

Your Genes Belong To Us

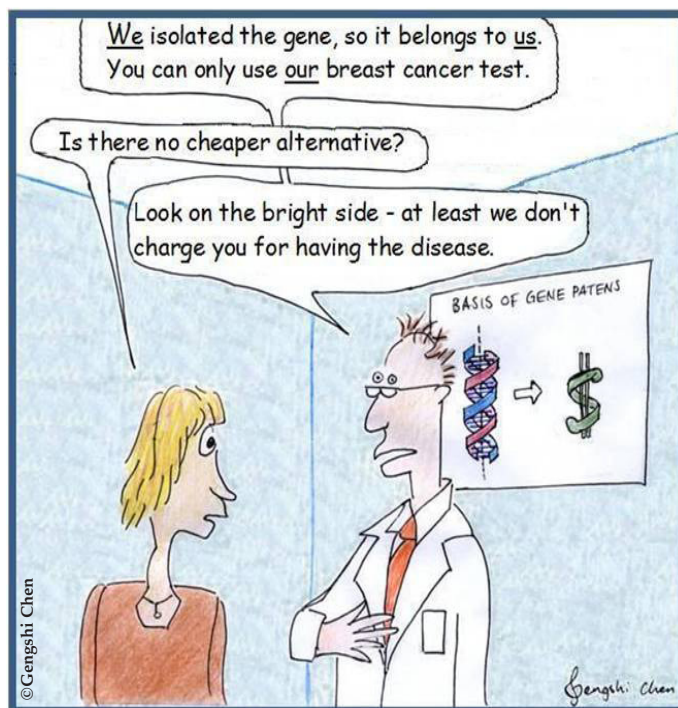
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Genee Girard, a 39-year-old woman living in the US, had to pay a staggering \$3200 for a single genetic test for the BRCA gene associated with breast and ovarian cancer, only to find that she was unable to request a second opinion upon receiving the positive test result. After consulting with doctors, Ms Girard was advised to have her ovaries surgically removed in order to diminish the 60% risk of developing ovarian cancer indicated by the genetic test. Because Myriad Genetics, which holds a patent on the BRCA genes, is the only laboratory to provide the genetic test, Ms Girard had to undergo the life-changing surgery without knowing for certain whether it was absolutely necessary [1].

Ms Girard is only one of tens of thousands of women in this situation, left with no choice but to accept the outcome of a single indeterministic genetic test result, which in addition is subject to human errors in the test laboratory. Other companies are unable to provide an alternative method of diagnosis because the gene in question is protected under patent laws [2]. Currently 20% of human genes are “owned” by individual biotechnology companies and research labs, making it illegal for others to carry out diagnosis and therapy, and limiting research using those genes [1,3].

The underlying principles of patents are to promote openness of publically beneficial findings, and to reward investors for the capital endowed in innovating and de-

velopment: it has to be new, be susceptible to industrial application and involve an inventive step. In addition, the Biotech Patent Directive adopted in 1998 by the EPO contains further criteria and restrictions to clarify the patentability of biotechnological matters [6].



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veloping a product. In return for disclosing the details of an invention and paying a maintenance fee, the patentee receives a 20-year monopoly over the patented product or process [4]. This argument has an appreciable value when considering inventions such as Tetra Pak® or SuperGlue. However, is the patenting of human genes a step too far? Do gene patents deprive the public of cost-effective health care, and what impact do they have on research in public institutions and competing companies?

The history of the British patent system as we know it today started in the 19th century, when the granting of patents became independent of the crown and turned into a regulatory matter for the state. With the passage of the Patent act in 1977, patent rights became an integrated part of British law.

It is worth noting that patents are country-specific, and the laws regulating them vary from country to country [4]. Generally, US patent laws are more liberal in the consideration of patentable matters than the European equivalent, allowing more gene patents to be approved [5]. The European Patents Office (EPO), an intergovernmental patent approval organisation, has 3 main criteria for the patentability of an

The association of BRCA1 with breast and ovarian cancer was discovered in 1994 by Mark Skolnick, founder of Myriad Genetics. He patented the gene and was granted a monopoly for the use of the gene in genetic testing, gene therapy, protein replacement therapy and the screening of drugs for cancer therapy [7]. In 1995, BRCA2, a related gene, was discovered and the patent rights were purchased by Myriad Genetics. The patents have allowed Myriad to, in effect, control the research and genetics testing of the BRCA genes in the US [8]. The BRCA1 and BRCA2 patents were approved by the EPO in 2001 and 2003 respectively, but cover a more restricted scope of rights than the US patents [1,9].

A law suit filed by the American Civil Liberties Union (ACLU) resulted in the invalidation of the BRCA gene patents in March 2010 at the US District Court for the Southern District of New York. The court decision taken by Judge Sweet was based on the argument that the isolated DNA is not markedly different from the natural state and that “DNA ... should be treated as the physical embodiment of ... nature”. In other words, although DNA is a chemical molecule, it should not simply be treated as other chemical compounds, since it also carries information and knowledge, which is not patentable. This is the first time an American court has found it unlawful to patent genes, a decision which could lead to the invalidation of 18.5% of the current patents of human genes [5,8].

Opponents to human gene patenting are concerned in principle by the action of owning genes – DNA is intrinsic and not an invention. The patents monopolise the gene test market and inhibit competition-derived reduction of health care costs. The revenue of Myriad Genetics in 2009 was \$326 million, most of which came from their BRCA analysis gene test [8]. Another problem arising from the nature of the monopolised market is that patients are prevented from receiving a second opinion on their test results. The intellectual property rights allow the patent holder to deny licensing the usage of the gene for the development of alternative diagnostic tests, in order to retain their monopoly of the test market. Critics also argue that the current patent system (especially in the US) is unfair, because it allows a gene to be patented before a working product has been developed. Moreover, even if only a single function of a gene is understood at the time of patenting, the patent may cover all other functions of the gene yet to be discovered. This is something that has become increasingly significant as we discover the complexity of gene function and regulation [4].

One of the main arguments against gene patenting is that it stifles research, prevents scientific advances and stops

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the development of new therapies. To limit the extent of this effect, there are research exemption rules in the patent laws of many European countries and in the US, which allow “pure” research to use patented genes without the need for a licence [10]. Hundreds of research papers on patented genes such as the BRCA genes prove that the concept works; researchers are making use of the exemption rule [8]. To further reduce the research dampening effect, some biotechnology companies provide subsidised licensing to research labs [11]. In a statement by Myriad Genetics, the company said, “It is important for us to point out that research activities with the patented technologies are not limited in any way by Myriad and are encouraged through subsidised costs for testing from the company to researchers.” Although this might encourage research on patented genes in non-profit labs, it is

unlikely that competitors are using these free licences, since new products developed with the gene may be under the protection of the existing patent, allowing Myriad to claim royalties on their research [12]. Other organisations, such as the not-for-profit Cancer Research UK, take a similar approach by granting free licences to all reputable research labs, and in doing so preventing research on the gene in question from becoming stagnant [11].

On the other side of the debate are supporters of gene patenting, who argue that patents are needed to provide an incentive for capitalists to invest in research. Due to the long process between the initial discovery of a gene and the commercialisation of the final diagnostic or therapeutic product, gene patenting is needed in addition to product patenting in order to drive initial research. A major problem with ending gene patenting is the risk of increased secrecy in the pharmaceutical and biotechnology industries as well as in academia, which would hinder research and result in wasteful research duplications. Gene patenting allows academics to publish their research openly, enabling further development [8,13].

The controversy of human gene patenting has been difficult to solve, partly due to the complexity of genetic material in terms of its function and regulation. New findings are constantly revealed, making it difficult for the law and ethics to keep up to speed with patentability criteria and case law. All gene sequence patents were granted prior to the completion of the first draft of the human genome project in 2000 by which time all human genome sequences became publically available [14]. The 20-year validity of patents means that the last gene sequence patent is going to expire in 2020, effectively solving the dilemma [8]. However, scientific advances continuously generate new uses and applications of already sequenced genes, such as genetic tests and drug screen targets, which may well be patentable. The scientific society and the general public should continue the debate in order to influence the way EPO and other patent offices are building up case law for the patentability of human genes, striving to achieve a balance between the incentive to invest in research, scientific progress and fair health care services. ■

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