

INCENTIVE FOR INNOVATION OR INVITATION TO INHUMANITY?:  
A HUMAN RIGHTS ANALYSIS OF GENE PATENTING AND THE CASE  
OF *MYRIAD GENETICS*

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I. INTRODUCTION

Eighteen years ago, the General Agreement on Tariffs and Trade (GATT) concluded its near decade-long Uruguay Round of multilateral trade negotiations.<sup>1</sup> Not only did the Uruguay Round transform the realm of international trade by creating the World Trade Organization (WTO), but, in a controversial move, it also brought intellectual property rights under the protective arm of the WTO.<sup>2</sup> In 1994, at the conclusion of the Uruguay Round, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was put into force, requiring all members of the WTO to adhere to measures providing significant protections for intellectual property rights.<sup>3</sup>

Though many applauded the creation of TRIPS, the agreement also saw instant backlash, not only by critics who saw this as a move away from the WTO's trade mission,<sup>4</sup> but also by human rights activists concerned that this new intellectual property regime would quash certain basic human rights,<sup>5</sup> such as the right to health, food security and access to information.<sup>6</sup> As a result of these human rights concerns, the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health in 2001, in which the WTO acknowledged the concerns that some intellectual property protections could harm human rights like access to healthcare and medicines. It therefore created some flexibility in the application of the TRIPS principles by allowing member states to overlook some patent rights that may impinge on access to essential medicines.<sup>7</sup>

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<sup>1</sup> *WTO Legal Texts*, WORLD TRADE ORG., [http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm) (last visited Feb. 27, 2012).

<sup>2</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement], *available at* <http://treaties.un.org/doc/publication/unts/volume%201869/v1869.pdf> (last visited Feb. 25, 2012).

<sup>3</sup> *Id.*

<sup>4</sup> JAGDISH BHAGWATI, IN DEFENSE OF GLOBALIZATION 183 (2004).

<sup>5</sup> See Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) (providing a list of basic human rights).

<sup>6</sup> Someshwar Singh, *TRIPS Regime at Odds with Human Rights Law*, Says UN Body, THIRD WORLD NETWORK (Aug. 28, 2000), <http://www.twinside.org.sg/title/odds.htm>.

<sup>7</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

Thus began the conflict between intellectual property rights and human rights. Though this conflict has mostly revolved around the clash between pharmaceutical patent rights and the right of access to medicines, the battle has entered additional fields like environmental law and food security.<sup>8</sup> This Note examines one area of the conflict—the right to patent genes versus the human right of access to the human genome. This human rights perspective<sup>9</sup> holds that the human genome and its countless components are the property of the entire human population, such that no person or entity can claim ownership to it. Specifically, this Note analyzes the key court decisions related to patenting of live, biological material to determine whether any human rights arguments have been made against such patents. Additionally, this Note analyzes from a human rights perspective the recent Federal Circuit Court of Appeals case involving Myriad Genetics, which questioned a company’s ability to patent a gene related to breast and ovarian cancers. This analysis considers the human rights issues related to genetic research and evaluates possible human rights violations that could result from patenting genetic material.

This Note proceeds in four Parts. Part II begins with an overview of the background and history of the human rights-intellectual property rights conflict, including a discussion of the arguments from both camps. Part III discusses international actions taken to establish a human right to the human genome and the implications this has on the ability to patent genes. Part IV analyzes some of the past landmark cases related to the patenting of biological material to determine whether any human rights implications were considered when granting those patents. Included with this final section is a discussion of the Myriad Genetics case to determine whether the recent decision of the Federal Court of Appeals acknowledged any human rights concerns with human gene patenting and what impact the human rights perspective may have had on the outcome of the case. Part V concludes.

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<sup>8</sup> See Richard Lee, *Food Security and Food Sovereignty* 3–5 (Ctr. for Rural Econ. Discussion Paper Series No. 11, 2007), available at <http://www.ncl.ac.uk/cre/publish/discussionpapers/pdfs/dp11%20Lee.pdf>; *Patents on Life*, GREENPEACE INT’L, <http://www.greenpeace.org/international/en/campaigns/agriculture/problem/genetic-engineering/ge-agriculture-and-genetic-pol/patents-on-life/> (last visited Feb. 27, 2012).

<sup>9</sup> One well-devised definition of a human rights approach to evaluating the effects of intellectual property rights explains that “[a] human rights approach takes what is often an implicit balance between the rights of inventors and creators and the interests of the wider society within intellectual property paradigms and makes it far more explicit and exacting. A human rights approach is predicated on the centrality of protecting and nurturing human dignity and the common good. . . . Or to put the matter another way, from a human rights perspective, intellectual property protection is understood more as a social product with a social function and not primarily as an economic relationship.” Audrey R. Chapman, *The Human Rights Implications of Intellectual Property Protection*, 5 J. INT’L ECON. L. 861, 867 (2002).

## II. BACKGROUND AND HISTORY OF THE CONFLICT BETWEEN INTERNATIONAL HUMAN RIGHTS AND INTELLECTUAL PROPERTY RIGHTS

### A. *The History of the Conflict*

As mentioned above, the WTO's TRIPS Agreement was the first important step in creating international regulations for intellectual property rights. Prior to the creation of the TRIPS agreement, efforts to harmonize intellectual property protections were generally unsuccessful,<sup>10</sup> and efforts that did succeed were typically bilateral treaties, resulting in a disorganized system of intellectual property protections that lack uniformity and consistency.<sup>11</sup> Beginning in the 1980s, the need for greater international intellectual property protections became increasingly evident, as rampant piracy "was undermining key industries that relied on intellectual property protection, such as the pharmaceutical industry, the music industry, the computer software industry, the publishing industry, and the motion picture industry."<sup>12</sup>

Initial efforts by the World Intellectual Property Organization (WIPO) to create multilateral intellectual property agreements and update prior intellectual property conventions<sup>13</sup> broke down in the 1980s.<sup>14</sup> WIPO's inability to succeed at updating international intellectual property protections was due to several factors, including the increased number of developing nations participating in WIPO, the "ideological split between socialist block and the non-socialist," fear of American dominance in intellectual and cultural production, and the United States' unwillingness to make any concessions that would require it to change its own intellectual property laws.<sup>15</sup>

In the end it was the GATT that was able to achieve what WIPO could not—the creation of a multilateral treaty on intellectual property rights protection—the Agreement on Trade-Related Aspects of Intellectual Property Rights.<sup>16</sup> As a creation of a trade organization, the TRIPS Agreement was intended to only regulate those aspects of intellectual property that affect trade, though many have criticized TRIPS for distorting the WTO's trade mission, and instead turning it into

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<sup>10</sup> Ralph Oman, *Intellectual Property After the Uruguay Round*, 42 J. COPYRIGHT SOC'Y U.S.A. 18, 19 (1994).

<sup>11</sup> *See id.*

<sup>12</sup> *Id.* at 24.

<sup>13</sup> The 1967 Paris Convention for the Protection of Industrial Property is generally considered the "cornerstone[] of the international intellectual property regime." Peter K. Yu, *Teaching International Intellectual Property Law*, 52 ST. LOUIS U. L.J. 923, 926 (2008). Other important intellectual property conventions include the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits. *Id.* at 926–27.

<sup>14</sup> Oman, *supra* note 10, at 19.

<sup>15</sup> *Id.* at 20–21.

<sup>16</sup> TRIPS Agreement, *supra* note 2.

a “royalty collection agency.”<sup>17</sup> Despite this apparently odd marriage of trade and intellectual property, TRIPS remains the most influential international intellectual property rights agreement, “mak[ing] protection of intellectual property rights an integral part of the multilateral trading system . . . .”<sup>18</sup>

TRIPS obligations require the highest level of intellectual property protection seen in any international agreement, and since all WTO members are bound by the TRIPS obligations, the Agreement provides robust protection for intellectual property rights throughout the world. Furthermore, the binding power of the WTO’s Dispute Settlement Body decisions means that members who violate the TRIPS Agreement could face devastating repercussions such as being required to pay compensation to or possible retaliation by the injured country.<sup>19</sup>

TRIPS obligations parallel many of the general WTO free trade requirements, including requiring each WTO member to grant all other WTO members “treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property,”<sup>20</sup> as well as most-favored-nation treatment<sup>21</sup> with regard to the protection of intellectual property.<sup>22</sup> Additionally, TRIPS provides for numerous intellectual property-specific requirements including extensive copyright protection,<sup>23</sup> protection of trademarks,<sup>24</sup> integrated circuit design, and most importantly for the purposes of this Note, protection of patents for essentially all types of inventions with a minimum patent term of twenty years.<sup>25</sup> Although the TRIPS agreement affords members discretion to exclude some types of inventions from patentability,<sup>26</sup> it requires that “patents shall be available and patent rights enjoyable without discrimination as to the place of

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<sup>17</sup> BHAGWATI, *supra* note 4, at 82–83, 182–83.

<sup>18</sup> *Frequently Asked Questions About TRIPS [trade-related aspects of intellectual property rights] in the WTO*, WORLD TRADE ORG., [http://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm#GATT1947](http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#GATT1947) (last visited Feb. 27, 2012).

<sup>19</sup> RALPH H. FOLSOM, INTERNATIONAL BUSINESS TRANSACTIONS (PRACTITIONER TREATISE) § 9.6 (2011).

<sup>20</sup> TRIPS Agreement, *supra* note 2, at art. 3, para 1.

<sup>21</sup> The WTO defines most favored-nation-treatment as follows: “Under the WTO agreements, countries cannot normally discriminate between their trading partners. Grant someone a special favour (such as a lower customs duty rate for one of their products) and you have to do the same for all other WTO members.” *Principles of the Trading System*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact2\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm) (last visited Feb. 27, 2012).

<sup>22</sup> TRIPS Agreement, *supra* note 2, at art. 4.

<sup>23</sup> For example, TRIPS provides fifty years of copyright protection for sound recordings and motion pictures. *See id.* at art. 12.

<sup>24</sup> *Id.* at art. 15.

<sup>25</sup> *Id.* at arts. 27–34.

<sup>26</sup> Specifically, WTO members may choose to exclude from patentability “(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.” *Id.* at art. 27, para. 3(a)–(b).

invention, the field of technology and whether products are imported or locally produced.”<sup>27</sup> Upon its passage in 1994, the TRIPS Agreement applied immediately to all WTO members. However, in perhaps its greatest concession to the disgruntled developing countries, the Agreement provided a transition period of four years (until January 1, 2000) for developing countries and transition economies, and an eleven-year transition period (until January 1, 2006) for least-developed countries.<sup>28</sup>

Though many lauded the TRIPS Agreement as an important and crucial step toward the protection of intellectual property rights, TRIPS was also scrutinized as an unfair policy toward developing countries,<sup>29</sup> resulting in human rights violations against some of the world’s poorest people.<sup>30</sup> Specifically, human rights advocates criticize TRIPS for putting private interests above basic rights “including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination . . . .”<sup>31</sup> Recognizing the tension that was developing between the human rights and intellectual property rights regimes, several international organizations began trying to ease this tension. For example, on November 9, 1998, WIPO organized a daylong panel discussion titled, “Intellectual property and human rights,” at which world intellectual property leaders discussed the causes of the conflict, and proposed various solutions.<sup>32</sup>

The most prominent advocate of advancing the human rights agenda in the intellectual property discourse was the United Nations. Beginning in 1999, the United Nations made several gestures intended to promote greater adherence to international human rights principles by intellectual property regimes. Specifically, in both its 1999 and 2000 Human Development Reports, the United Nations Development Programme “identif[ied] circumstances attributable to the implementation of the TRIPS Agreement that constitute contraventions of international human rights law . . . .”<sup>33</sup> Furthermore, in November 1999, the

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<sup>27</sup> *Id.* at art. 27, para. 1.

<sup>28</sup> *Frequently asked questions about TRIPS [trade-related aspects of intellectual property rights] in the WTO*, WORLD TRADE ORGANIZATION, [http://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm) (last visited Feb. 27, 2012)

<sup>29</sup> Haochen Sun, *Reshaping the TRIPS Agreement Concerning Public Health—Two Critical Issues*, CTR. FOR INT’L DEV. HARV. U., 1 & n.3 (2002), available at <http://www.cid.harvard.edu/cidtrade/Papers/haochensun.pdf>.

<sup>30</sup> Singh, *supra* note 6.

<sup>31</sup> Sub-Commission on Human Rights Res. 2000/7, Intellectual property rights and human rights, ESCOR, Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., 25th mtg., U.N. Doc. E/CN.4/Sub.2/Res/2000/7 (2000) [hereinafter Resolution 2000/7].

<sup>32</sup> *See Intellectual Property and Human Rights*, WORLD INTEL. PROP. ORG., <http://www.wipo.int/tk/en/hr/paneldiscussion/> (last visited Feb. 27, 2012).

<sup>33</sup> Resolution 2000/7, *supra* note 31, at 2. According to the 1999 Human Development report, “Intellectual property rights under the TRIPS agreement need comprehensive review to redress their perverse effects undermining food security, indigenous knowledge, biosafety and access to health care.” U.N. Dev. Programme, *Human Development Report*

United Nations Committee on Economic, Social and Cultural Rights presented statements at the Third Ministerial Conference of the WTO in Seattle, Washington.<sup>34</sup> The Committee's statement broadly encouraged the WTO "to assess the impact that trade liberalization may have on the effective enjoyment of human rights . . . ." and it specifically signaled "a strong warning against the negative consequences of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), particularly on food security, indigenous knowledge, bio-safety and access to health care . . . ."<sup>35</sup>

As a culmination of its efforts to bring human rights to the forefront of the intellectual property dialogue, the United Nations Commission on Human Rights put forth a declaration in 2000 titled *Intellectual Property Rights and Human Rights*.<sup>36</sup> To show that it was not a total rejection of intellectual property rights, the Declaration affirmed "the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which one is the author" pursuant to article 27, paragraph 2 of the Universal Declaration on Human Rights.<sup>37</sup> However, the Declaration also revealed concerns about global intellectual property regimes by announcing that "the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination . . . ."<sup>38</sup>

By acknowledging that a right to intellectual property protections exists, while at the same time pronouncing the harm that those protections may impose on other human rights like access to proper health care, the United Nations recognized the apparent conflicts "between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other . . . ."<sup>39</sup> In other words, this Declaration expressed the United Nations' fear that protecting the intellectual property rights of technology related to essential medicines, food production, or other basic health provisions, would cause prices of such health provisions to increase and access to those health products to decrease in poor countries, thereby violating the human right of health of millions of people. As a result of this apparent conflict, the report called on the WTO and particularly the Council on TRIPS to "take fully into account the existing State obligations

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1999, at 10 (1999) [hereinafter 1999 Human Development Report], available at [http://hdr.undp.org/en/media/HDR\\_1999\\_EN.pdf](http://hdr.undp.org/en/media/HDR_1999_EN.pdf).

<sup>34</sup> Statement of the U.N. Committee on Economic, Social and Cultural Rights to the Third Ministerial Conference of the World Trade Organization (Seattle, 30 November to 3 December, 1999), U.N. Doc. E/C.12/1999/9 (Nov. 26, 1999), available at <http://www.cetim.ch/en/documents/codesc-1999-9-eng.pdf>.

<sup>35</sup> *Id.* at para. 4.

<sup>36</sup> Resolution 2000/7, *supra* note 31.

<sup>37</sup> *Id.* at para. 1.

<sup>38</sup> *Id.* at para. 2.

<sup>39</sup> *Id.*

under international human rights instruments . . . .”<sup>40</sup> Thus, the United Nations called out the WTO by letting it know that decades before it obliged its member states to protect intellectual property rights under the TRIPS Agreement, the United Nations had obliged many, if not all, of those same member states to protect international human rights.

In response to the United Nations’ call to action, the WTO members adopted a special Ministerial Declaration during the Doha Round of trade negotiations in 2001 to clarify some of the concerns about the TRIPS Agreement’s impact on public health.<sup>41</sup> Though the Declaration did not go so far as to discuss all the human rights implications and violations resulting from the TRIPS Agreement, it did make some important concessions to an area of human rights that seemed particularly threatened by the TRIPS regime: public health. The Declaration recognized the threat that intellectual property rights may have to the prevention and treatment of diseases like HIV/AIDS, tuberculosis and malaria, and in a bold statement declared that the WTO member states

agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.<sup>42</sup>

The Declaration goes on to allow important concessions for developing and least-developed countries, particularly in the realm of intellectual property relating to pharmaceuticals.<sup>43</sup> In addition to granting governments a substantial amount of discretion in their use of patented pharmaceuticals, the Doha Declaration also extended the TRIPS Agreement transition period for least-developed nations from 2006 to 2016.<sup>44</sup> Though this Declaration may not have gone as far as human rights advocates would have hoped, the Doha Declaration was a significant WTO step toward acknowledging the negative implications of global intellectual property rights protections, and that in some cases, the negative impact on human rights outweighs the benefits that the intellectual property rights may have on private interests and the potential for future innovation.

As demonstrated above, the years following the TRIPS Agreement’s international debut brought the human rights-intellectual property rights debate to

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<sup>40</sup> *Id.* at para. 7.

<sup>41</sup> World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 20 November 2001, WT/MIN(01)/DEC/2 (2001), available at [http://trade.ec.europa.eu/doclib/docs/2005/march/tradoc\\_121933.pdf](http://trade.ec.europa.eu/doclib/docs/2005/march/tradoc_121933.pdf).

<sup>42</sup> *Id.* at para. 4.

<sup>43</sup> *Id.* at paras. 5–7.

<sup>44</sup> *The Doha Declaration on the TRIPS Agreement and Public Health*, WORLD HEALTH ORG., [http://www.who.int/medicines/areas/policy/doha\\_declaration/en/index.html](http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html) (last visited Feb. 28, 2012).

center stage. Though both human rights and intellectual property rights advocates have evidently recognized the validity of each other's arguments, and though several praiseworthy negotiations, compromises and concessions have been reached, the debate between the two camps continues. In particular, disagreements remain about how far the intellectual property rights regimes should go in accommodating human right concerns. What follows is a discussion of the arguments by both the human rights and intellectual property rights advocates to show the seemingly impossible task of creating a perfect compromise.

### *B. The Human Rights Argument*

An initial evaluation of the human rights arguments against international intellectual property rights protections presents somewhat of a conundrum, since the United Nations Universal Declaration on Human Rights, at least vaguely, recognizes intellectual property rights as a basic human right. Not only does the Declaration recognize a right to own property,<sup>45</sup> but it also specifically declares that “[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”<sup>46</sup> Without explicitly calling this an intellectual property right, this article of the Declaration essentially defines intellectual property and declares it a universal right. Within that same article however, the Declaration also says that “[e]veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and to *share in scientific advancement and its benefits*.”<sup>47</sup> Thus within the same article, the Declaration grants protection of both intellectual property rights and a right to freely benefit from all scientific advancement.

Clearly at odds with itself, the human rights community, in its arguments for the protection of certain human rights like basic health and food security over intellectual property rights, essentially makes a judgment call about which human rights rank higher than others. Although human rights advocates have not necessarily ignored that intellectual property rights are in themselves a basic human right, they argue that it is necessary to sacrifice some levels of intellectual property protections to guard other, more essential human rights. Specifically, as the United Nations has argued, some intellectual property protections ought to be forgone in order to reduce

impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food of plant variety rights and the patenting of genetically modified organisms, “bio-piracy” and the reduction of communities’ (especially indigenous communities’) control over their own genetic and natural resources and cultural values,

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<sup>45</sup> Universal Declaration of Human Rights, *supra* note 5, at art. 17.

<sup>46</sup> *Id.* at art. 27(2).

<sup>47</sup> *Id.* at art. 27(1) (emphasis added).

and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health . . . .<sup>48</sup>

As evidenced by this United Nations statement, there are several human rights that are threatened by global intellectual property protections. However, the particular right that human rights advocates most strongly defend as needing protection over intellectual property rights is that of access to essential medicines. Access to medicines is considered a central component of the basic human right to health,<sup>49</sup> yet nearly two billion people throughout the world lack access to essential medicines.<sup>50</sup> Although gaining access to medicines has always been a challenge for developing countries, after the TRIPS Agreement went into force, which expanded the “protection of pharmaceutical products and processes,” the cost of patented essential medicines like HIV/AIDS medications became exorbitantly high for developing countries, thus exacerbating the already pandemic-sized problem of treating HIV/AIDS patients in those poor countries.<sup>51</sup> As explained by one human rights advocate, “[t]he exclusive monopoly that owners of intellectual property enjoy for a period of time with respect to the manufacture, marketing, sale, and distribution of the medicines they produce permits pharmaceutical corporations to demand higher prices for their products.”<sup>52</sup> These higher prices of patented pharmaceuticals “place essential medicines beyond the reach of many developing countries.”<sup>53</sup>

After the enactment of the TRIPS Agreement but prior to the Doha Declaration, governments of developing nations often took measures into their own hands to retaliate against the restrictive effect that pharmaceutical patents had on access to essential medicines. For example, in 1997 the South African government enacted the Medicines and Related Substance Control Amendment Act, which made essential medicines more affordable by permitting South Africa’s Minister of Health to allow the parallel importation of patented drugs and the

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<sup>48</sup> Resolution 2000/7, *supra* note 31, at 2.

<sup>49</sup> See U.N. Econ. & Soc. Council [ECOSOC], Comm. on Econ. Soc., & Cultural Rts., The Right to the Highest Attainable Standard of Health, ¶ 44, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) (asserting that governments must take measures to ensure that its citizens have access to appropriate healthcare).

<sup>50</sup> Erika George, *The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines*, 18 IND. J. GLOBAL LEGAL STUD. 167, 168 (2011) (citing to U.N. Human Rights Council (H.R.C.), *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, 11th Sess., ¶ 14, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (by Anand Grover) (citing World Health Organization [WHO], *WHO Medicines Strategy: Countries at the Core, 2004-2007* (2004))).

<sup>51</sup> *Id.* at 169.

<sup>52</sup> *Id.* at 180.

<sup>53</sup> *Id.*

manufacturing of generic HIV/AIDS medicines, and by allowing the government to enact price-controlling measures.<sup>54</sup>

Pharmaceutical companies responded to this Act by filing suit against the South African government for patent infringements.<sup>55</sup> In retaliation to this lawsuit, HIV/AIDS and human rights activists ignited a social movement against the pharmaceutical companies and generated enough support and influence that the pharmaceutical companies eventually dropped their suit against the South African government.<sup>56</sup> The activists framed their movement around human rights arguments, asserting that the South African government had an obligation to “ensure adequate access to healthcare.”<sup>57</sup> The South African conflict between health activists and pharmaceutical companies provides a shining example of how human rights movements have succeeded in containing the detrimental impact of international intellectual property rights regimes on the right to basic healthcare.

While access to essential medicines has been the most successful argument against the advancement of intellectual property protections, human rights advocates have presented additional anti-intellectual property arguments. For example, human rights advocates argue that if intellectual property rights regimes are not forced to consider human rights, researchers and inventors will focus their efforts on the most lucrative innovations, which are not necessarily the innovations that are most beneficial to the world’s poorest populations. As stated by the 1999 Human Development Report, “[i]n defining research agendas, money talks, not need—cosmetic drugs and slow-ripening tomatoes come higher on the priority list than drought-resistant crops or a vaccine against malaria.”<sup>58</sup> Thus, because of the profit-generating motives behind intellectual property rights, innovations that will result in higher profits will take precedent over innovations that would result in greater promotion of human rights.

Furthermore, human rights advocates argue that the increased protection of intellectual property rights has intensified the technological inequalities between the developed and developing worlds. In 1999, “[i]ndustrial countries [held] 97% of all patents worldwide” and around the same time “more than half of global royalties and licensing fees were paid to the United States, mostly from Japan, the United Kingdom, France, Germany and the Netherlands.”<sup>59</sup> Not only are the wealthy countries deciding what areas of research and development will get most attention and funding, but also the profits generated from intellectual property

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<sup>54</sup> See Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.), available at <http://www.doh.gov.za/docs/legislation/acts/1997/act90.pdf>.

<sup>55</sup> Pharm. Mfrs.’ Ass’n of S. Afr. v. President of the Republic of S. Afr., Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division).

<sup>56</sup> George, *supra* note 50, at 186.

<sup>57</sup> Heads of Argument on Behalf of the Treatment Action Campaign, ¶ 1.2.2, Pharm. Mfrs.’ Ass’n of S. Afr. v. President of the Republic of S. Afr., Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division), available at <http://www.tac.org.za/Documents/MedicineActCourtCase/pharmace.txt>.

<sup>58</sup> 1999 Human Development Report, *supra* note 33, at 6.

<sup>59</sup> *Id.* at 68.

rights are staying in those wealthy countries. Additionally, the human rights camp argues, “patent laws pay scant attention to the knowledge of indigenous people, leaving it vulnerable to claim by others. These laws ignore . . . diversity in views on what can and should be owned . . . . The result is a silent theft of centuries of knowledge from developing to developed countries.”<sup>60</sup> Therefore, the world’s poorest people are benefiting the least from intellectual property protections, and at the same time are the recipients of the greatest harm that intellectual property protections inflict on other essential human rights.

### C. *The Intellectual Property Argument*

Viewed by human rights advocates as defending the private interests of powerful and wealthy industries like pharmaceutical and high-tech industries, intellectual property rights advocates often face an uphill battle when defending the protection of intellectual property over the protection of other basic human rights. However, the intellectual property camp is not without sound arguments as to why intellectual property rights do not need to be sacrificed to protect and promote other basic human rights. An initial argument intellectual property advocates often bring up in the context of human rights is that the right to the protection of one’s ideas and inventions is in and of itself a human right recognized by the United Nations.<sup>61</sup> Thus, while rights to health, food security, etc. are also important human rights, they should not necessarily trump the right to intellectual property. One conceptual path that has been used to support this argument is that “rights that protect the connection between a creator of an information product and the information product belong in the category of human rights because they protect the personality of the creator.”<sup>62</sup>

One of intellectual property advocates’ strongest arguments asserts that in the long run, protection of intellectual property rights will actually be more beneficial to the protection of other human rights like health and food security because intellectual property protections provide incentives for innovation.<sup>63</sup> The argument follows that as technology for medicines, food production, and environmental protection becomes more innovative, they will benefit people throughout the world by finding cures to more diseases, increasing the quantity and quality of food production, and creating more environmentally friendly technologies. Thus, by limiting intellectual property protections now, we are only doing a disservice to the promotion and advancement of human rights in the future. Indeed, one of the basic principles of the TRIPS Agreement is that, as a result of the Agreement, “intellectual property protection should contribute to technical innovation and the

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<sup>60</sup> *Id.*

<sup>61</sup> Universal Declaration of Human Rights, *supra* note 5, at art. 27(2).

<sup>62</sup> Peter Drahos, *The Universality of Intellectual Property Rights: Origins and Development*, WORLD INTELL. PROP. ORG. (1998), available at <http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf>.

<sup>63</sup> DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 63 (2009).

transfer of technology. Both producers and users should benefit, and economic and social welfare should be enhanced . . . .”<sup>64</sup>

Still other intellectual property rights advocates argue that strong intellectual property policies can actually promote development and reduce poverty.<sup>65</sup> These advocates claim that “over time there are dynamic gains from the introduction of new products, information, and creative activities.”<sup>66</sup> Additionally, countries with stronger intellectual property rights protections attract multinational companies, thereby increasing foreign direct investment and eventually increasing overall growth.<sup>67</sup> An economic case study of Lebanon serves as an example of the potentially positive effect of intellectual property rights protection on growth and development. The study found that if the country were to strengthen its intellectual property rights it would first, benefit from increased foreign direct investment, second, it would “experience increases in product development by local firms,” third, Lebanese firms would “find it easier to enter into joint ventures and technology-sharing or product-licensing agreements with foreign firms,” and fourth, “the average quality of products and services on the market should rise.”<sup>68</sup>

A final argument expressed by the intellectual property camp is that countries with stronger intellectual property rights protections experience less “brain drain” because the educated members of those countries have a stronger incentive to stay in their native country as opposed to immigrating to find better jobs.<sup>69</sup> India provides an impressive example of how greater intellectual property protections improved the country’s high-tech employment opportunities. As one researcher described, “[i]n the years before strong IP laws and policies encouraged innovators in India, much of the country’s educated cadre of information technology workers left the country to work elsewhere.”<sup>70</sup> However, now that India enjoys “stronger IP institutions and legislation . . . to encourage and reward local innovation, the Indian software industry employs some 500,000 software engineers, and Indian-produced software is used worldwide.”<sup>71</sup>

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<sup>64</sup> *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm) (last visited Feb. 28, 2012).

<sup>65</sup> Carsten Fink & Keith E. Maskus, *Why We Study Intellectual Property Rights and What We Have Learned*, in *INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH* 1, 2 (Carsten Fink & Keith E. Maskus eds., 2005).

<sup>66</sup> *Id.* at 3.

<sup>67</sup> *Id.* at 7.

<sup>68</sup> Keith E. Maskus, *Strengthening Intellectual Property Rights in Lebanon*, in *INTELLECTUAL PROPERTY AND DEVELOPMENT*, *supra* note 65, at 259, 289.

<sup>69</sup> See generally *Intellectual Property (IP) and Brain Drain*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, COMMITTEE ON DEVELOPMENT AND INTELLECTUAL PROPERTY (CDIP), *INTELLECTUAL PROPERTY (IP) AND BRAIN DRAIN* (2011), available at [http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_7/cdip\\_7\\_4\\_rev.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_4_rev.pdf) (discussing the linkages between intellectual property and brain drain).

<sup>70</sup> Rita Hayes, *Promoting Intellectual Property for Economic Growth*, 36 *VAND. J. TRANSNAT’L L.* 793, 795 (2003).

<sup>71</sup> *Id.*

As evidenced by the many strong arguments on both sides of the human rights-intellectual property debate, neither side is definitively in the right, nor is there an easy solution that will lead to an obvious overall benefit. Instead the pros and cons of both the staunch protection of human rights and the expanding protection of intellectual property rights must be balanced against each other. This balancing effort has been ongoing since the signing of the Doha Declaration, as advocates on both sides of the debate have come to realize the need for some compromise.<sup>72</sup>

However, as intellectual property rights expand into ever increasing realms, the need once again to take a step back and evaluate the potentially harmful effects of those expanding rights becomes necessary. A recent example of a controversial expansion of intellectual property rights is that of gene patenting. Once considered purely natural subject matter, genes have slowly crept into the realm of intellectual property due to advanced genetic research that has enabled research and development companies to claim property rights and obtain patents for those genes. This new patenting phenomenon has, of course, been subject to great criticism.<sup>73</sup> Critics have emerged from a variety of paradigms, one of which is the human rights paradigm. What follows is a discussion of argument of the human right to access to the human genome and what, if any role it has played in scrutinizing the right to patent genes.

### III. HUMAN RIGHTS AND THE HUMAN GENOME

“The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.”<sup>74</sup> This introductory article to the Universal Declaration on the Human Genome and Human Rights captures the United Nations’ general sentiment that there is something almost sacred to humanity about the human genome. The human genome is our core connection to every other person on the planet, and according to this Declaration, it must be guarded, and research and experiments relating to it must be carefully kept in check.

The Declaration on the Human Genome was created at a time when human biological research was reaching exciting breakthroughs, and the mapping of the human genome was coming to fruition. In 1990, the Human Genome Project began

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<sup>72</sup> See Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 MINN. INTELL. PROP. REV. 47, 57–61 (2003) (discussing the various options for how intellectual property rights and human rights might coexist).

<sup>73</sup> Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 1 YALE J. HEALTH POL’Y L. & ETHICS 403, 403–04 (2005).

<sup>74</sup> Universal Declaration on the Human Genome and Human Rights: From Theory to Practice, UNESCO Gen. Conf. Res., 29 C/Res.16, *reprinted in* Records of the General Conference, UNESCO, 29th Sess., 29 C/Resolution 19, at art. 1 (Nov. 11, 1997) [hereinafter Declaration on the Human Genome], *available at* <http://unesdoc.unesco.org/images/0012/001229/122990eo.pdf>.

with a goal to identify and map the 20,000–25,000 genes that constitute the human genome.<sup>75</sup> Once considered lofty, futuristic ideas, processes like cloning and genetic altering were becoming a reality, thereby igniting ethical concerns about genetic research. The United Nations’ response to the ever-growing bioethical issues relating to human genome research came from its Educational, Scientific and Cultural Organization (UNESCO),<sup>76</sup> whose constitution requires it to promote “collaboration among the nations through education, science and culture . . . .”<sup>77</sup> After four years of preparation, UNESCO’s International Bioethics Committee completed what it considered a sufficiently credible document about this controversial topic to present it as a resolution to the General Assembly.<sup>78</sup> The Declaration was well received by the General Assembly, and on March 10, 1999, the General Assembly adopted the Declaration, thereby endorsing a bold bioethical statement intended to influence the future research decisions of its member states.<sup>79</sup>

Several sections of the Declaration are meaningful when considering the ethical and human rights issues relating to gene patenting. Beginning in Article 10, the Declaration establishes that “respect for the human rights, fundamental freedoms, and human dignity of individuals” should prevail over any other concern involving the human genome.<sup>80</sup> Even more pertinent to the concept of patenting genes, Article 12 asserts:

- (a) Benefits from advances in biology, genetics and medicine, concerning the human genome, *shall be made available to all*, with due regard for the dignity and human rights of each individual.
- (b) Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and *humankind as a whole*.<sup>81</sup>

Article 12(a) thus stresses the importance of making genetic information freely available to all people. This assertion apparently contradicts the logic of

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<sup>75</sup> HUMAN GENOME PROJECT INFORMATION, [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/about.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml) (last visited Feb. 29, 2012).

<sup>76</sup> Noëlle Lenoir, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 30 COLUM. HUM. RTS. L. REV. 537, 546 (1999).

<sup>77</sup> United Nations Educational, Scientific and Cultural Organization Const. art. 1(1), Nov. 16, 1945, 4 U.N.T.S. 275, 278.

<sup>78</sup> Lenoir, *supra* note 76, at 546.

<sup>79</sup> Adopted as a resolution by the General Assembly, G.A. Res. 152, U.N. Doc. A/RES/53/152 (Mar. 10, 1999).

<sup>80</sup> Declaration on the Human Genome, *supra* note 74, at art. 10.

<sup>81</sup> *Id.* at art. 12 (emphasis added).

gene patenting, which allows researchers who discover genes to have exclusive rights to research and profit-generating activities involving those genes. Upon closer observation of Article 12(b), its mandates potentially cut both ways when it comes to the ethics of patenting genes. On one hand, patents are often considered crucial for the furtherance of scientific research, thus gene patenting could promote the goals of 12(b) by encouraging advancements in human genome research. On the other hand, gene patents create limitations as to who is allowed to perform certain types of research on those patented genes, thus directly violating the call for freedom of research. Furthermore, though patenting genes may lead to more cures and remedies for genetic disorders in the long run, thereby offering “relief from suffering and improv[ing] the health of individuals and humankind as a whole,”<sup>82</sup> in the short run, gene patents can limit the amount of research doctors can conduct on behalf of specific patients and on the amount of information they can convey to their patients. This result would seem to violate 12(b) by potentially causing more present suffering and reducing the likelihood of improving individuals’ health.

Finally, Article 18 also conveys affirmations pertinent to the ethics of gene patenting. This Article declares that “States should make every effort . . . to continue fostering the international dissemination of scientific knowledge concerning the human genome . . . [and] to foster scientific and cultural cooperation, particularly between industrialized and developing countries.”<sup>83</sup> As mentioned above,<sup>84</sup> one human rights argument against international intellectual property rights protections is that wealthy nations own the vast majority of patents, thereby causing developing nations to suffer from inaccessibility to high-priced patented goods and a lack of transmission of scientific information. Therefore, in assessing the obligations contained in Article 18, it seems that patenting genes could restrict the “international dissemination of scientific knowledge concerning the human genome”<sup>85</sup>—especially to developing countries.

Apart from this United Nations Declaration, other individuals and organizations have expressed their human rights concerns about the impact of gene patents. For example, an official at the International Center for Technology Assessment to the Commissioner of Patents and Trademarks expressed his concern that “[t]he public has a strong interest in keeping the human genome freely accessible not only for the use of scientific research, but also because it is the foundation of human life and thus should not be patented by any one person.”<sup>86</sup> Though this concern was about patenting the entire human genome, and not just one gene, the same concerns about keeping information about particular genes freely accessible exists.

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<sup>82</sup> *Id.* at art. 12(b).

<sup>83</sup> *Id.* at art. 18.

<sup>84</sup> *See supra* Part II.B.

<sup>85</sup> Declaration on the Human Genome, *supra* note 74, at art. 18.

<sup>86</sup> Letter from Andrew Kimbrell, Int’l Ctr. for Tech. Assessment, to Mark Nagumo, Comm’r of Patents and Trademarks, and Linda S. Therkon, Assistant Comm’r for Patents 3 (Mar. 22, 2000) (Comment 50 on Revised Utility Examination Guidelines), *available at* <http://www.uspto.gov/web/offices/com/sol/comments/utilguide/akimbrell.pdf>.

Similarly, one British woman, Wendy Watson, who became a health rights advocate after being diagnosed with breast cancer, helped organize the Hereditary Breast Cancer Foundation (HBCF). Watson was motivated to create the HBCF after finding out that Myriad Genetics had gained patent rights to genes related to breast cancer.<sup>87</sup> Watson lobbied before the European Parliament, arguing she had been one of the research subjects that enabled Myriad to isolate the gene, and that “[n]o company should benefit commercially from that kind of research.”<sup>88</sup> Watson’s group made ardent human rights arguments against gene patenting, asserting that “claims on behalf of intellectual property are becoming more and more commercial, thereby linking them with the powerful forces of pharmaceutical corporations and placing them on uneven par with the human rights claims of isolated individuals.”<sup>89</sup> It appears that people like Watson may have had some influence on European policy makers because, though the United States has been somewhat more open to the idea of patenting genes, the European Union has shown greater reservations in its approach to opening patent law to the human genome.<sup>90</sup> For example, as early as 1993, an E.U. Proposed Directive explicitly found that parts of the human body are unpatentable.<sup>91</sup> This early legislation has resulted in the E.U. being more cautious about granting patents related to genetic material.

Despite the concerns about the human rights implications of gene patenting, U.S. patent law has gradually moved toward increased acceptance of the patentability of human genes. This steady acceptance began in 1980, when the U.S. Supreme Court affirmed the patentability of living organisms,<sup>92</sup> continued in 1995 by allowing patents on human cells,<sup>93</sup> and has reached the current era where over twenty percent of all human genes have been patented.<sup>94</sup> In the United States’ most recent stamp of approval of gene patenting, the United States Court of Appeals for the Federal Circuit held for the first time in July of 2011 that genes are patentable subject matter.<sup>95</sup> What follows is a review of U.S. jurisprudence regarding genetic

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<sup>87</sup> RICHARD PIERRE CLAUDE, *SCIENCE IN THE SERVICE OF HUMAN RIGHTS* 166 (2002).

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> Barbara Looney, Note, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 *LAW & POL’Y INT’L BUS.* 231, 234 (1994).

<sup>91</sup> *Id.* (citing Amended Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, 1993 O.J. (C 44) 36, 40).

<sup>92</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980).

<sup>93</sup> Patricia A. Lacy, *Gene Patenting: Universal Heritage vs. Rewards for Human Effort*, 77 *OR. L. REV.* 783, 783 (1998).

<sup>94</sup> John Schwarts & Andrew Pollack, *Judge Invalidates Human Gene Patent*, *N.Y. TIMES*, Mar. 29, 2010, at B1; see also Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCI.* 239, 239 (2005).

<sup>95</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), reh’g denied (Sept. 13, 2011), reh’g denied (Sept. 16, 2011), cert. granted, judgment vacated sub nom. *Ass’n for Molecular Pathology v. Myriad Genetics*,

patenting to determine if U.S. courts have considered any human rights arguments as part of their decisions. Most importantly, the following section will evaluate what, if any, human rights arguments have been made in recent case against Myriad Genetics.

#### IV. HUMAN RIGHTS CONSIDERATIONS IN U.S. CASE LAW RELATED TO GENETIC AND BIOLOGICAL PATENTING

##### A. *Human Rights in Pre-Myriad Cases*

Often considered the genesis of U.S. jurisprudence related to the patentability of biological material, *Diamond v. Chakrabarty*<sup>96</sup> set forth a seemingly lenient standard for such a controversial subject matter.<sup>97</sup> The central question in *Chakrabarty* was whether a live, human-made bacterium was patentable.<sup>98</sup> While the U.S. Patent and Trademark Board of Appeals found that as a living organism, the bacterium was not patentable subject matter,<sup>99</sup> both the U.S. Court of Customs and Patent Appeals and the U.S. Supreme Court disagreed—holding that “anything under the sun” that has a man-made component is patentable subject matter.<sup>100</sup> Focusing most of its energy on statutory interpretation, the Court in *Chakrabarty* paid little attention to the petitioner’s ethical arguments.<sup>101</sup> The Court referenced the “parade of horrors” described in petitioner’s and *amici* briefs and acknowledged concerns that “genetic research may pose a serious threat to the human race”<sup>102</sup> and that “genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life.”<sup>103</sup> However, the Court did little more than mention these concerns, and instead deferred responsibility by stating that “[w]hatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.”<sup>104</sup> Therefore, though the Court did not reject the ethical/human rights arguments, it did not factor them in to its final decision in *Chakrabarty*.

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*Inc.*, 132 S. Ct. 1794 (U.S. 2012) and *opinion vacated, appeal reinstated*, 2010-1406, 2012 WL 1500104 (Fed. Cir. Apr. 30, 2012).

<sup>96</sup> 447 U.S. 303 (1980).

<sup>97</sup> Marina L. Whelan, iBrief, *What, if Any, Are the Ethical Obligations of the U.S. Patent Office? A Closer Look at the Biological Sampling of Indigenous Groups*, 2006 DUKE L. & TECH. REV., no. 14, at 1, ¶ 19.

<sup>98</sup> *Chakarabarty*, 447 U.S. at 307.

<sup>99</sup> See Application of Chakrabarty, 571 F.2d 40, 45 (C.C.P.A. 1978).

<sup>100</sup> *Chakrabarty*, 447 U.S. at 309.

<sup>101</sup> For the Court’s brief discussion of petitioner’s ethical concerns, see *id.* at 316–17.

<sup>102</sup> *Id.* at 316.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* at 317.

Despite the *Chakrabarty* Court's congressional call to action, Congress was surprisingly quiet after the controversial decision.<sup>105</sup> Perhaps due to the legislature's uncertainty about how to deal with this new scientific matter, Congress did not make any relevant legislation for seven years after the *Chakrabarty* decision.<sup>106</sup> It was not until the Patent and Trademark Office (PTO) approved patents on genetically altered animals<sup>107</sup> that Congress decided to act.<sup>108</sup> In response to the PTO's decision and the public outcry that followed, the House Subcommittee on Courts, Civil Liberties, and the Administration of Justice held hearings in 1987 relating to animal patents.<sup>109</sup> Though obviously animal rights issues led the discussions, Representative Robert Kastenmeier from Wisconsin, the congressman responsible for organizing the hearings, expressed his concerns that the course that the PTO had taken might eventually lead to patents of human beings.<sup>110</sup> Thus it is evident that Congress was anticipating future human rights concerns that would result from the continued acceptance and expansion of patents of live organisms. These hearings may have opened the dialogue and exposed many concerns about biological patents, but they failed to produce any real legislation.<sup>111</sup>

Over a decade later, Congressional interest in biological patenting re-emerged due to concerns about the patentability of human embryos and human genes.<sup>112</sup> One particularly interesting statement made by the director of the PTO at a 2000 House Subcommittee Hearing entitled "Gene Patents and Other Genomic Inventions" stated

the USPTO does take notice of the legitimate concerns regarding access to genomic inventions. Clearly, inventors and owners of genomic patents need to be acutely aware of the heavy responsibility inherent in that ownership; their licensing and other technology transfer practices need to strongly account for the powerful public desire to ensure that the

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<sup>105</sup> Anna Lumelsky, *Diamond v. Chakrabarty: Gauging Congress's Response to Dynamic Statutory Interpretation by the Supreme Court*, 39 U.S.F. L. REV. 641, 660 (2005).

<sup>106</sup> *Id.*

<sup>107</sup> Patent and Trademark Office Notice: Animals – Patentability, 1077 Off. Gaz. Pat. & Trademark Office 24 (April 21, 1987). Interestingly, this announcement by the PTO explicitly excluded human multicellular living organisms, thereby showing the PTO's hesitation about patents related to human bodily parts. *Id.*

<sup>108</sup> Lumelsky, *supra* note 105, at 660–62.

<sup>109</sup> *Id.* at 661 (citing *Patents and the Constitution: Transgenic Animals: Hearing on Supplemental Appropriations Act Before the H. Subcomm. on Courts, Civil Liberties, and the Admin. of Justice*, 100th Cong. 2 (1987)).

<sup>110</sup> *Id.* at 662.

<sup>111</sup> *Id.* at 663.

<sup>112</sup> *Id.* at 670.

use of these inventions for the greater good of all humankind is not unduly burdened.<sup>113</sup>

This cautionary statement provides evidence that, though the PTO was moving forward with genomic patents, it was aware of concerns that the restrictive nature of patents might hinder general accessibility to the positive outcomes of genetic research. While various congressional hearings were held during this time and human rights arguments were made, the legislature was unable to pass any bills that would limit the scope of human patenting.<sup>114</sup>

Between these seasons of bioethical debates at Congress, the judiciary received another opportunity to weigh in on the genetic patenting controversy with the 1990 case of *Moore v. Regents of the University of California*.<sup>115</sup> In this landmark case, the California Supreme Court held that a patient whose cells had been extracted and patented by researchers had no legal rights to his patented cells or to any economic gain that resulted from the patents.<sup>116</sup> The majority opinion gave little, if any, consideration to the ethical implications of its decision. However, in a fiery dissenting opinion, Justice Mosk expressed grave concerns with the majority's decision.<sup>117</sup> In a particularly poignant statement connecting the exploitation of patented genetic material with other forms of human rights violations, Justice Mosk asserted that

our society acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique human persona. One manifestation of that respect is our prohibition against direct abuse of the body by torture or other forms of cruel or unusual punishment. Another is our prohibition against indirect abuse of the body by its economic exploitation for the sole benefit of another person. The most abhorrent form of such exploitation, of course, was the institution of slavery. Lesser forms, such as indentured servitude or even debtor's prison, have also disappeared. Yet their specter haunts the laboratories and boardrooms of today's biotechnological research-industrial complex.<sup>118</sup>

By comparing genetic patents to various forms of slavery, Justice Mosk provided a strong human rights argument against genetic patenting. This case provides further

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<sup>113</sup> *Gene Patents and Other Genomic Inventions: Hearing before the H. Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 106th Cong. 29 (2000) (statement of Todd Dickinson, Under Sec'y of Commerce for Intell. Prop. and Dir. of the U.S. Patent & Trademark Office, Dep't of Commerce), available at [http://commdocs.house.gov/committees/judiciary/hju66043.000/hju66043\\_of.htm](http://commdocs.house.gov/committees/judiciary/hju66043.000/hju66043_of.htm).

<sup>114</sup> Lumelsky, *supra* note 105, at 671–72.

<sup>115</sup> 793 P.2d 479 (Cal. 1990).

<sup>116</sup> *Id.* at 488–97.

<sup>117</sup> *Id.* at 506–23 (Mosk, J., dissenting).

<sup>118</sup> *Id.* at 515.

evidence that, while human rights arguments have continually made their way into decisions relating to genetic patents, they have generally been the minority view, and have thus had no limiting effect on the expansion of such patenting.

In 2003, the U.S. District Court for the Southern District of Florida received its chance to weigh in on the genetic patenting debate in the case of *Greenberg v. Miami Children's Hospital Research Institute, Inc.*<sup>119</sup> This case involved a dispute over a patent for an isolated gene that causes Canavan disease.<sup>120</sup> A research physician who had received tissue from a patient suffering from the disease discovered and patented the gene.<sup>121</sup> The court in this case, like the court in *Moore*, granted the defendant's motion to dismiss, holding that the plaintiffs had no legal rights to the patented genes.<sup>122</sup> Unlike in *Moore*, there was no dissenting opinion and no mention of any human rights or ethical arguments.

From these three influential cases and the congressional responses that followed, it is evident that though human rights arguments have made their way into some decisions, they are the minority view. As such, the expansion of genetic patenting has in no way been restrained by human rights concerns. During the past decade, the number of gene patents has continued to grow with little resistance. However, the smooth sailing of genetic patenting hit a rough patch of water in the form of the American Civil Liberties Union's (ACLU) case against Myriad Genetics. The following section will review this most recent case in the fight against genetic patenting to determine if human rights have had any influence on the courts' decisions.

### *B. The Myriad Genetics Case from a Human Rights Perspective*

On May 19, 2009, the ACLU and the Public Patent Foundation filed a lawsuit against Myriad Genetics and the PTO asserting the unconstitutionality of patenting two human genes, the mutations of which are associated with most cases of hereditary breast and ovarian cancers.<sup>123</sup> The main allegations listed in the complaint asserted that "human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought, [therefore] the challenged [patent] claims are invalid under Article 1, section 8,

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<sup>119</sup> 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

<sup>120</sup> *Id.* at 1066. Canavan disease is caused by the lack of a certain enzyme that leads to a build up of a particular acid in the brain. This build up results in severe mental disabilities. See *Canavan Disease*, PUBMED HEALTH (Nov. 14, 2011), <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0002553/>.

<sup>121</sup> *Greenberg*, 264 F. Supp. 2d at 1067.

<sup>122</sup> *Id.* at 1077–78. The only claim that the court did not dismiss was plaintiff's claim of unjust enrichment.

<sup>123</sup> *ACLU Challenges Patents on Breast Cancer Genes: BRCA*, ACLU, <http://www.aclu.org/free-speech-womens-rights/aclu-challenges-patents-breast-cancer-genes-0> (last visited Oct. 22, 2011).

clause 8 of the United States Constitution and 35 U.S.C. § 101.”<sup>124</sup> These allegations were of consequence not just to Myriad, but to hundreds of other biotechnology companies who also hold patents to human genes.<sup>125</sup>

The plaintiffs alleged that, as a consequence of Myriad’s patents to the two genes, BRCA1 and BRCA2, and also to technology related to testing for those genes, ease of access to information and diagnosis involving breast and ovarian cancer was being restricted.<sup>126</sup> Furthermore, plaintiffs alleged that, because Myriad “chooses not to license the patents broadly . . . [w]omen are thereby prevented from obtaining information about their health risks from anyone other than the patent holder, whether as an initial matter or to obtain a second opinion.”<sup>127</sup> Finally, contrary to the goals of patent rights, plaintiffs asserted that “[g]ene patents can serve as a disincentive to innovation in molecular testing because they deny access to a vital baseline of genomic information that cannot be invented around.”<sup>128</sup> Therefore, other scientists are limited in the amount of research they can perform on the patented genes because “threat of enforcement from a patent holder and ensuing litigation costs lead to a chilling effect as clinical laboratories are reluctant to develop new tests, even when new tests could directly benefit patients.”<sup>129</sup>

In their memorandum in support of motion for summary judgment, plaintiffs framed their arguments against Myriad as violations of federal and constitutional law. Their first argument asserted that Myriad’s patent claims violate 35 U.S.C. § 101<sup>130</sup> because “human genetic sequences and the scientific inquiry of looking at a gene or comparing two human genes constitute natural phenomena, laws of nature, and abstract ideas and thus are not patentable subject matter.”<sup>131</sup> Second, “[t]hey also constitute patents on thought, knowledge, and ideas in violation of the First Amendment.”<sup>132</sup> Finally, “[b]ecause they patent basic scientific principles, not inventions or discoveries, they have impeded rather than advanced science and thus also violate the U.S. Constitution, Article 1, Section 8, Clause 8 (the

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<sup>124</sup> Complaint at 29, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515) [hereinafter *Complaint*].

<sup>125</sup> C.H., *Myriad’s Gene Patentability Gene-uinely Unclear*, THE ECONOMIST (Aug. 4, 2011, 3:47 PM), <http://www.economist.com/blogs/schumpeter/2011/08/myriads-gene-patent-battle>.

<sup>126</sup> *Complaint*, *supra* note 124, ¶ 2.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* ¶ 88.

<sup>129</sup> *Id.*

<sup>130</sup> 35 U.S.C. § 101 (2006) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”). Plaintiffs claimed that Myriad patents violated this provision because they were not for the discovery of any new item, but instead were items that occurred in nature.

<sup>131</sup> Plaintiff’s Memorandum of Law in Support of Motion for Summary Judgment at 19, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515).

<sup>132</sup> *Id.* at 1.

intellectual property clause).”<sup>133</sup> Plaintiffs asserted that because Myriad’s patents resulted in restrictions to rather than the progress of science and they limit thought and knowledge, those patents were in violation of the Constitution.

Though plaintiffs’ arguments relied on constitutional and federal law as opposed to international human rights law, some common threads between constitutional rights and human rights exist that make parts of these arguments consistent with human rights arguments. Namely, plaintiffs’ arguments that Myriad’s patents restrict rather than encourage scientific advancements and limit patients’ abilities to benefit from information about the patented genes are similar to the assertions made in the Universal Declaration on the Human Genome and Human Rights encouraging openness in research and access to scientific innovations.<sup>134</sup> Thus, while not directly relying on human rights law to state a claim against Myriad, plaintiffs used arguments that are consistent with the human rights arguments against genetic patenting.

Defendants responded to the plaintiffs’ complaint by trying to get the suit dismissed for lack of subject matter jurisdiction, standing, and personal jurisdiction.<sup>135</sup> However, the district court disagreed with the defendants, and it refused to dismiss the case.<sup>136</sup> Therefore the suit moved forward, and by the time the court heard arguments on the merits in 2010, eleven parties had submitted amicus briefs either defending or refuting plaintiffs’ claims of the invalidity of the suit.

Of those eleven amicus briefs, only one made a significant human rights argument. That brief was filed by five public interest groups: the National Women’s Health Network, Asian Communities for Reproductive Justice, Center for Genetics and Society, Generations Ahead and Pro-Choice Alliance for Responsible Research.<sup>137</sup> In their brief, the groups made two strong human rights arguments. First, they argued that “[g]ene patents cause harm to patients, in particular to women, by inappropriately stifling innovation and competition and interfering with health access.”<sup>138</sup> Within that argument, they stated that such

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<sup>133</sup> *Id.* The relevant constitutional provision grants Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8, cl. 8.

<sup>134</sup> See Declaration on the Human Genome, *supra* note 74.

<sup>135</sup> See Memorandum of Law in Support of Defendants’ Motion to Dismiss, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515); Defendant USPTO’s Memorandum of Law in Support of Motion to Dismiss, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515).

<sup>136</sup> *Ass’n For Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 393 (S.D.N.Y. 2009).

<sup>137</sup> See Brief for Amici Curiae Nat. Women’s Health Network, Asian Communities for Reproductive Justice, Center for Genetics and Society, Generations Ahead, Pro-Choice Alliance for Responsible Research, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09 Civ. 4515).

<sup>138</sup> *Id.* at 9.

restrictions are particularly detrimental to racial and ethnic minorities because researchers more often exploit their unique genes.<sup>139</sup> Furthermore, by reducing competition and thus increasing costs of medicine, gene patents are also more detrimental to the poor.<sup>140</sup> Second, the groups argued that “[h]uman genes are part of the common heritage of humanity and should not be removed from the public domain.”<sup>141</sup> Within this argument, the brief discussed the Universal Declaration on Human Rights and the Human Genome, and asserted that patenting human genes is contrary to international law by violating the notion that the human genome is part of the “common heritage of humanity,” and therefore cannot be owned by any individual or corporation.<sup>142</sup> Such commercial ownership would deprive the rest of humanity of its right of access to the human genome. Though these human rights arguments did not necessarily make a significant impression on the court’s decision, as will be discussed below, the court was at least provided with this information such that it could contemplate the human rights implications of its decision

In March of 2010, the district court came down with a controversial ruling—holding that both the patents for the BRCA1 and BRCA2 genes and the patents for methods of analyzing the gene sequences were invalid.<sup>143</sup> In its discussion of the parties’ arguments, the court acknowledged that there “exists a deep disagreement between the parties concerning the effects of gene patents on the progression of scientific knowledge.”<sup>144</sup> Although the court did not necessarily explicitly address the human rights implications of these genetic patents, the court indirectly agreed with the possibility that if such patents do inhibit the progress of scientific knowledge, there would be an overall detriment to humanity.<sup>145</sup> While the human rights arguments certainly played a minor role in the preparation for and outcome of the district court decision, that they were at least recognized indicates that human rights concerns about gene patenting remain relevant.

Despite the court’s indirect acknowledgement of the implications that gene patents have for scientific progress and the impact that has on fundamental human rights, the court based its holding on findings that Myriad’s gene patents were for phenomena of nature, and that the isolated DNA sequences were not “markedly different from native DNA as it exists in nature.”<sup>146</sup> Therefore, the genes did not constitute patentable subject matter under 35 U.S.C. § 101.<sup>147</sup> The court similarly held that, “because the claimed comparisons of DNA sequences are abstract mental processes, they also constitute unpatentable subject matter under § 101.”<sup>148</sup> Since

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<sup>139</sup> *Id.* at 9–11.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 16.

<sup>142</sup> *Id.* at 20.

<sup>143</sup> *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 184.

<sup>144</sup> *Id.* at 207–08.

<sup>145</sup> *See id.* at 207–11.

<sup>146</sup> *Id.* at 232.

<sup>147</sup> *Id.*

<sup>148</sup> *Id.* at 185.

the court was able to find Myriad's patents invalid under the natural phenomena and abstract mental processes exceptions to 35 U.S.C. § 101, the court dismissed plaintiff's constitutional claims by way of constitutional avoidance.<sup>149</sup> By dismissing plaintiffs' constitutional claims, the court failed to consider those arguments that were most related to the human rights arguments against genetic patents.

As would be expected, the district court's ruling stunned the biotechnology community.<sup>150</sup> Whereas most indications seemed to be pointing in the direction of increased acceptance of patent rights for genetic material, the Myriad case threw a significant wrench in the progress of genetic intellectual property rights.<sup>151</sup> Prior to this decision, the U.S. patent office had allowed for the patenting of many isolated and purified genes. Following the district court's holding, many concerned biotechnology companies question whether the nearly 2,000 already existing gene patents were still valid.<sup>152</sup>

What, if any, were the human rights implications of the district court's decision? As previously mentioned, the district court acknowledged the argument that gene patents may restrict the flow of relevant scientific knowledge instead of promoting it, which the Universal Declaration of Human Rights to the Human Genome explicitly condemned. However, the court's holding relied on the natural phenomenon exception to patent rights, and gave no real consideration to a human rights interest in gene patents. Indeed, the court chose not to address the plaintiffs' constitutional arguments, which are perhaps the closest that the plaintiffs made to a human rights argument.

As scholars and practitioners tried to unpack the holding and implications of the district court's decision, several made at least passing reference to the human rights implications of the decision. For example, one scholar wrote a paper entitled *Interpreting Myriad: Acquiring Patent Law's Meaning Through Contemporary Jurisprudence and Humanistic Viewpoint of Common Heritage of DNA*.<sup>153</sup> In that paper, the author felt that one important lesson from the district court's opinion is that

*Myriad* reminded us that whenever exclusive rights are conferred upon a selected few, the majority suffers. *Myriad's* product of nature doctrine is a fervent reminder that a more positive outcome might result if patenting is forever foreclosed on human genes, thereby ensuring that majority is

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<sup>149</sup> *Id.* at 237–38.

<sup>150</sup> *Genetic Shock: A surprising court ruling in America may loosen the drug industry's grip on important genes*, THE ECONOMIST (Mar. 30, 2010), <http://www.economist.com/node/15810599>.

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> Saby Ghoshray, *Interpreting Myriad: Acquiring Patent Law's Meaning Through Contemporary Jurisprudence and Humanistic Viewpoint of Common Heritage of DNA*, 10 J. MARSHALL REV. INTELL. PROP. L. 508 (2011).

never deprived of a common heritage of mankind. Perhaps, the days may not be too far, when patenting of human genes is not legally possible.<sup>154</sup>

Thus, while the district court may not have necessarily made any human rights connections to its decision against Myriad, many human rights advocates interpreted the decision as a victory for its movement.

That victory was, however, short lived. Following the district court's decision, Myriad and its fellow defendants filed an appeal. In their appellate brief, the appellants argued that the case should be reversed for two main reasons.<sup>155</sup> First, the appellants argued that the patented materials do not fit within the § 101 natural phenomena, laws of nature, or abstract ideas exception, but rather that they are "undisputedly compositions of matter."<sup>156</sup> Second, the patented research methods that the district court also found invalid should be revalidated because "methods that include 'transformations' of a human sample" and that require "extracting, processing, and analyzing a human tissue" are patent-eligible subject matter.<sup>157</sup>

In their response, the appellees stuck to their original arguments and the findings of the district court, that Myriad's patents are invalid because they encompass materials that are natural phenomena, products of nature, and abstract ideas.<sup>158</sup> Though the district court had rejected appellee's constitutional arguments, the appellees chose to include those same arguments in their brief.<sup>159</sup> By including those constitutional arguments, the appellees kept intact their only arguments that had any resemblance to a human rights argument.

In addition to the parties' briefs, twenty-five third parties submitted amicus briefs. Two of those briefs, both in support of the appellees, made some mention of human rights. Interestingly, the groups that filed a human rights-influenced amicus brief to the district court—National Women's Health Network, the Asian Communities for Reproductive Justice, the Center for Genetics and Society, Generations Ahead, the Pro-Choice Alliance for Responsible Research and Alliance for Humane Biotechnology—filed a similar appellate brief, but dropped their "common heritage of humanity" argument.<sup>160</sup> Instead the group focused on what seemed to be the winning "natural phenomena" arguments, with the addition

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<sup>154</sup> *Id.* at 539.

<sup>155</sup> Brief for the Appellants, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406).

<sup>156</sup> *Id.* at 17.

<sup>157</sup> *Id.* at 53, 55.

<sup>158</sup> Brief for the Appellees, *Ass'n for Molecular Pathology*, 653 F.3d 1329 (No. 2010-1406).

<sup>159</sup> *Id.* at 60.

<sup>160</sup> Brief of Amici Curiae Nat. Women's Health Network, the Asian Communities for Reproductive Justice, the Center for Genetics and Society, Generations Ahead, the Pro-Choice Alliance for Responsible Research and Alliance for Humane Biotechnology, *Ass'n for Molecular Pathology*, 653 F.3d 1329 (No. 2010-1406).

of their argument about the disproportionate harm that gene patents have on women of color and low-income women.<sup>161</sup>

A different amicus brief, filed by the International Center of Technology Assessment, The Indigenous Peoples Council on Biocolonialism, Greenpeace, Inc., Friends of the Earth and the Council for Responsible Genetics, picked up the human rights arguments.<sup>162</sup> Specifically, this brief maintained that gene patents have “significant negative scientific, social, cultural and environmental consequences.”<sup>163</sup> Of particular human rights significance, the groups argued that “[p]atents on indigenous people’s genes facilitate the exploitation of indigenous peoples and violate international law.”<sup>164</sup> The brief provided examples of remote and relatively homogenous indigenous people whose genes have been viewed as “treasure troves” by genetic researchers.<sup>165</sup> Such indigenous groups have often felt that researchers have exploited their genes, and that their religious, cultural, and legal rights have been violated as a result.<sup>166</sup> The brief affirmed the idea that “properly excluding gene sequences as impermissible subject matter pursuant to the product of nature doctrine would serve to protect the rights, under international and federal law, of Indigenous peoples, that are currently being violated.”<sup>167</sup> This brief provided the court of appeals with a strong human rights concern that gene patenting could lead to the exploitation of certain susceptible groups.

The amicus brief submitted by the Southern Baptist Convention presented similar concerns about the impact of genetic patents on humanity. It began its argument by proclaiming “[t]he patenting of human genes is an affront to humanity. The possibility of obtaining a patent on a person’s genes also encourages physicians and researchers to treat people in a dehumanizing way. For many people, the patenting of genes also violates their religious beliefs.”<sup>168</sup> While this brief was clearly religiously motivated, it also put forward arguments concerning genetic patents turning people into commodities and negatively impacting the human right to proper healthcare by “alter[ing] the relationship between individuals and researchers.”<sup>169</sup>

Beyond those two briefs, the remaining interested parties generally ignored human rights concerns, and following in suit, the July 2011 decision of the Court

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<sup>161</sup> *Id.* at i–ii.

<sup>162</sup> Brief of Amici Curaie Int’l Ctr. of Tech. Assessment, The Indigenous Peoples Council on Biocolonialism, Greenpeace, Inc., Friends of the Earth, and the Council for Responsible Genetics, *Ass’n for Molecular Pathology*, 653 F.3d 1329 (No. 2010-1406).

<sup>163</sup> *Id.* at 12.

<sup>164</sup> *Id.* at 24.

<sup>165</sup> *Id.* at 25.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at 29.

<sup>168</sup> Brief of Amici Curaie S. Baptist Convention at 2, *Ass’n for Molecular Pathology*, 653 F.3d 1329 (No. 2010-1406).

<sup>169</sup> *Id.* at 5–6.

of Appeals for the Federal Circuit made no reference to human rights.<sup>170</sup> In a two-to-one decision, with Judge Bryson dissenting, the court affirmed in part and reversed in part. Specifically, the court affirmed that the method claims for comparing or analyzing the isolated DNA sequences were not patentable. However, the court reversed the district court's decision in a significant part by holding that the actual isolated DNA sequences themselves were patent-eligible subject matter, in addition to the method claim for screening potential cancer therapeutics.<sup>171</sup> To refute the claim that the isolated DNA sequences were natural phenomena and therefore not patent eligible, the court found that the DNA sequences were removed from their native environment and substantially manipulated, thereby producing a "molecule that is markedly different from that which exists in the body."<sup>172</sup>

Though it may seem that this ruling was a partial victory for both parties, in terms of the human rights implications, the very act of finding genes patentable made the outcome an outright defeat for human rights advocates. Despite this defeat, there has been little, if any, audible outcry from the human rights community following the court of appeals' decision. Perhaps activists are waiting for the U.S. Supreme Court to determine the *Myriad*'s ultimate fate.

This wait may be longer than expected, however, considering the tumultuous subsequent history of the Federal Circuit's opinion. First, in October 2011, the ACLU announced its decision to appeal the Federal Circuit opinion.<sup>173</sup> After the ACLU submitted its cert petition on December 7, 2011,<sup>174</sup> nine amicus briefs were filed in support of the petition. While several of these briefs focused on the standing, First Amendment, and patentable subject matter issues,<sup>175</sup> some added distinctively human rights arguments. For example, one such amicus brief argued that patenting genes reduces both access to and quality of essential medical care for women—particularly minority and socio-economically disadvantaged women.<sup>176</sup>

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<sup>170</sup> See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), reh'g denied (Sept. 13, 2011), reh'g denied (Sept. 16, 2011), *cert. granted, judgment vacated sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (U.S. 2012) and *opinion vacated, appeal reinstated*, 2010-1406, 2012 WL 1500104 (Fed. Cir. Apr. 30, 2012).

<sup>171</sup> *Id.* at 1358.

<sup>172</sup> *Id.* at 1352.

<sup>173</sup> Tom Harvey, *Utah firm's gene patent case could go to the Supreme Court*, SALT LAKE TRIB. (Oct. 12, 2011, 11:22 PM), <http://www.sltrib.com/sltrib/money/52711149-79/court-myriad-genes-aclu.html.csp>.

<sup>174</sup> Petition for Writ of Certiorari, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 653 F. 3d 1329 (Fed Cir. 2011) (No. 11-725) 2011 WL 6257250.

<sup>175</sup> See e.g., Brief of Amici Curaie Kali N. Murray and Erika R. George, *Ass'n for Molecular Pathology*, 653 F.3d 1329 (No. 11-725).

<sup>176</sup> Brief of Amici Curaie National Women's Health Network, et al., *Ass'n for Molecular Pathology*, 653 F.3d 1329 (No. 11-725).

The Supreme Court eventually granted cert in March 2012, but merely to vacate the Federal Circuit opinion and remanding the case “for further consideration” in light of the Court’s decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>177</sup> Justice Breyer wrote the unanimous *Prometheus* opinion, which held that a particular diagnostic test related to autoimmune diseases was not eligible for patents because the test was a mere recitation of a law of nature.<sup>178</sup> The day the *Prometheus* decision came out, Myriad’s stock took a plunge—signifying fears that this ruling meant the Supreme Court would overrule the *Myriad* decision.<sup>179</sup> Once the case was remanded, however, patent supporters felt more optimistic because the case would return to the more patent-friendly Federal Circuit.<sup>180</sup>

Regardless of the outcome of the Federal Circuit’s second attempt at resolving the *Myriad* dispute, the case may still make its way to the Supreme Court. If the Supreme Court does eventually hear the case, Myriad may have cause for concern. Kenneth Chahine, a visiting professor at the University of Utah College of Law who has followed the case closely, stated, “I would say the ACLU probably has a better chance at the Supreme Court than they do at the Federal Circuit. . . . It’s not unusual for the Supreme Court to disagree, or at least partially disagree, with the Federal Circuit.”<sup>181</sup> Furthermore, as the highest court in the United States, the Supreme Court’s decisions attract more international attention and tend to give more consideration to international law than do lower U.S. courts.<sup>182</sup> As such, it is possible that the Court will be influenced by the European Patent Office’s 2004 decision to revoke Myriad’s patents on the breast/ovarian cancer genes.<sup>183</sup>

Indeed, in recent years, the Court has given greater deference to international perspectives. For example, Justice Kennedy expressed in a 2010 case that “[t]he judgments of other nations and the international community are not dispositive as to [the Court’s constitutional interpretation]. But ‘[t]he climate of international opinion concerning the acceptability of [the Court’s decision]’ is also ‘not irrelevant.’”<sup>184</sup> Thus with the Court’s willingness to consider international and foreign trends, perhaps the human rights groups should not raise their white flag just yet.

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<sup>177</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (citing to *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012)).

<sup>178</sup> *Prometheus*, 132 S. Ct. 1289.

<sup>179</sup> Andrew Pollack, *Justices Send Back Gene Case*, NY TIMES (Mar. 26, 2012), available at [http://www.nytimes.com/2012/03/27/business/high-court-orders-new-look-at-gene-patents.html?\\_r=1](http://www.nytimes.com/2012/03/27/business/high-court-orders-new-look-at-gene-patents.html?_r=1).

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> See DAVID SLOSS ET AL., THE U.S. SUPREME COURT AND INTERNATIONAL LAW: CONTINUITY OR CHANGE 1 (2011).

<sup>183</sup> *European Patent Office revokes ‘Myriad/breast cancer’ patent*, PHG FOUND. (May 21, 2004), <http://www.phgfoundation.org/news/1350/>.

<sup>184</sup> *Graham v. Florida*, 130 S. Ct. 2011, 2033 (2010).

#### IV. CONCLUSION

Though international organizations like the United Nations have made definitive declarations regarding the human rights implications of intellectual property rights and specifically rights to the human genome, the international outcry about patenting isolated human genes has been minimal. Specifically, it is yet to be determined how the international human rights community will respond to the view of U.S. courts that genes are patentable subject matter. If the U.S. Supreme Court eventually hears the *Myriad* case, its decision will likely draw international attention as a landmark intellectual property decision. If the Court does hear the case, chances are the international human rights implications will not be the Justices' primary consideration. But regardless of what decision the Court makes and what legal arguments it uses to support its decisions, it is likely that there will be a response from the international human rights community, especially if the Court finds *Myriad's* patents valid.

The conflict between human rights and intellectual property rights is far from black and white, especially in the realm of gene patenting where there are obvious positive implications for encouraging the advancement of genetic research. Thus, if legal decision makers continue to move toward greater protection of gene patenting, there will be positive outcomes like discovering cures for diseases, allowing people to better understand their genetic make-up, and perhaps even completely eliminating certain genetic disorders. However, these advancements may come at a cost, both financially and in terms of the cost of limited access to valuable information. Though clearly there are economic motivations behind gene patenting, hopefully those financial incentives will not overshadow the underlying purpose for allowing patents in the first place—to motivate innovative research that will benefit *all* of humanity.