COMMENTARY | Genetics inMedicine

"I prefer a child with …": designer babies, another controversial patent in the arena of direct-to-consumer genomics

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In December 2009, claiming priority from an earlier US patent application filed in December 2008, the Californian direct-to-consumer genetic testing company 23andMe filed US Patent Application Serial No. 12/592950. A Notice of Allowance for this case was issued by the US Patent and Trademark Office in June 2013, and it will issue as US Patent No. 8543339 on 24 September 2013. It contains claims to a computer system and to a computer program, but our focus here is on the patent's claims to a method for gamete donor selection:

"A method for gamete donor selection,[1] comprising (i) receiving a specification including a phenotype of interest that can be present in a hypothetical offspring; (ii) receiving a genotype of a recipient and a plurality of genotypes of a respective plurality of donors; (iii) using one or more computer processors coupled to one or more memories configured to provide one or more computer processors with instructions to determine statistical information including probabilities of observing the phenotype of interest resulting from different combinations of the genotype of the recipient and genotypes of the plurality of donors; and (iv) identifying a preferred donor among the plurality of donors, based at least in part on the statistical information determined, including comparing the probabilities of observing the phenotype of interest resulting from different combinations of the genotype of the recipient and the genotypes of the plurality of donors to identify the preferred donor."

Taken out of "patentese," what 23andMe is claiming is a method by which prospective donors of ova and/or sperm may be selected so as to increase the likelihood of producing a human baby with characteristics desired by the prospective parents, the selection being based on a computerized comparison of the genotypic data of the egg provider with that of the sperm provider. The phenotypic characteristics that may be on the users' (e.g., parents') "shopping list" can include both disease-related and non–disease-related traits, such as height, eye color, muscle development, personality characteristics, and risks of developing age-related macular degeneration or certain types of cancer.[2] Figure 4 of the patent application lists the following alternative choices: "I prefer a child with": "longest expected life span"/"least expected life cost of health care"/"least expected cumulative duration of hospitalization." Figure 6 visualizes a choice between the "offspring's possible traits" of "0% likely endurance athlete" and "100% likely sprinter."[2] Of note, sex is also mentioned as an example of the phenotypic characteristics. 23andMe's claim is extremely broad insofar as it concerns "selection" for *any* phenotypic trait, which of course includes polygenetic traits that might be more than a bit difficult to select for; however, in 23andMe's favor, we must point out that what is claimed is *not* a cast-iron, fool-proof method *guaranteeing* that the eventual child will have all the phenotypic traits on the parents' shopping list, an impossible task, but merely a method of improving the chances that the baby has the "right" characteristics.

It has been said that taking out a patent on a technology that one disapproves of provides a further way, beyond that of statute law, to prevent others from adopting it for a while. For example, in 1997, Stuart Newman and Jeremy Rifkin filed a US patent application directed to human/animal chimeras. Stuart Newman opposed patents on living things. "[H]e had no intention of making the creatures. His goal was to set a legal precedent that would keep others from profiting from any similar 'inventions.'"[3,4] However, there is no indication that this is the rationale behind the case discussed in this commentary.

Moreover, at no stage during the examination of the patent application did the patent office Examiner question whether techniques for facilitating the "design" of future human babies were appropriate subject matter for a patent (http://portal.uspto.gov/pair/PublicPair, patent application number 12/592950). It might be argued that this is not surprising—unlike the patent law operating across Europe (the European Patent Convention, or EPC), US patent law contains no explicit clause excluding from patent-eligibility inventions that contravene morality. Yet the utility requirement of US patent law includes a morality aspect which, admittedly, is very rarely applied by the US Patent and Trademark Office, but which was, for example,

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invoked when the human/animal chimera patent application mentioned above was rejected. In a press release, the US Patent and Trademark Office explained that: "[T]he courts have interpreted the utility requirement to exclude inventions deemed to be "injurious to the well-being, good policy, or good morals of society." … [I]nventions directed to human/nonhuman chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement."[5] This raises the interesting speculation as to whether the US Patent and Trademark Office might have considered objecting to 23andMe's patent claims as injurious to morality and the well-being of the society.

Although we cannot address that question here, we should like to note that the genetic selection of children has been advocated by philosophers such as Savulescu and Kahane,[6] who argue that prospective parents would "aim to have the child who, given his/her genetic endowment, can be expected to enjoy most well-being in his/her life." They emphasize that this includes the selection of both non–disease-related and disease-related characteristics. Others, such as Sandel,[7] argue against it on the basis that it indicates that the parents have undesirable attitudes that are at odds with the norm of unconditional love for one's child: "The problem lies in the hubris of the designing parents." He makes it clear that his objections concern the selection of non–disease-related traits: "To appreciate children as gifts or blessings is not to be passive in the face of illness or disease … In caring for the health of their children, parents do not cast themselves as designers or convert their children into products of their will or instruments of their ambition. The same cannot be said of parents … who aspire to bioengineer their child's intellectual endowments or athletic prowess."[7]

Again, we cannot elaborate here on this debate,[8] but it is clear that selecting children in ways such as those patented by 23andMe is hugely ethically controversial. The use of preimplantation genetic diagnosis to avoid implantation of embryos bearing serious genetic abnormalities is by now becoming commonplace, but a computerized process for selecting gamete donors to achieve a baby with a "phenotype of interest" that the prospective parent "desires in his/her hypothetical offspring," as 23andMe puts it,[2] seems to have much broader implications, for this process also entails the selection of traits that are not disease related.

What makes this case even more surprising is the fact that 23andMe is no stranger to controversy regarding its patenting activities. In the days following its May 2012 announcement[9] on the company blog that it was to be granted a US patent for a test for propensity to develop Parkinson disease, the blog was filled with reactions of upset customers, the providers of the genetic and phenotypic data which constitutes 23andMe's biobank.[10] Since 23andMe is a commercial entity, clearly intended to bring profit to its investors at some stage at least, its attempts to seek patents are not surprising. Moreover, such attempts are not inherently problematic. However, for a company that invites audience participation, and so needs customers and their goodwill to maintain and expand its most valuable asset, i.e., its biobank, it is surprising that, following the uproar that greeted the announcement of its Parkinson disease patent, 23andMe has pursued this patent with no apparent public discussion. For instance, do the consumers who have also allowed 23andMe to use their genotypic data for the research conducted by the company agree with the use of their information for the purpose of developing a method for gamete donor selection? Public trust is central to the continuing success of human genetics research in general and biobank-based research in particular. We urge maximal transparency by all engaged in human genetics research.

DISCLOSURE

The authors declare no conflict of interest.

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