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Short Communication

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## Explaining the benefits of human genome patent

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### Abstract

*Gene patenting has been facing backlash for decades now. Even Michael Crichton, science fiction novelist, as joined the bandwagon speaking against gene patent.<sup>1</sup> Such hostility towards patents, the professional interests of academics, researchers and inventors are under the threat of losing their rights over the work they have done. The biotech industry can never be out of discoveries. With constant biological changes, new diseases are appearing and they have to dig deeper. However, not all progress is free. Rewarding the inventors is not at all unfair. This paper will demonstrate that (i) patents are a foundation of the industry. They need to innovate further progress. The reason patent law exists to protect the inventions for a limited period of time. The paper will also demonstrate that (ii) the social myths about gene patent are not really manifested in reality. It will discuss the argument against gene patenting and then will present counter arguments with empirical evidence whether the myths are really true.*

**Keywords:** Patent system, Concerns, criticisms, Genome patenting, DNA testing

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## 1. Introduction

### 1.1. Essence of the Industry

Gene patents are important to the biotech industry. Banning them can close down a big part of the market and limit the progress in scientific development.<sup>2</sup> Inventions need huge investments and time. In 2014, Tufts University analyzed the expenses of bringing a new drug to market and discovered that the expenses are over \$800 Mn. Developing new prescriptions which will gain market approval is estimated to \$2,558 mn.<sup>3</sup>

People against gene patents argue that it is easy to develop a molecular finding once a gene's scientific literature is identified. However, the financial documents said something different. The Genomic Health prospectus in 2005 showed that they used \$20 mn to fund research and development programs for a variety

<sup>1</sup> Michael, Crichton. *Patneting Life*, *The New York Times* (13 February 2007) <[http://www.nytimes.com/2007/02/13/opinion/13crichton.html?\\_r=0](http://www.nytimes.com/2007/02/13/opinion/13crichton.html?_r=0)> accessed 17 May 2016.

<sup>2</sup> Geoffrey, Karny. (2007). *In Defence of gene patenting: The principles of our patent system are sound and bring immense benefits* (*Gen*, 1 April 2007) <<http://www.genengnews.com/gen-articles/in-defense-of-gene-patenting/2052/>> accessed 17 May 2016.

<sup>3</sup> Tufts Centre for the Study of Drug Development. *News* (18 November 2014) <[http://csdd.tufts.edu/news/complete\\_story/pr\\_tufts\\_csdd\\_2014\\_cost\\_study](http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study)> accessed 17 May 2016.

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of cancers.<sup>4</sup> Third Wave's 10-K account for 2005 showed that they spent \$8.4 mn on research.<sup>5</sup> The biotechnology industry, the National Institute of Health (NIH), in the US spent \$49 bn alone on biomedical research in 2004, spending 36% on the national biomedical research.<sup>6</sup> The cost of development of biopharmaceuticals is above \$1.2 bn.<sup>7</sup> According to studies, the pharmaceutical industry is the prime area benefitting from the encouraging effect of patents than any other areas of science.<sup>8</sup> Patents are important especially for new companies, which needs substantial investment from outside. The innovation, due to patents, brought in fresh companies into the biotech industry in the last two decades.<sup>9</sup> These are certainly huge investments and it would never have taken place knowing that there will be competition for the same product.

## 1.2. Innovation

Without the existence of the patents, the innovation would be injured by the 'appropriability problem'.<sup>10</sup> The appropriability problem states that if an invention does not recover the production costs because it is a public domain, then it loses value as an innovation.<sup>11</sup> To avoid this problem, the genetic researchers protect their inventions or discoveries through trade secrets.<sup>12</sup> This restricts the free flow of information in the scientific community. If geneticists turn to trade secrecy, then the emphasis on traditional disclosure of the information would disappear. Patents solve both problems: bringing funds in innovation and distribute knowledge to the scientific community.<sup>13</sup> Some researchers even support patents. Patents encourage scientists and researchers to create or discover technology that works hand to hand with patents.<sup>14</sup> On the contrary, patents itself are not the problem, it is the overly limiting or dominant licensing policies of the patent holder.<sup>15</sup>

## 1.3. Place of human gene patent in constitution

The purpose of patent law is to protect intellectual property. The University of Utah supports that the patent system works as exactly constructed: to protect inventions.<sup>16</sup> Geoffrey Karyn, a patent lawyer in the US, discussed the role of the constitution for a patent in relation to human genes. According to Karyn, the constitution provides for patents. The inventors have the right to prevent others from the free use of the invention for a limited amount of time<sup>17</sup>, which is 20 years.<sup>18</sup> The right is limited anyways and there is no guarantee of commercial profit from the patent. Once the patent expires, it becomes a public domain.

Property rights are very much valued today however intellectual property rights are much controversial and something like human genomic patents adds fuel to the debate. This is so because it does not have an individual creator but dozens of researchers contributing to the genetic discovery and the expenditure comes from public funds. Therefore, the public feels that the patented genetic materials are only used for profit and

<sup>4</sup> Genomic Health INC, Genomic Health: Common Stock (2005). <[http://www.nasdaq.com/markets/ipos/filing.ashx?filingid=3699759#F09100B4E424B4\\_HTM\\_104](http://www.nasdaq.com/markets/ipos/filing.ashx?filingid=3699759#F09100B4E424B4_HTM_104)> accessed 17 May 2016.

<sup>5</sup> Third Wave Technologies: 2007 Annual Report (2007). <[http://media.corporate-ir.net/media\\_files/irol/12/123192/TWT-AR07.pdf](http://media.corporate-ir.net/media_files/irol/12/123192/TWT-AR07.pdf)> accessed 17 May 2016.

<sup>6</sup> Elias, A. Zerhouni. (2005). US biomedical research: Basic, translational and clinical sciences. *JAMA* 294, 1352.

<sup>7</sup> PhRMA. (2013). Profile (2013). <<http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf>> accessed 18 May 2016.

<sup>8</sup> James, Bessen., and Michael, J. Meurer. (2004). Lessons for patent policy from empirical research on patent litigation. *LCLR*, 9, 1.

<sup>9</sup> Nikki, Buck. (2013). Greed is good, for patients: How the biotechnology industry saves lives, one gene patent at a time. *NJTIP*, 11, 60.

<sup>10</sup> Kenneth, W. Dam. The Economic Underpinning of Patent Law' (*John M Olin Law and Economics Working Paper*) <[http://www.law.uchicago.edu/files/files/19.Dam\\_Patent.pdf](http://www.law.uchicago.edu/files/files/19.Dam_Patent.pdf)> accessed 18 May 2016.

<sup>11</sup> Birgitte, Anderson. If Intellectual Property Rights is the Answer, What is the Question?: Revisiting the Patent Controversies' (*Instituto de Economia*) <[http://www.ie.ufrj.br/datacenter/ie/pdfs/seminarios/pesquisa/intellectual\\_property\\_rights\\_what\\_is\\_the\\_question.pdf](http://www.ie.ufrj.br/datacenter/ie/pdfs/seminarios/pesquisa/intellectual_property_rights_what_is_the_question.pdf)> accessed 18 May 2016.

<sup>12</sup> Abigail, Lauer. The disparate effects of gene patents on different categories of scientific research. *HJLT*, 25, 180.

<sup>13</sup> Dam (n 10).

<sup>14</sup> Buck (n 9).

<sup>15</sup> Sirpa, Soini., Segolene, Ayme., and Gert, Matthijs. (2008). Patenting and licensing in genetic testing: Ethical, legal and social issues. *EJHS*, 16, 10.

<sup>16</sup> Lynne, Peeples. The gene hunt: Should finders be keepers? (*Scientific American*, 29 July 2009) <<http://www.scientificamerican.com/article/gene-patents-breast-cancer-lawsuit-myrriad/>> accessed 17 May 2016.

<sup>17</sup> Karyn (n 2).

<sup>18</sup> TRIPS, art 33.

not connected to the welfare of the society.<sup>19</sup> What the public is missing is the point that patents of genetic materials are strongly connected to the welfare and a large number of contributors.

Scientific progress exists because of publication of research and it is valued worth billions of funds. However, it cannot be free. There has to be some limits and respecting patent right is the limit if the people wants to be benefitted. Such was the case in *Madey v. Duke University* where the university removed Madey forcefully and operated the equipment patented under Madey's name. As a result, Madey sued the university for infringing the patent.<sup>20</sup>

A patent is a contract between the inventor and the public. The limited market opportunity by the patent gives the inventors the chance to bring profit on innovation. By bringing in the investment fund for research plus patent protection speeds up the innovation, thus benefiting society.<sup>21</sup>

There are benefits that the economy enjoys due to the patent system but they are indirectly related. The biotech industry is one of the fastest growing industries in the world and according to the Romanow Report in 1997 till 2003, it created 86,000 to 130,000 jobs in Canada alone.<sup>22</sup> The Amylin Pharmaceuticals is a perfect example how patented innovation created jobs. The company stated their research and development expenses worth \$136.3 Mn with 1500 jobs, which, without patent protection, would not have been possible.<sup>23</sup>

#### 1.4. Counterarguments to myths

There has been a number of empirical research on the evidence of the myths against human gene patent. One of the arguments against gene patent is that it brings the tragedy of the anti-commons which means a single resource having numerous patents. This makes access very expensive.<sup>24</sup> Rebecca Eisenberg, however, stated in her paper that patents do not pose any problems to research as much as the policymakers made it out to be. Rather it poses problems to the very express laws of the government of utilization of inventions.<sup>25</sup>

According to Walsh, a 2003 survey showed that even with increasing patents, academic researchers were able to access to the knowledge without any problems.<sup>26</sup> The reason for the limitation is the geneticists lack of will to accept the market price and terms.<sup>27</sup> Additionally, Walsh's study found that only 1% reported a delay of their project due to patents but no one was forced to quit their research. Furthermore, 22 out of 23 respondents in the study, stated that there were no fees for the patented technology. Only one respondent in the study said that he had to pay a licensing fee but it ranged to \$100. This shows that patents have very insignificant effect on research on scientific literature.<sup>28</sup> One respondent stated that it is very reasonable for the royalty paid for a therapeutic invention and royalty stacking does not pose any threat to research and development process.<sup>29</sup> Where license prices are too high for smaller businesses, firms provide discounts over research equipment. Incyte, for example, started allowed single-gene searches for free in 2000 and Myriad offers discount rates, less than half the market price for academics for research on breast cancers.<sup>30</sup>

While scholars like Walsh have found that patents have little effect on research, others do not believe so. The reason is the Myriad controversy that is used as the main justification for patent reform. This shows how

<sup>19</sup> David, B. Rensik. (2004). *Owning the Genome: A Moral Analysis of DNA Patenting* (SUNY).

<sup>20</sup> *John M J Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

<sup>21</sup> Donald, J. Willison., and Stuart, M. Macleod. (2002), *Patenting of genetic material: Are the benefits to society realised?* *CMAJ*. 167, 259.

<sup>22</sup> Timothy, Caulfield. 'Sustainability and the balancing of the health care and innovation agendas: the commercialization of genetic research.

<sup>23</sup> Gene, Quinn. *How patented innovation created jobs and economic growth (IP Watchdog, 24 January 2011)* <<http://www.ipwatchdog.com/2011/01/24/how-patented-innovation-creates-jobs-and-economic-growth/id=14589/>> accessed 19 May 2016.

<sup>24</sup> John, P. Walsh., Charlene, Cho., and Wesley, M. Cohen. *View from the Bench: Patents and Material Transfers*.

<sup>25</sup> Rebecca, S. Eisenberg. (1990). *Patenting the human genome*. *ELJ*, 39, 721.

<sup>26</sup> Walsh, Cho., and Cohen. (n 24).

<sup>27</sup> Timothy, Caulfield., Robert, M. Cook-Deegan., F. Scott, Kieff., and John, P. Walsh. (2009). *Evidence and anecdotes: An analysis of human gene patenting controversies*. *NB*, 24, 1091.

<sup>28</sup> Walsh, Cho., and Cohen. (n 24).

<sup>29</sup> Wesley, M. Cohen., and Stephen, A. Merrill (eds). *Patents in the Knowledge-Based Economy* (National Research Council 2003) 285.

<sup>30</sup> Richard, Gold, E., and Julia, Carbone. (2010), *Myriad genetics: In the eye of the policy storm*. *GM*, 12, 39.

one controversy can make both the government and non-government offices to take actions.<sup>31</sup> In Belgium, for example, the controversy caused the government to adopt a research exemption to gene patent.<sup>32</sup> Research exemption is a right given to researchers to conduct research on genes or drugs without being subject to patent infringements. The Myriad case put fear in people that patents on human genes would negatively affect the people. This is because the Myriad Genetics controversy fitted well with the economic theories that were concerned with the consequences. People understood the theoretical outcome. Also the media played a big role framing the controversy and public's point of view about the risks and benefits of genomic mapping industries.<sup>33</sup> Although the fears with the case have a good reason, there is hardly any data on it and one empirical research cannot be used to justify all actions of gene patents. One should not generalise the gene patent to other uses.<sup>34</sup>

It is true that researchers are becoming more private and unwilling to share their research but the blame cannot be put on the patent. The studies on academic secrecy cannot be relied on because they are based on combined issues and the specific reason cannot be seen.<sup>35</sup> The reason could be the increasing commercial and scientific competition. Therefore, some suggested lessening the commercial direction to aid the flow of research.<sup>36</sup> Another solution could be looking into the very competitive nature of the academic process<sup>37</sup> and developing extra mechanisms to help the researchers subject to their commercial interests.<sup>38</sup>

Similarly, studies have criticised that the monopoly created by the patent created cost inefficiencies for health care systems. A French study by Sevilla agreed that while patents on human genes allow research organisations to get returns on research and development costs, the patent laws should restrict the monopoly power of the patent holder.<sup>39</sup> However, in the United Kingdom, patient access to genetic tests is not restricted by patents because most of the tests are done by the National Health Service than by private companies. Therefore, the UK did not face any negative results due to patent laws.<sup>40</sup> Companies are very much aware of the consequences of challenging the NHS which would only end up in bad publicity.<sup>41</sup> It is true that the access and costs are a major concern due to a monopoly and therefore challenging the policy is reasonable. However, what patent does is provide monopoly for a limited amount of time in exchange for the disclosure of description of the genetic invention for further development.<sup>42</sup> Although patents are supposed to control access, commercialise inventions and create premium prices disregarding whether it is ethical or not. It is reasonable for the government to focus on the efficacy of commercialization of biological inventions through patents but it should be done subject to the entire purpose of the patent system.<sup>43</sup> However, judging by the situation of NHS and private companies, it is clear that biotech companies cannot charge however they wish because of government supervision and the companies will be accountable if they abuse their monopoly. Any charges will be reasonable based on production costs. Therefore, it is very unfair to strike down patents because patents itself is not at fault. There is already a mutual understanding between public administration and the biotech companies in the UK and same could be adopted in the United States and internationally. According to Kieff, that even if patents did not exist, difficulties around the costs will hinder development. The competitive nature of a senior scientist could lead him or her to mock the subsequent research of a junior geneticist.<sup>44</sup> The

<sup>31</sup> Matthew, M. Karlan. (2011). Patent policy, natural products, and the gene patent debate: Seeking the proper judicial mode of analysis. *ASAL*, 67, 95.

<sup>32</sup> Geertrui, Van, Overwalle., and Esther, Van, Zimmeren. Reshaping belgian patent law: The revision of the research exemption and the introduction of a compulsory license for public health (*Centre for Intellectual Property Rights*) <[https://www.iip.or.jp/e/e\\_publication/pdf/vol64\\_overwalle\\_and\\_zimmeren.pdf](https://www.iip.or.jp/e/e_publication/pdf/vol64_overwalle_and_zimmeren.pdf)> accessed 19 May 2016.

<sup>33</sup> Timothy, Caulfield., Tania, Bubela., and C. J. Murdoch, Myriad and the mass media: The covering of a gene patent controversy. *GM*, 9, 850.

<sup>34</sup> Buck (n 9).

<sup>35</sup> Caulfield, Deegan, Kieff., and Walsh. (n 27).

<sup>36</sup> Leonard, Taylor, Jr (2005). Best practices for the licensing of genomic inventions. *FR*, 70, 18413.

<sup>37</sup> Jerome, R. Ravetz. *Scientific Knowledge and its Social Problems* (Transaction Publishers 1973).

<sup>38</sup> Caulfield, Deegan, Kieff., and Walsh. (n 27).

<sup>39</sup> Christine, Sevilla, Francois Eisinger., and Jean-Paul, Moatti, Do gene patents limit the diffusion of genetic testing? The case of DNA tests for breast cancer susceptibility (*International Association of Health Policy*, 26 June 2007) <<http://www.healthp.org/node/77>> accessed 19 May 2016.

<sup>40</sup> Naomi, Hawkins. (2011). The impact of human gene patents on genetic testing in the UK. *GM*, 13, 320.

<sup>41</sup> Biomedical Patents. *Parliamentary Office of Science and Technology* <<http://www.parliament.uk/briefing-papers/POST-PN-401.pdf>> accessed 19 May 2016.

<sup>42</sup> Caulfield (n 22).

<sup>43</sup> Timothy, Caulfield. (2008), Human gene patents: Proof of problems. *CKLR*, 84, 133.

question should not be whether gene patents effects the access to care or resources because they do, but whether compromising situations from the limitations is acceptable.<sup>45</sup> But regardless of the criticisms of the patent system, it is reasonable to say that the gene patent debate should be communicated to the public by the most reliable and best evidence possible and the current evidence against the human genomic patents is less than ideal.<sup>46</sup>

## 2. Conclusion

To conclude this paper, we can firstly say that while there are good reasons for concerns, criticisms and distrust on the patent system, the feared problems have not broadly evidenced in reality. Those that do come up in data has to do less with the patents and more with the commercial and competition issues. Even though there are some who are recognizing the benefits of patents, the habit to interfere and suggesting policy moderation and proposing research exemption remains. Even if one does adopt research exemption, it is unlikely that it would solve the so-called existing anti-commons problem, or limited access issues, especially DNA testing. And, if there are any reforms, they need to be subjected to the essence that the patents system provides for evolving and sharing research technologies. Due to a lack of strong data of issues and a miscommunication between the issues and answers suggested may be the reason why no one trusts the patent system. However, one should admit that an effect of these controversial policy arguments may have been to get both administrative and funding agencies, such as USPTO and NIH, and patent holders to the serious outcomes of both sides of the patent issuing, that is, overly liberated patent granting and too restrictive measures. Whether this warning will have any effect on innovation and scientific progress, remains a question for all. Therefore, future research on these issues, possible outcomes in reality and possible solutions, should be encouraged.

Due to misinformation and miscommunication about genomic mapping and their patents, the actual purpose of the patent system has vanished. The true principles of the patent have supported and contributed a great deal to the genomic technology around the world and brought about the benefits to the humankind.<sup>47</sup>

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<sup>44</sup> Arti, Kaur, Rai. (2001). [Evolving scientific norms and intellectual property rights: A reply to kieff. 95.](#)

<sup>45</sup> Anderson (n 11).

<sup>46</sup> Caulfield (n 43).

<sup>47</sup> Karny (n 2).