, seems quite normal.

Although 23andMe has filed various patent applications, until now it has only drawn the attention of its consumers to

Table 1 23andMe's patent families published by 1 September 2012

Family no.	Earliest priority date	Patent/patent application publication nos.	Summary of the broadest method claim
1	15 October 2007	WO2009/051749; US-A-2009/118131	A method of comparing genetic information from a grandparent and a (presumed) grandchild involving calculating the similarity of the two sets of information and displaying this graphically and in color.
		WO2009/051766; US-A-2009/119083	A method of comparing genetic information from two individuals involving comparing their genetic information and displaying this graphically using different symbols to represent genes that are identical and those that are "half"-identical.
2	15 October 2007	WO2009/051768; US-A-2009/112871	A method of sharing data between two data records that involves, on request from one data record holder, providing read-access to that requestor to selected data areas of non-public data from the other record.
3	26 August 2008	WO2010/024894; US-A-2010/057374; US-A-2010/057807	A method of providing a merged genetic information data set for an individual that consists of merging two or more genetic data information data sets for that individual and deciding, where there is a conflicting overlap, which input to use.
4	05 December 2008	WO2010/065139; US-A-2010/145981	A method of identifying a preferred gamete (sperm or ovum) donor to achieve a desired phenotype in the offspring of a particular recipient and a donor, by comparing the genetic data of the recipient and those of a set of possible donors and selecting the donor whose gametes are most likely to combine with those of the recipient to produce offspring with the desired phenotype.
5	31 December 2008	WO2010/077336; US-A-2010/223281; EP-A-2370929	A method of determining a relative relationship between two individuals that includes comparing genetic data for the two, calculating a predicted degree of genetic relationship between the two, and advising one if the other individual is likely to be a relation.
6	30 November 2009	WO2011/065982; US-A-2011/130337; US-B-8187811; CA-A-2782207	A method of screening an individual for susceptibility to Parkinson disease that includes determining whether the individual's DNA has particular abberrations (single-nucleotide polymorphisms) at one or more of seven specific locations.

one patent case.[8] Moreover, the communication was made the day before the US patent was granted, even though the initial application was filed in 2009, and the research results were published in *PLoS Genetics* in 2011[6] and then rapidly drawn to the attention of its consumers. The delay in drawing attention to the patent application seems odd, given that 23andMe even recently underlined that "open dialogue about complicated issues like patents is important" and that it wanted to be "as open as possible about our intentions, including letting people know about our patent and why we have filed it."[8]

How likely is it that these events might result in a loss of trust, and why is the issue of trust relevant in the first place? It seems that the strong position 23andMe has enjoyed so far in motivating customers to participate in research by providing phenotypic data may be weakened. Presumably motivated at least in part by altruism, paying customers have contributed to an increase of the informational value of the company's database by providing data. Altruism, confidence in scientific progress, and trust in research and researchers are quite common persuaders to induce participation in biobank research.[13] Studies[14–18] have shown that individuals donating biological samples and phenotypic information consider this to be an altruistic act. More relevant in this context is the importance of the donors' trust in the research and researchers, and the reputation of the entity planning the research.[14,15,18] 23andMe appears to have been successful in meeting these expectations. The fact that it provides participants with their personal genetic information may also be a strong motivating factor.

Now that it is clear that 23andMe is seeking patents, it is possible that various customers will withdraw their support because they do not consider such activities to be in line with their altruistic participation in the research projects. As one customer wrote on 23andMe's blog after the announcement of the patent: "this is simply crowd-sourced greed. As a longtime 23andMe customer, this patent is extremely disappointing and alarming. Our family is done with your service."[8]

In the context of biobanks, it has also been reported that donors are concerned with social fairness. Studies[19–23] have shown public distrust of for-profit companies in the context of biobanking, as many participants consider a profit motive to be at odds with their altruistic aim in participating. The point is not that there is anything inherently wrong in making a profit or using DTC genetic testing to create revenues, but rather that this may be perceived as conflicting with the open, altruistic, science-driven, and common-good image that 23andMe has clearly been trying to create. As one correspondent commented: "I would not have talked my mother and others in my support group into participating if I had understood this was going to be a profit-driven enterprise. I believe 23andMe has been disingenuous in gathering a free database."[8]

This is not a case of 23andMe failing to meet the explicit expectations of participants; it did (by finding the biomarkers). Rather, this is a case of promising to build something with communal resources, building it, and then claiming ownership and (potentially) charging for access. The implied suggestion that the result would be a community good was misleading. An analogy might help: a company in a village next to a river says: "the village needs a bridge, give us the wood and we'll build it"; the wood is given; the bridge is built; but the company charges a toll. In both cases, the contributors (the research participants/villagers) did not realize that contribution did not guarantee public ownership. The fault lies not in 23andMe/the builder owning the result, but in the lack of transparency in the appeal for the necessary contributions. The contributors did not understand what was going on until after their contribution was made, and, had they understood, many might not have contributed. Having been misled, contributors may in the future be less likely to contribute to the attainment of public goods, fearing that they might not be public after all, which, in turn, might lead to a more morally impoverished community.

The trust issue is not only related to the nature of the goals the company is pursuing (profit driven or not), but also to the extent of transparency surrounding the company's strategies. As far as the latter is concerned, the question of whether the participants had given truly informed (and thus valid) consent is clearly regarded as crucial by various correspondents. For example: "It would seem that the ethics of one company profiting from the knowledge of others because it patented a gene variant could do with some scrutiny, especially if it turns out that patients, who provided samples …, were not aware that the results would be patented."[8]

23andMe responded as follows to this comment: "We make reference to our intent to pursue intellectual property rights for discoveries made from our research in both [our] terms of service … and in our research consent document …."[8] The relevant passages from the terms of service and consent documents mention that 23andMe might develop intellectual property and that participants have no right to share in any profits. The terms of service state: "By submitting … user content, you give 23andMe … a perpetual … license to … create derivative works from any user content you submit …. You acquire no rights in any research or commercial products that may be developed by 23andMe …. You specifically understand that you will not receive compensation for any research or commercial products …."[24] The consent document provides: "If 23andMe develops intellectual property and/or commercializes products or services, directly or indirectly, based on the results of this study, you will not receive any compensation."[25]

However, the word "patent" itself is only used in the context of information presented to the users. As stated in the terms of service: "You agree that 23andMe … own all legal right, title, and interest in and to the services, including any intellectual property rights which subsist in the services …. You further acknowledge and agree that the services … contain proprietary and confidential information that is protected by applicable intellectual property … laws. You further acknowledge and agree that information presented to you through the services … is protected by … patents …."[24]

The wording used by no means makes it clear that patents would be sought for the research results. Various users indicated

that they were unaware that 23andMe was planning to apply for patents, whereas, as noted by one of the bloggers: "everyone coming to [23andMe's] service, either by paying it or by funded invitation … needs to know clearly what this is about and make their own informed decision to join or not."[8]

Based on these reactions, it is clear that the consent procedure currently used is ethically inadequate,[26] especially in relation to patents. The reactions to the PD patent show the limitations of the use of a vague and unclear consent when there are potential commercial applications. We do not suggest that 23andMe has done the research without consent; rather the issue is whether the consent extended to cover the patenting of results. Participants may consent to donate biological materials and phenotypic data for the development of clinical applications. However, if they are not aware that this might be happening through commercialization involving patents, this might undermine the original trust and show the original consent to be invalid since participants were not told clearly "what it was about" and hence were not able to make "their own informed decisions to join or not." These words, of one of the contributors to the blog reacting to the PD patent, illustrate the core ethical idea underlying consent. Although it may be impossible to inform people of all possible research uses of their material or data, the consent document should contain sufficient and adequately clear information to allow the individual to decide whether the project accords with her moral values and aspirations. Put more generally, consent serves to respect and promote the autonomy of people considering whether to participate in research.[26]

The reactions of various 23andMe users and participants suggest that this requirement was not met. This is problematic because it may result not only in a loss of trust, but also because it contravenes the principle of non-instrumentalization. As argued by bioethicist Julian Savulescu with regard to the use of leftover body material: "To ask a person's permission to do something to that person is to involve her actively and to give her the opportunity to make the project a part of her plans. When we involve people in our projects without their consent, we use them as a means to our own ends."[27] The reason why participants may perceive a research project as conflicting with their moral values may relate specifically to its commercial or IP aspects.

Despite 23andMe's emphasis on the participant-driven nature of their research, it seems that its strategy regarding the PD project is not based on a true, well-informed involvement of the participants. As observed by one user: "Stating that "it is written in sections 13 and 22 and sections 3 and 5 that people signed" is not close to a decent answer to people you asked for partnering with you to advance research on PD. A company can be for profit or for social profit. You have the right to choose any form you like …, but please make it clear. If you choose to be for profit only, I don't think you used the right messaging to call for participation of people … And remember you can only play it once. Trust is not something you can reclaim easily."[8]

Obviously, informed consent remains an imperfect tool to protect participants from being harmed.[28–30] For example, participants do not always read informed consent forms, and even those who do frequently do not understand.[28] Moreover, many people make the decision to participate before the consent process is finalized.[31]

Nonetheless, research shows that many participants have a desire to know about commercial aspects of research projects they might participate in.[31,32] Would this information make them change their minds about participating? Cook and Hoas conducted an interview study exploring the decision-making processes that participants use when deciding to participate in human subject research. They found, unsurprisingly, that trust plays an important part: "A trusting relationship with a healthcare provider or researcher seems to influence the decisions a prospective human subject makes."[31]

Cook and Hoas[31] were also interested in what was regarded as important information for the decision making. They found that most participants desired more information about the commercial purposes: "Prior to taking part in the interviews, most participants had not realized that some studies might be designed for commercial purposes, such as extending a patent .... Participants thought it was dishonest not to be transparent about … the full purpose of a study."

Most participants wanted to know whether a study had a commercial purpose, and most reported that such information could influence their decisions about taking part in research in the future. To quote one participant: "I think the study participant should be told exactly what is going on. It's coercion otherwise." Another stated: "Patents. Sure. Absolutely, for sure. I absolutely want to know." Even participants who stated that such information would not influence their decision still felt they should be informed about them.[31]

Because information regarding commercial and IP aspects of a study could make people change their mind about participating, withholding this information or not presenting it clearly and concisely, even if not legally required, may be ethically problematic as it may prevent informed decision making.

As noted by Cook and Hoas in the context of another interview study (with institutional review board (IRB) members) "the purpose of a study including commercial purposes" is an issue "that may have a bearing on protection of human subjects but that (is) not well covered by … regulatory guidance."[33] They found that: "most IRBs were uncertain about how to handle disclosure of commercial purposes of research to either the IRB or the research participant …. The IRB members reported that the commercial purpose of a study was generally not "on the table" during the review process.[33] To quote one IRB member: "They say that the informed consent is already so long and … there is no room to add another thing. But what is really important? It is like there is this fear that if you allow that kind of disclosure, the whole shebang will fall apart …. The trouble is how informed do people have to be? If the study was being conducted to extend a patent—I would not be willing to participate. And I would want to know that. Definitely. So there is intentional dishonesty in omitting information that could sway decision making."[33]

What patent-related information should be disclosed to gain adequate informed consent? In our view, the participant should be clearly advised that the researchers may seek to patent the results. They should also be informed of what licensing policy will be adopted, e.g., (non)exclusive licensing and (no) royalty-free licensing of nonprofit entities. The participants' attention must be clearly drawn to this information, and its meaning must be understandable to a layperson. Not least, the word "patent," rather than just "intellectual property", should be used and explained.

In addition to the question of what ought to be disclosed to participants, the question might also be raised whether the research setting (nonprofit vs. for-profit) makes a difference to the ethically required level/extent of disclosure. In this regard, we note that the kinds of patent claims filed by 23andMe could just as well be from a nonprofit applicant (cf. the patents of the University of Utah Research Foundation related to the *BRCA1* and *BRCA2* genes). Seeking these kinds of patents has become standard practice for universities.

It could be argued that, in situations in which participants might assume there is no intent to commercialize, e.g., if research is done by academics or by companies suggesting an altruistic motive, the need to be transparent about the intent to commercialize is stronger. Perhaps participants who take part in research by for-profit organizations ought to expect that patenting will be involved. However, the reactions of several 23andMe users show that they had not realized or expected this. Moreover, studies suggest that, even if research is clearly intended for commercial purposes, participants recruited through people they trust do not appreciate the extent of the commercial dimension unless it is drawn to their attention, at which stage they show the belief that they should have been informed of this.[31] Therefore, in our view, the standards of disclosure should be the same for research conducted in profit and nonprofit settings.

23andMe's PD patent is of concern also for reasons other than those discussed above. The diagnostic method claims are similar to the claims licensed to Myriad Genetics for assays for *BRCA1/2*, i.e., the type of claim that might be used to prevent others screening for PD susceptibility. As noted by Cook-Deegan and Heaney, a "single blocking patent on a normal gene or any common disease-associated variant can be sufficient, if exclusively licensed to just one provider, to limit testing by other laboratories for that clinical condition."[34] The validity of such claims however is in doubt following the US Supreme Court's decision in *Mayo v. Prometheus*[35] from March 2012, i.e., after 23andMe's patent application was accepted but before it was granted. In that case, the Supreme Court found that methods that are based on "laws of nature" are not patentable.

Moreover, one claim of the international patent application covers the use of unproven (or even undiscovered) drugs in PD therapy. The intention with such a claim is to cover the activities of potential collaborators (e.g., licensees) in drug discovery and development, as well as those of potential competitors. Because this is the only thing 23andMe might have to offer to a pharmaceutical research and development company, other than the ability to mine their database, this claim, although speculative, is significant. Although 23andMe's granted PD patent was limited to the prognostic method, it should be noted that in April 2012 they filed a continuation patent application in the United States, USSN 13/452341, which may be used to seek patent coverage for the other aspects of their "invention."

Conclusion

The issues discussed in this article raise the question as to how an insufficiently informed participant can be regarded as an empowered participant or true partner in research. On the basis of the company communications, many customers clearly believed they were participating in an altruistic exercise to promote development of diagnostic tests and therapies. Yet, an analysis of 23andMe's patent portfolio has revealed that the exercise adds significant value to the company's database in ways that might hinder rather than promote the development and accessibility of diagnostic and treatment options. That there has been some loss of trust in 23andMe's consumer community is clear from reactions to the announcement of the patent. For some, what undermined trust was not so much the profit motive but rather the fact that the company did not provide any clear indication to consumers that it was seeking patents on its discoveries. Obviously, we are not suggesting that the quotes in this article are representative for all participants. It is unknown how many people will change their mind about participating and how many of those would change their mind again if a strategy of clear and forthright communication about patent policies were to be adopted.

Patents are undoubtedly useful and important tools in smoothing the progression to market of novel diagnostic and therapeutic techniques, and no company need be reluctant to be open about the fact that it seeks to patent its inventions. We wish to emphasize that we see no inherent conflict between patenting and behaving responsibly. However, an important lesson to be drawn seems to be that any (private or public) organization involved in research that relies on human participation needs to be transparent, not only about its research goals but also about its strategies and policies regarding commercialization, including patenting and licensing policies. Such transparency is crucial to enable potential participants to make their own decisions as to whether those goals and policies are in line with their moral values, and, if so, whether they want to contribute to those goals by making information or body material available for those purposes. In the absence of such transparency, talk of "participant-centric research," "empowered" research participants, and "democratized genomics" will continue to sound rather hollow.

DISCLOSURE

The authors declare no conflict of interest.

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