

The Ethics of Patenting the BRCA Genes for Breast Cancer Research

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1 BRCA Background Information

Breast cancer is the second leading cause of death for women after heart disease. Both BRCA genes are strongly associated with hereditary breast cancer. Mutated BRCA genes are thought to be responsible for a majority of inherited breast cancer cases. Those with BRCA gene mutations have a high risk of developing breast cancer. This high risk of breast cancer for mutation carriers has led many of them to have prophylactic surgery that removes the breasts.

In Europe and elsewhere, such as in Canada, Myriad has had patents on isolated forms of the BRCA genes since the mid-1990s. It is important to note that the patent is not on the BRCA genes in one's body, but BRCA genes that have been isolated or extracted from the human body so that they may be studied in the laboratory. It is only through isolating genes from its natural environment that we may then examine the nucleotide sequences composing the genes and determine whether there are or are not any mutations. The isolated BRCA genes may be patented in Europe even though their structures are identical to the structures of non-isolated BRCA genes found in the human body. Such a patent in law is commonly known as a *product patent* since it is a patent on a chemical or biological entity. A product patent is a patent on the product itself.

Myriad first isolated BRCA genes by using a common laboratory method called RT-PCR. Myriad not only has product patents in Europe on the genus of isolated BRCA genes and all their various mutations but they also have patents on the use of such genes and on any conceivable test that detects for BRCA gene mutations in the

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relevant countries. In legal parlance, this latter patent is sometimes referred to as a *use patent* in that it is a patent on the use of the product for a purpose, such as for testing for genetic mutations. This use patent on isolated BRCA genes is of such a scope that it grants patents on their diagnostic test for BRCA mutations and even on any other BRCA detection test invented by someone else that is vastly different from Myriad's. In granting exclusive rights to Myriad, this means they also have a use patent in Europe on any future therapeutic uses, such as gene therapy, of the BRCA genes; even on uses that have not been developed yet. In essence, Myriad has a monopoly in Europe on isolated BRCA genes, on the use of such genes, and on detection tests for them, where one must in some way have Myriad's consent or pay money to look at, examine, or in any way use isolated alleles of BRCA 1 and 2 that come from oneself or anybody else. This applies even to breast cancer researchers in Europe who are attempting to find a cure for the disease or invent better BRCA diagnostic tests. To note, in order to maintain an exclusive market, Myriad has not widely licensed others to use its patents to create better tests.

Patents or intellectual property rights on things found in nature appear to be controversial in that they initially seem to be about discoveries rather than inventions. As patents are generally thought to apply to inventions that have been created and did not previously exist before, such as on a new kind of engine or a new machine that can clean one's house, finding some new natural phenomena, species of animal, or law of nature appears to be a discovery of something that has already existed and now has been uncovered. Although in law they are not explicitly defined, on common understandings of what discovery and invention mean, it would seem that the BRCA DNA are a discovery rather than an invention since the nucleotide sequence of the BRCA genes have existed before we even knew about the existence of genes in the first place. It is not the case that such genes have been invented or, in other words, have been newly brought into existence by genetic scientists, where such genes did not exist before.

To note, a U.S. Supreme Court ruling in June of 2013 has denied the legitimacy of Myriad's product patents on isolated BRCA DNA and the concomitant comprehensive use patents in the U.S. based on the fact that such isolated genes are a product of nature, and as such, they cannot be patented.¹ However, in the legal sphere in Europe, genetic discoveries are *eligible* to be patented if they are useful and isolated even though they may be products of nature. In regard to being eligible for being patented in Europe, the invention versus discovery distinction does not carry enough weight, and it can be superseded. For, being useful and isolated is sufficient for being eligible to be patented. Isolated BRCA genes are very useful since they allow one to test for whether or not one has a mutated individual variant of BRCA 1 or 2, where the BRCA gene mutation is expressed in a dominant pattern. In the legal domain of Europe, the usefulness of BRCA genes provides utilitarian reasons for in part supposedly justifying the eligibility of patenting isolated BRCA genes. It initially appears that the discovery of the BRCA genes is extremely useful

¹ See Supreme Court of the United States, *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al.* (Washington, DC, 2013). Accessed April 19, 2015. http://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf.

to the female human population. Taking into account the additional fact that the BRCA genes in question are isolated, there may be an opening in the laws in Europe that may allow for the eligibility of Myriad's patents.

Under the European Patent Convention, there is an exclusion clause to patents that the invention or discovery must not threaten the *ordre public* or morality. The *ordre public* is in regards to the protection of public security and the physical integrity of individuals, and morality is simply about what is morally right and wrong. Let us call this clause *the ethical exclusion provision*. This ethical exclusion provision is a special condition in that it explicitly links morality with the legal domain in writing. Regardless of whether there is or is not a link generally between ethics and law, there is such a link specifically in the case for patents in the sense that moral arguments against a particular patent not only may demonstrate that such a patent is grounded in immoral foundations, but due to at least the ethical exclusion provision, it also then may show that the patent should not be legal. I later will rely on the ethical exclusion provision to object on legal grounds that Myriad should not have their comprehensive BRCA patents in Europe. The role this provision will play is that once I provide good reason to believe that Myriad morally should not have their comprehensive BRCA patents, which is the main thrust of this paper, then I later will invoke the ethical exclusion provision in the final section of this paper to contend that we also have good reason to believe that having such comprehensive patents is not legal. We will now move on to the main focus of my paper, where I present my moral arguments against Myriad.

2 The Argument from the Right to Bodily Ownership

I will not examine any other potential arguments against Myriad's patents such as arguments based on a right to life, health, or human dignity. Rather, our specific narrow aim here is to only assess the right to bodily ownership and see whether or not it can be revitalized and used against Myriad. Many view this line of argument concerning the right to bodily ownership to be problematic, such as the Nuffield Council of Bioethics and Stephen Crespi, but our aim here is to see whether such supposed problems can be overcome.² To note, all normative claims from here forward should be understood to be moral normative claims unless otherwise specified. Relying on ethical reasons will not only hopefully demonstrate that there are specific strong moral reasons against Myriad, but given the ethical exclusion provision, they also may resultantly show that there are certain strong normative reasons in the realm of law that having such comprehensive patents also should not be legal.

The Nuffield Council on Bioethics is an independent body that has produced a detailed document on the legal and ethical aspects of patenting DNA.³ They

² See Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (London, England, 2002). Accessed April 19, 2015. <http://nuffieldbioethics.org/wp-content/uploads/2014/07/The-ethics-of-patenting-DNA-a-discussion-paper.pdf>; Stephen Crespi, "Patenting and Ethics—A Dubious Connection," *Journal of the Patent & Trademark Office Society* 85 (2003): pp. 31–47.

³ See Nuffield Council of Bioethics, *ibid*.

anticipate an objection against Myriad that people cannot, for example, be owned by others as slaves, and there is a powerful right to what may be called *bodily ownership*. This deontological right simply is that one generally owns one's own physical body and parts of one's physical body. Although there may be limited exceptions to this right, such as in relevant cases of informed consent to give a certain isolated part of your body to others, your body, attached right arm, and attached left leg are your own. Unless it is an exception such as in a relevant case of informed consent, one has a right to ownership over one's physical body such that others cannot infringe on such rights and claim to own parts of one's body, sell them, give them away, use them at their own will, deny others from using them in a certain way, etc. It is specifically the agent who is originally constituted by the body part in question that owns his or her body part. For certain isolated body parts, such as a spare kidney or cells donated for scientific research, the body part can be given to another if there is informed consent by the previous owner. The right of bodily ownership is legitimately lost when one agrees to have one's body part removed and donated or when it is simply discarded. Also, there may be body parts whose ownership rights cannot be given to others based on informed consent. For instance, if I consent that you fully own all the parts of my body completely as such so that you can do with it what you will, then this is obviously not morally permissible. Furthermore, for non-isolated body parts, the right to bodily ownership generally applies to parts that are in one's body rather than in someone else's.

Just as many rights, such as the freedom of speech, have certain limitations and restrictions like not being able to lie and yell "Fire!" in a crowded theater, there may be other limitations to the right to bodily ownership. The right to bodily ownership over an entity includes a control right or an essential property right over that entity. Here, control rights and essential property rights are synonymous. An essential property right is essential in the sense that one owns the product itself, and one can control and use the product for certain purposes, such as testing it for genetic mutations and choosing where to donate it for scientific research. In this respect, an essential property right corresponds to a significant extent to the rights one has from having both a product and use patent. One can be said to own the *product* in that one has the right to possess it and *use* it in the above respects. However, it is not a complete correspondence with having comprehensive product and use patents in that, for example, an essential property right does not include the right to make a profit from the sale of the product or from the use of the product as one might have with comprehensive product and use patents. It also does not include the right to own all inventions that involve the use of the product, such as owning all BRCA diagnostic tests. If I have an essential property right over isolated alleles of BRCA 1 and 2 that came from my body, then I have the right to possess such alleles in the sense that I can have them, for example, be tested for mutations. I may also transfer ownership rights of such alleles to others by, for instance, choosing to donate them to my favored breast cancer research laboratory. In this respect, such isolated alleles from one's body can be said to be one's *own*.

However, despite such substantial control rights, it still may be the case that if I do have the right to bodily ownership qua essential property rights over isolated alleles of BRCA 1 and 2 that have come from my body, I do not have the income

right over such alleles to commercialize them and sell them for profit. A commercial right does not necessarily entail an essential property right, but it does cover the ability to profit from the product and the use of the product. For example, if such genes can be commercialized, it might be the case that Myriad does not have essential property rights and ownership over my isolated alleles of BRCA 1 and 2, but they do have commercial income rights over them like a licensee. In such a circumstance, only Myriad can financially profit from isolated BRCA genes and their use. Insofar as commercial rights involve the right to make a profit on the *product* itself as well as on the *use* of the product, income rights cover certain limited aspects of Myriad's product and use patents. I leave open the possibility that Myriad may have income rights over isolated BRCA genes, but for our purposes, I need not make the strong claim that we have both control and income rights to isolated BRCA alleles that came from our respective bodies. I make the weaker claim here and only contend that we have the right to bodily ownership in respects to having control rights or essential property rights over such isolated alleles of BRCA 1 and 2 that have come from our own respective bodies (there is a qualification to my statement that I will not take a stand on Myriad's income rights. While I do not take a stand on Myriad's income rights specifically on the isolated BRCA genes themselves, I later will discuss Myriad's income rights on BRCA tests). This is a substantial and important right in that we can choose to test, examine, and donate our respective isolated alleles of BRCA 1 and 2 so long as we do not profit from them. As I will argue later, if we have control rights over such genes, then Myriad should not have their comprehensive product and use patents over such genes. As my contention is specifically and only against Myriad's control rights to isolated BRCA genes, I object only to limited and specified aspects of Myriad's product and use patents.

There is also the question of whether certain body parts can be commercialized in the first place. It may be the case that there are certain restrictions on the right to bodily ownership, where certain body parts like a spare kidney cannot be sold because such sales, for example, might undermine respect for human life and dignity. While it is an interesting question whether BRCA DNA may be commercially sold or not, given our primary focus on essential property rights rather than on income rights, I will leave this question for another time. I leave open the possibility that there may be restrictions on the right to bodily ownership for BRCA DNA in that such genes may not be commercialized.

The right to bodily ownership in the essential property rights sense not only appears to be on firm moral grounds, but it is also on firm grounds in the legal sphere as well. Dianne Nicol states that, "There is one universally-accepted exclusion [to patents] that could be said to be so obvious that it goes without saying: that human beings cannot be patented."⁴ If correct, this contention against Myriad criticizes the comprehensive patents they have on BRCA genes in Europe. In what follows I will build off of and add to this initial argument for the right to bodily ownership in order to only object to Myriad's essential property rights aspect of

⁴ See Dianne Nicol, "On the Legality of Gene Patents," *Melbourne University Law Review* 29 (2005): p. 822.

their BRCA patents. I will only focus on Myriad's essential property rights for naturally occurring BRCA DNA rather than for synthetic BRCA cDNA.

One potential problem for the application of the right to bodily ownership to the Myriad case is that Myriad's essential property rights are not rights on genes in situ or naturally within the body. The patents that in part grant essential property rights are for isolated genes; genes that are outside of their normal environment and that have been isolated from the human body via the use of human-made tools. Moreover, the product itself has a useful application. Isolated genes are useful to society because they allow scientists to test whether or not one has a genetic mutation. For example, Article 5 of the European Union's *EC Directive 98/44/EC* states:

An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.⁵

Although I later will object and provide reasons against EC Directive 98/44/EC in that I will contend that Myriad should not have their comprehensive product and use patents on isolated BRCA genes, this move of patenting useful isolated genes rather than in situ genes apparently allows isolated genes to legally be candidates for being patented in Europe. While this move of focusing on isolated and useful genes contains supposed conditions for the eligibility of being patented, I will object to these conditions on moral grounds. Most on both sides of the debate view this move of focusing on isolated and useful genes as being sufficient to refute the argument from the right to bodily ownership. For example, although the Nuffield Council stands opposed to Myriad's patents, they believe that shifting the patent to isolated genes allows one to bypass the argument from the right to bodily ownership. Since isolated and useful genes are no longer a part of one's body, one no longer has ownership rights over them, and they are eligible to be patented. However, I believe if we dig a little deeper into this line of argument concerning the right to bodily ownership, we will see that it cannot be so quickly and easily dismissed.

Being isolated and useful are posited as sufficient conditions for a biological entity to be eligible to be patented in Europe. However, I believe that there are counterexamples demonstrating that even if these conditions are satisfied, certain biological entities are still not eligible to be patented. There is a current common medical procedure regarding a biological entity, where the entity has the property of being isolated and being useful in which we would be disinclined to confer the eligibility of being patented. When one has a tumor, it is common for doctors to perform a biopsy and isolate or remove a sliver or small sample of the tumor to see whether the tumor is benign or malignant. Just as BRCA genes are isolated and then information can be gathered concerning its nucleotide sequences, a sliver of a tumor is isolated and then information can be gathered regarding whether the tumor is

⁵ See The European Parliament and of the Council, "Directive 98/44/EC," *Official Journal of the European Communities* (1998): p. 218. Accessed April 19, 2015. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>.

benign or malignant. Moreover, as with isolating BRCA genes, isolating a small sample of a tumor is generally extremely beneficial to society as it allows one to know whether a tumor is benign or malignant, and if malignant, it allows a patient to take the appropriate steps to remove the tumor and then hopefully return to living a normal and meaningful life.

For tumor biopsies, we would not say that a surgeon would be eligible to patent isolated slivers of a tumor to have essential property rights over them based on the fact that the surgeon has isolated a useful sliver. First, regarding the *in situ* tumor itself, if anyone owns the tumor, it is the patient who owns the tumor just as the patient would be said to own a mole on his body that develops later in life due to exposure to the sun. Therefore, if anyone owns the sliver of tumor, it is the patient who owns the sliver. To say that the doctor is eligible to patent the sliver would be quite odd. For, imagine that the first doctor who ever removed a sliver of someone's tumor for a biopsy patented isolated slivers from that tumor since, in part, it was supposedly eligible to be patented given that it was isolated and useful. This doctor has essential property rights on all isolated slivers from this tumor. What follows from having such product and use patents are that when our patient decides to have a biopsy on his tumor, this doctor with the product and use patents strangely can disallow any test be run on the isolated sliver even though the patient very much wants the tests to be run on it because the patient may be dying. For, this doctor owns the sliver, and it is his property. In virtue of having essential property rights to the relevant tumor slivers, this doctor may refuse to have what is now his sliver that used to be in another person's body, be tested. This seemingly odd conclusion draws on the intuition that it should be the case that the patient still has the right to bodily ownership over the sliver, at least in the essential property rights sense, such that the patient has the moral right to choose whether or not the relevant isolated sliver should be tested. It is the patient who has the moral right to bodily ownership over the tumor sliver at least in the essential property rights sense, and thus, the patient has the right to choose to have the test be run rather than ultimately the doctor. If the patient still has such a right to bodily ownership over the sliver, then this provides good reason to believe that the sliver is not eligible to be patented in the essential property rights sense any more than the human race or *in situ* organs are eligible to be so patented due to a right to bodily ownership. Therefore, it appears that tumor slivers should not be even eligible to be patented at least in the essential property rights sense based on conditions of isolation and usefulness.

Just as there is good reason to deny the eligibility of being so patented in the tumor case, I believe there is good reason to deny it in the newer BRCA case as well. To note, the analogy with the tumor case is merely for illustrative purposes, and the force of my argument for the right to bodily ownership qua essential property rights in the BRCA case can be made independent of the tumor scenario. There is strong reason to believe that Myriad should not even be eligible for having full product and use patents on BRCA genes in Europe based on the properties of being isolated and useful because it is the patients that have the right to bodily ownership over their respective isolated BRCA alleles, at least in the essential property rights sense. In other words, it appears that Myriad should not be put in the situation where they have the authority to deny everyone in Europe from testing

isolated BRCA alleles generated from their respective bodies in virtue of the fact that Myriad technically owns and has patents in the relevant countries to all isolated BRCA genes. It is the actual patients who have the moral right to bodily ownership at least in the essential property rights sense over their isolated alleles of BRCA 1 and 2, which grants them the moral right to be able to choose to have the respective isolated alleles be tested.

This moral intuition of bodily ownership still holds when we also come to realize that Myriad's patents allow them to deny patients from donating such alleles to their favored breast cancer research lab. A patient who will die from breast cancer due to BRCA mutations may wish to still leave a contribution and possible lasting impact to the world by donating BRCA alleles from her body to her favored breast cancer research laboratory, but Myriad strangely can deny that they be donated for research at all. When viewing the logical implications of Myriad's patents, we reach the moral intuition that individuals do have control rights to choose that such genes be donated for research and where they should be donated. In other words, we *own* such alleles in the relevant sense that we can control them by deciding whether tests should be run on them, that they be donated for research, and where they can be donated. Thus, individuals have the right to not even put such genes in Myriad's hands at all despite Myriad's possible desire to possess them, and Myriad cannot be said to own such genes in the control rights sense where they can deny that tests be run on them, deny that they can be donated for research, and deny a patient's intention to donate them to a particular lab. Myriad cannot do what they will with one's isolated alleles of BRCA 1 and 2, and they do not have essential property rights over them. Therefore, when viewed from the perspective that Myriad's patents technically allow them to deny all relevant parties from getting tested, from donating them at all, and from donating them to the patients' favored lab, we then come to realize that Myriad should not have comprehensive product and use patents for the isolated BRCA genes in Europe.

Also, recall that this right to bodily ownership for our respective isolated BRCA genes can be legitimately lost for various reasons such as when such DNA is donated to scientific research. Moreover, recall that with essential property rights, it still may be the case that we do not have commercial rights over such genes but Myriad does, or it may be the case that no one can commercialize such genes at all.

Given all of the above, the argument from the right to bodily ownership may be saved from the particular counters raised against it in the current literature. Drawing out the fact that Myriad's patents technically allow them to deny everyone from testing their isolated alleles of BRCA 1 and 2, from even donating such alleles, and from donating them to one's favored lab are new contributions to the literature. These contributions help to draw on the intuition that we still have the right to bodily ownership at least in the essential property rights sense over our respective isolated alleles of BRCA 1 and 2, and Myriad does not have such essential property rights. Even though many on both sides of the debate believe the argument from the right to bodily ownership does not work against Myriad, my new insights and contentions demonstrate that this general line of argumentation concerning the right to bodily ownership indeed can be resuscitated and saved from the current extant objections against it.

Notice that my contention is not a circular argument, where I simply assume that one generally has the right to bodily ownership for non-isolated body parts and then immediately conclude from this alone that one has bodily ownership over the relevant isolated alleles of BRCA 1 and 2. Rather, I examine the BRCA patents and their logical implications to draw on the intuitions via a priori conceptual analysis that we have the right to bodily ownership at least in the essential property rights sense over the respective alleles in question. The right to bodily ownership provides a criticism against Myriad in that Myriad morally should not have their comprehensive product and use patents, although, for instance, they may have partial license in that only they can commercialize such genes. The intuition for the right to bodily ownership is elicited from the Myriad case when we realize that their comprehensive patents allow them to deny all relevant parties from getting tested, from being able to make donations for research at all, and from being able to make such donations to their favored lab. As we can see, this claim concerning the right to bodily ownership for isolated BRCA genes is arrived upon via conceptual analysis by examining the Myriad case from new perspectives regarding the logical consequences of the patents. However, more argumentation is required to establish this claim in that it needs to be rigorously defended from possible objections. It is to this objective that we now turn.

3 Objections

The first entertained objection is that my contention against Myriad may lead to problems elsewhere. If Myriad's essential property rights are unethical in part because they would allow Myriad to stop an individual from having her specific alleles of BRCA 1 and 2 be tested, Myriad's use patents on diagnostic BRCA tests would also be unethical for the same reason. Since Myriad has a patent on all of such testing procedures, they in principle can stop a patient from having access to any BRCA tests even if the patient wants to be tested and has essential property rights over her isolated alleles of BRCA 1 & 2. Therefore, it seems that by my above line of reasoning against Myriad, I am also committed to the position that Myriad's patents on BRCA diagnostic tests are unethical. However, Myriad's patents on diagnostic tests are legally designed to stop people from using any such BRCA testing procedure without Myriad's authorization. It is unclear that there is something morally wrong about this state of affairs, especially for diagnostic tests they invented themselves. Thus, it appears there is something wrong with my original argument against Myriad's essential property rights on isolated BRCA genes since it leads to a consequence about Myriad's patents on BRCA diagnostic tests that may be false.

In response, there first are serious independent worries about Myriad's patents on all BRCA diagnostic tests. First, if someone else invents a different test, then it appears they should be able to patent it due to the merit of inventing something new. For instance, if someone invents a different vacuum cleaner from others, then this person should be able to patent the invention. Also, Myriad's comprehensive use patents disallow other research groups from creating and providing better diagnostic

tests for BRCA gene mutations. Ignoring Myriad's patents, a French test developed at the Institut Curie can detect the BRCA 1 gene mutations that Myriad's cannot.⁶ Myriad's test is reported to miss detecting about ten to twenty percent of genetic mutations for the BRCA 1 gene. This leads to the possible conclusion that women who have a mutated individual variant of BRCA 1 still may not know that they have this mutation even after taking Myriad's test. No other companies legally are allowed to try and improve the test, even though their new test may be significantly different from Myriad's. The excessively broad nature of Myriad's use patent that covers all and any diagnostic test for BRCA gene mutations places severe constraints on anyone attempting to improve upon Myriad's faulty tests.

It appears to be of a greater benefit that the patent system allows for limited use patents such that scientific knowledge about new inventions is placed in the public sphere rather than having excessively broad use patents. For, this allows others to develop further inventions that improve upon previous designs. In other words, this allows others to create a product that fulfills a similar function but that is constructed in a different manner from previous designs such that it does not infringe upon the existing patents. This is widely known as inventing around. The nature of Myriad's broad use patents eliminates the ability to invent around, and thus, it eradicates the natural utility of patents to allow for future progress in inventions from others in a competing market place of ideas; inventions that fulfill a similar or the same function. Moreover, this monopoly power also means that patients do not have a legal option for a distinct second-opinion on a BRCA test because technically and legally-speaking, no other company besides Myriad has the right to run differently designed diagnostic tests on the genes. This is problematic especially since it has been shown that Myriad's tests are flawed in that they could not identify all known BRCA mutations. Furthermore, Myriad's test generally costs more than other more efficient and precise tests that have been developed by others who have chosen to ignore Myriad's patents. Therefore, given the above, we may at least conclude that it is highly controversial that Myriad should have such broad use patents on BRCA diagnostic tests.

Nevertheless, the above particular objector who attacks my argument from the right to bodily ownership may simply set aside these possible worries and not delve into them any further by focusing only on the diagnostic tests that Myriad themselves invented. This also presents the objector's strongest hand since we now are only discussing tests that Myriad themselves invented. Let us assume for the sake of argument a hypothetical situation where only Myriad's tests that they invented exist. Other companies are perfectly allowed to invent around by creating and patenting different tests that may be more accurate and cheaper. However, no one has done so. Hence, in principle, Myriad may deny someone from having access to any existent BRCA test. My argument against Myriad's essential property rights on isolated BRCA genes still seems to disallow Myriad from owning the diagnostic tests they invented themselves in this situation. Yet, in this scenario, it really

⁶ See S. Gad, M. Scheuner, S. Pages-Berhouet, V. Caux-Moncautier, A. Bensimon, A. Aurias, M. Pinto, D. Stoppa-Lyonnet, "Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing," *Journal of Medical Genetics* 38 (2001): p. 388.

appears that they should have ownership of their diagnostic tests because they invented them.

My response to this hypothetical situation is that Myriad has the right to own their tests since they invented them. However, just as there are restrictions on the freedom of speech, there are restrictions on their right to ownership over their tests. For instance, they must provide reasonable access to the use of their tests and cannot outright deny someone from using their test based on such things as whim, personal vendetta, or a sheer desire to display their power. Myriad can have ownership rights on their tests even though they cannot have such rights over isolated BRCA genes. This is because they invented such tests but did not invent BRCA genes. Creating a new invention carries moral weight in being able to own your own invention based at least in significant part on the merit of having put in the work and ingenuity to *create* such an entity. However, making a discovery of a natural entity in-and-of-itself does not necessarily add significant moral weight for having ownership over that entity. For instance, if I discover a new species of animal or law of gravity, significant moral weight is not added to the possibility that I own all members of that species or the physical law, respectively.

Since Myriad invented their BRCA tests, they can have ownership and commercial rights over them in the sense that they can physically possess them before they sell them to buyers, they can choose the terms of transferring property rights of their tests to others, and they can choose who they would like to give the tests to for free as a donation for charity. This is an important moral difference that distinguishes Myriad being able to own their BRCA tests but not being able to own isolated BRCA genes. However, the possible hypothetical where they withhold any access to such tests demonstrates that there are restrictions. Myriad has limitations on their particular ability to choose the terms of transferring property rights of their tests to others in light of the hypothetical situation put forth by the objector. It would be morally wrong for Myriad to restrict access to their tests no matter what for an individual based on such things as whim or a sheer desire to exercise power maliciously. On the other hand, they could have an overriding morally relevant reason for restricting such access, such as that their test is faulty and dangerous to the life of patients. However, barring any such reasons for restricting access, the intuition drawn from the objector's hypothetical is that it would be wrong for them to outright deny a woman, who may have a mutated individual variant of BRCA 1 or 2, access to their tests. Just as it would be unethical for a biopharmaceutical company who invents a cure for cancer to withhold it from the world based on whim, there is a moral obligation for Myriad to provide reasonable access to all for their BRCA tests. Hence, Myriad can own their tests that they invented in the sense that they can physically possess such tests before they ship them out to buyers, they can choose the terms of transferring property rights of their tests to others, such as to hospitals, so long as the terms fall in the spectrum of being reasonable, and they can choose who they would like to give the tests to as a free donation for charity so long as everyone else has reasonable access to the tests. However, as noted, there are restrictions on such ownership rights, especially in regards to their right to choose the terms of transferring property rights of their tests to others. In this respect, the objection at hand is accounted for in that there is a morally relevant difference

between Myriad's claim to essential property rights on isolated BRCA genes versus the BRCA tests they invented themselves. Myriad's tests are inventions but the isolated BRCA genes are not. As a result, the hypothetical situation in which Myriad can deny a patient from having access to their tests does not lead to the counterintuitive conclusion that they cannot own their tests, but rather, it leads to the conclusion that there are restrictions on Myriad in regards to the handling of their tests; tests that they do in fact own.

Furthermore, recall that I have argued against the claim that being isolated and useful allows for the eligibility of patenting isolated BRCA genes. This along with the fact that Myriad did not invent BRCA genes allows us to claim that Myriad does not own all isolated BRCA genes in the specified control rights sense because they cannot deny that tests be run on certain isolated genes and choose whether and where they can be donated for research. They may not even come into possession of isolated BRCA genes despite their possible desires to have them because patients may choose to donate their isolated BRCA alleles elsewhere. However, they do own their own invention in regards to their BRCA test in the relevant sense that they can possess the tests before sales are made, choose the terms of transferring property rights of their tests to others within a reasonable spectrum and with my above noted restriction, etc.

As a second objection, one may counter that isolated alleles of BRCA 1 and 2 are not owned by individuals, but rather, they are a common resource and are publically owned like public parks and navigable waterways. While this public property view is an interesting idea, there must be a justification for such a position, and the standard justification offered is that it allows for freedom of access from monopolization in order to advance medicine.⁷ For instance, if Myriad owns all isolated BRCA genes, then one must in some way get Myriad's consent to examine any of such genes in order to advance the relevant research. Moreover, such consent may be denied by Myriad. Having public ownership of isolated BRCA genes disallows for such monopoly power and commercialization of genes. On this view, BRCA genes are public property precisely in the sense that no one person or company can own all isolated BRCA genes such that they potentially can stunt scientific research, and such genes also cannot be commercialized, although BRCA diagnostic test inventions may be commercialized by the respective inventor.

While it is debatable whether public ownership of such genes themselves will allow for a greater advancement in medicine, let us grant the objector for the sake of argument that this is the case and that there should be no commercialization and monopoly ownership of isolated BRCA genes. The response to this objection is to first point out that the right to bodily ownership is consistent with there being no monopoly on isolated BRCA genes. The argument from the right to bodily ownership attempts to provide good reason to believe that Myriad should not have

⁷ See Nuffield Council of Bioethics, *ibid.*; Stephen Munzer, "Property, Patents, and Genetic Material," in Justine Burley and John Harris, eds., *A Companion to Genethics* (Oxford: Blackwell Publishers, 2002), pp. 438–454; Donna Dickenson, "Alternatives to a Corporate Commons: Biobanking, Genetics and Property in the Body," in Imogen Goold, Kate Greasley, Jonathan Herring, and Loane Skene, eds., *Persons, Parts and Property* (Oxford: Hart Publishing Ltd., 2004), pp. 177–196.

the relevant comprehensive patents, and such an impediment to scientific research should not exist.

Second, the right to bodily ownership also can allow for the elimination of being able to commercialize isolated genes. Recall from above that I discussed how there may be a possible limitation on the right to bodily ownership for one's respective isolated alleles of BRCA 1 and 2 in that it may not be morally permissible to commercialize such alleles. In entertaining the objection at hand, since we are granting the objector for the sake of argument that such commercialization is not permissible, then the right to bodily ownership can account for this by being relevantly restricted. Hence, the right to bodily ownership allows for freedom of access from monopolization in order to advance medicine, and it can allow for the elimination of commercializing isolated BRCA genes. The justification for the public property view can be mirrored by the right to bodily ownership.

However, an advantage the right to bodily ownership has over the public property view is that it allows for individuals to have the basic right to choose to have their respective isolated alleles of BRCA 1 and 2 be tested for mutations without fear that someone in the commons can snatch them away and deny this right. Furthermore, it allows for individuals to have the right to choose, for example, which breast cancer research laboratory they would like their remaining cells leftover from their BRCA test to go to for donation without fear of having someone in the commons take away this choice.

In essence, the right to bodily ownership can account for the main motivating force behind the claim that isolated BRCA genes are public property while also allowing for the protection of certain essential individual rights that a strong public property view will have difficulties protecting. In fact, many of those who maintain that isolated genes should be part of the commons such that there can be no private monopoly on them and no commercialization, readily accept that there are certain individual rights to bodily ownership over one's respective isolated alleles that largely carry overriding weight in deliberation. As standardly conceived, the public property view for genes generally is consistent with and accepts the right to bodily ownership. For example, Donna Dickenson argues for the public property view while maintaining that individuals are still the *formal owners* of their respective isolated alleles and thus, have corresponding rights over them. She writes:

Essentially, I am advocating a similar right of public access to the inherently public property of the human genome, with strictly limited rights of exclusion for the formal owner – so that the resource is open for widespread use, substantially free of patent or licensing restrictions.⁸

Thus, in a way, the right to bodily ownership can be interchangeable with the standardly conceived public property view, and the entertained objection need not be an objection at all. For, the right to bodily ownership is largely an overriding right on both accounts since this is consistent with allowing for essential property rights of being able to choose whether or not one's isolated BRCA alleles will be tested as well as being able to decide which laboratory will receive one's donation.

⁸ See Donna Dickenson, *ibid.*, p. 178.

Without such rights, a strong public property view will be highly problematic. Furthermore, an advocate of the right to bodily ownership can agree with the public property advocate and allow for isolated genes to be public property in the relevant specified sense that there can be no monopolization and commercialization of isolated BRCA genes. Hence, in this fashion the entertained objection may be diffused.

One may raise another counter based on Locke's political philosophy. Locke acknowledges that the existence of property rights poses a moral problem because God gave the world to human beings in common, so how can there be a justification of individuals having private property rights? Locke answers this question by contending that individuals own their own bodies and their labor. When a person puts her labor into an un-owned object, the labor and the object, in a sense, become fused together and cannot be separated. Since the object in the commons is un-owned and the person owns her own bodily labor, she has the corresponding property rights on this fused entity, so long as she can use it rather than leave it to spoil. There is an expansion of rights here and a moral significance to labor, where an individual has rights to her own body and labor, but upon using her bodily labor and mixing it in with an un-owned object, her rights expand to include rights on the good in question.

Though the earth, and all inferior creatures, be common to all men, yet every man has a *property* in his own *person*: this no body has any right to but himself. The *labour* of his body, and the *work* of his hands, we may say, are properly his. Whatsoever then he removes out of the state that nature hath provided, and left it in, he hath mixed his *labour* with, and joined to it something that is his own, and thereby makes it his *property*. It being by him removed from the common state nature hath placed it in, it hath by this *labour* something annexed to it, that excludes the common right of other men...⁹

Here, we can see that if one attempts to use Locke to object to my previous argument from the right to bodily ownership, it will not work. Even though a scientist puts in her own labor in isolating the BRCA genes and figuring out their nucleotide sequence, the scientist cannot have a property right to isolated BRCA genes on Locke's view because as I have argued, isolated BRCA genes like un-isolated ones are owned rather than un-owned objects. Individuals have a right to bodily ownership at least in the essential property rights sense over their isolated alleles of BRCA 1 and 2. However, unless there is a consensual transfer of property rights, Locke's theory requires that property rights be only conferred in instances when labor is mixed with something that is not already owned. For example, for Locke, if I out of the blue till your field that you farm every year, then this does not mean that your field is now mine. This is due to the fact that the field was previously owned by you. Property rights are given when there is a mixing of one's labor with *un-owned* things. Thus, Locke's view cannot be used as an objection against the argument from the right to bodily ownership. For, in order to use Locke, one would

⁹ See John Locke, in C. B. Macpherson, ed., *Second Treatise of Government* (Indianapolis: Hackett Publishing Co, 1980), p. 19.

first have to directly argue against the right to bodily ownership in the essential property rights sense and the corresponding contention I have put forth for it by claiming that all the relevant isolated BRCA genes really are un-owned in the essential property rights sense.

4 Conclusion

I have discussed how Myriad has product and use patent rights on isolated BRCA genes in Europe. In this paper, I have narrowly focused on the argument from the right to bodily ownership and the specific objections presented against it. There are several different lines of argument being heavily debated on the Myriad case. However, the purpose of this present inquiry is to exclusively examine the right to bodily ownership and whether this particular line of argument may provide a good reason against Myriad's BRCA patents qua essential property rights. Although this contention against Myriad is dismissed by many on both sides of the debate, by digging more deeply into and elaborating upon this particular line of argument, we can see that based on my new insights, the right to bodily ownership does actually provide a strong and noteworthy moral reason against the essential property rights aspect of Myriad's BRCA product and use patents. Hence, given the ethical exclusion provision, I now may conclude that it provides strong normative reasons in the legal sphere in Europe against this aspect of Myriad's BRCA patents as well.

To note, I do not conclude that Myriad's product and use patents qua essential property rights are definitively immoral because this would require having to also take into consideration all of the other various lines of argument for and against Myriad in the BRCA literature; arguments that may potentially override the reasons provided here. However, I do freshly conclude that the argument from the right to bodily ownership can be revitalized in spite of the particular objections presented against it in the literature, and it does provide a good ethical and legal reason against the essential property rights aspect of Myriad's patents in Europe that cannot be ignored.¹⁰

¹⁰ I would like to thank Paul Park, Wayne Norman, Suzannah Sorg, Kyung Hee Park, Carlos Mariscal, Eric Silverman, and an anonymous reviewer for *The Journal of Value Inquiry* for their help with this paper.