THE SBMATE PATENT:

AMERICAN INGENUITY OR LOOTING OF A TANZANIAN RESOURCE?

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Today's pirates don't come with eye patches and daggers clenched in their teeth, but with sharp suits and claiming intellectual property rights. So those rich countries which take seeds away from their poorer neighbors and then try to patent them are guilty of theft- plain and simple: biopirates by another name. –New Scientist[1]

National and international regulation of all areas of bioscience must strike a balance between promoting innovation and addressing public concerns. – British BioIndustry Association[2]

I. THE SBMATE CONTROVERSY

A. Introduction

Issued on September 1, 2009, the U.S. Patent for the sorghum aluminum tolerance gene, SbMATE, is assigned to the United States of America and the Brazilian Agricultural Research Corporation.[3] This patent is notable because it has enormous commercial potential,[4] yet its ownership and scope are controversial. In fact, critics believe that the SbMATE patent is a "biopiracy" patent, in which biological material from a developing country was used to develop a patent without creating any ownership rights for the developing country.[5] It is argued that the SbMATE gene comes from a Tanzanian farmers' variety of sorghum and, furthermore, that the SbMATE patent will harm Tanzanians.[6] At the very least, the SbMATE patent story demonstrates the complexity of both patentable subject matter and biopiracy determinations.

B. The Importance of the SbMATE Gene and the SbMATE Patent

The SbMATE gene used in the SbMATE patent was developed from sorghum,[7] which is a type of domesticated grass.[8] Sorghum is important in agriculture, and is

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[1] *Editorial: Lest We Starve- Rich Nations Have To Get Tough With Rader's of the World's Gene Banks*, NEW SCIENTIST, Feb. 1998, at 33.

[2] *Benefits of Bioscience*, BIOINDUSTRY ASSOCIATION (Nov. 10, 2010), http://www.bioindustry.org/cgi-bin/contents_view.pl?LEVEL1=12.

[3] U.S. Patent No. 7,582,809 (filed May 17, 2007), http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=sbmate.TI.&OS=TTL/sbmate&RS=TTL/sbmate.

[4] Edward Hammond, AFRICAN CENTRE FOR BIOSAFETY, BRIEFING PAPER, AFRICA'S GRANARY PLUNDERED: PRIVATIZATION OF TANZANIAN SORGHUM PROTECTED BY THE SEED TREATY 12 (2009), *available at* http://www.biosafetyafrica.org.za/images/stories/dmdocuments/ACB_Briefing_Privatising%20Tanzanian%20Sorghum_sbMATE%20Gene_Dec_2009.pdf.

[5] *See* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 436 (2006) (discussing biopiracy patents).

[6] Hammond, *supra* note 4, at 4.

[7] U.S. Patent No. 7,582,809 (filed May 17, 2007).

[8] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, SORGHUM AND MILLETS IN HUMAN NUTRITION (1995), http://www.fao.org/docrep/t0818e/t0818e01.htm.

considered the fifth most important cereal crop grown in the world,[9] as certain varieties of sorghum are used to make food products and food items.[10] Sorghum is also a notably hardy crop, as it may be grown with limited water and generally without the application of fertilizer or other food inputs.[11] Because of these features, sorghum is generally grown in harsh environments where other crops grow or yield poorly.[12]

Sorghum is particularly important to the developing world in Asia and Africa because it is an vital food staple that, along with millet, is "the principle source[] of energy, protein, vitamins and minerals for millions of the poorest people . . ."[13] In fact, sorghum is referred to as a "course grain" or a "poor people's crop" because it is consumed mostly by disadvantaged groups.[14]

The demand for sorghum is not as high as it might be because removing the pericarp, or hull, requires a lot of manual labor.[15] Furthermore, sorghum flour "may have taste, texture, and consistency characteristics that are less appealing than those of maize or wheat flours."[16] Because of such problems, sorghum is not usually traded on international markets.[17]

The SbMATE gene that is found in some varieties of sorghum is particularly desirable because it enables plants to grow in aluminum-rich soil, which is normally toxic to crops.[18] As noted in the patent for SbMATE, aluminum toxicity "is a primary limitation for crop production in developing countries," and "reduces food security in parts of the world where it is most tenuous."[19] Crops such as wheat, rice, and maize are unable to grow in aluminum-rich soil because aluminum in such soil takes a chemical form that is toxic to them.[20] This toxicity both "stunts the growth of crop plant roots and inhibits the uptake of key minerals."[21] In contrast, the SbMATE gene allows crops to neutralize the toxic effects of aluminum at their root tips, so that crops with the gene can grow normally.[22]

The inventors of the SbMATE patent also believe that the SbMATE gene can help prevent phosphorus deficiency, which limits crop production in such soils and is associated with acidic soils.[23] It is believed that a transporter like SbMATE "can facilitate the efflux of citric acid from roots [and may] significantly increase the ability of crop plants to acquire [phosphate] from acid soils . . . ."[24]

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[9] *Sorghum*, U.S. GRAINS COUNCIL, http://www.grains.org/sorghum (last visited Nov. 10, 2010).

[10] *Id.*

[11] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, SORGHUM AND MILLETS IN HUMAN NUTRITION (1995), http://www.fao.org/docrep/t0818e/t0818e01.htm.

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] The International Development Research Centre, *Projects in Tanzania: Sorghum Utilization*, (Nov. 12, 2010) http://www.idrc.ca/en/ev-83069-201_800129-1-IDRC_ADM_INFO.html.

[16] *Id.*

[17] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, SORGHUM AND MILLETS IN HUMAN NUTRITION (1995), http://www.fao.org/docrep/t0818e/t0818e01.htm.

[18] Hammond, *supra* note 4, at 9.

[19] U.S. Patent '809.

[20] Hammond, *supra* note 4, at 9.

[21] *Id.*

[22] *Id.*

[23] U.S. Patent '809.

[24] *Id.*

The U.S. patent application for SbMATE was filed on May 17, 2007, and was assigned to both the United States of America, as represented by the Secretary of Agriculture, and the Brazilian Agricultural Research Corporation.[25] The inventors of the patent were listed as government researchers from the U.S. Department of Agriculture, the Brazilian Agricultural Research Foundation (Embrapa), and Texas A&M University.[26] The Patent Cooperation Treaty (PCT) application[27] for the SbMATE patent was filed almost a year later on May 9, 2008, and the applicants listed on it were similar to those listed on the U.S. patent, although the PCT Application also included The Texas A & M University System for all countries except the U.S. [28] National phase processing for the PCT application was requested for Australia and the European Patent Office.[29] Tanzania was not mentioned anywhere in either the U.S. patent or the PCT application.[30]

The inventors of the U.S. patent stated that "the single locus …identified as controlling aluminum tolerance … [was] developed from two highly [aluminum] tolerant sorghum cultivars."[31] These cultivars are listed as SC283 and a recombinant inbred population created from SC283.[32] When the patent inventors described the research done with these cultivars, they cited to findings in a 2004 research paper by some of the patent's listed inventors.[33]

The authors of this research paper worked for institutions such as the U.S. Department of Agriculture, Cornell University, Texas A & M University, and the Brazilian Agricultural Research Foundation (Embrapa).[34] The research paper stated that the authors used two Al tolerant sorghum inbred lines, SC283 and SC566-14.[35] The paper further stated that the SC283 line was collected in Tanzania, while the SC566 line was collected in Nigeria.[36] The SC283 Tanzanian sorghum line mentioned in the paper is a relatively common Tanzanian farmers' variety of sorghum that is also known internationally as either IS7173 or Msumbji.[37]

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[25] *Id*.

[26] *Id.*; Hammond, *supra* note 4, at 12.

[27] A PCT application allows inventors to seek patent protection "for an invention simultaneously in each of a large number of countries by filing a single 'international' patent application instead of filing several separate national or regional applications." World Intellectual Property Organization, *Protecting Your Inventions Abroad: Frequently Asked Questions About The Patent Cooperation Treaty(PCT)* (April 2006), *available at* http://www.wipo.int/pct/en/infoline.html. The Patent Cooperation Treaty is administered by the World Intellectual Property Organization (WIPO), and it has been signed by more than 125 countries. *Id.*

[28] W.I.P.O. Patent No. 144,257, http://www.wipo.int/pctdb/en/fetch.jsp?LANG=ENG&DBSELECT=PCT&SERVER_TYPE=19-10&SORT=41299579KEY&TYPE_FIELD=256&IDB=0&IDOC=1639472&C=10&ELEMENT_SET=B&RESULT=1&TOTAL=1&START=1&DISP=25&FORM=SEP-0/HITNUM,B-ENG,DP,MC,AN,PA,ABSUM-ENG&SEARCH_IA=US2008063216&QUERY=%28FP%2fsbmate%29+.

[29] *Id.*

[30] U.S. Patent '809.

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] Jurandir V. Malgalhaes et al., *Comparative Mapping of a Major Aluminum Tolerance Gene in Sorghum and Other Species in the Poaceae*, 167 Genetics 1905, 1906 (2004).

[35] *Id.*

[36] *Id.*

[37] *See, e.g.,* Hammond, *supra* note 4, at 12; Patents on Tanzanian Sorghum Raise Legal, Ethical Questions, http://www.twnside.org.sg/title2/wto.info/2010/twninfo100102.htm (last visited Jan. 17, 2011).

C. Expectations for the SbMATE Patent

Among other claims, the SbMATE patent claims isolated and recombinant DNA sequences, a transgenic seed and plant, and a method of producing the genetically transformed plant.[38] Both the U.S. patent and the PCT application state that "SbMATE can work across species to enhance tolerance to [aluminum] in other important crops grown in localities worldwide."[39]

More specifically, it is stated in the patent that the SbMATE patent technology can be used to create genetically modified versions of crops such as maize, wheat, and rice, so that these crops may also grow in aluminum rich and acidic soils.[40] As the inventors of the SbMATE patent noted, aluminum toxicity is "the primary limitation for crop production in developing countries, including 38% of the farmland in Southeast Asia, 31% in Latin America, and 20% of the arable lands in East Asia and Sub-Saharan Africa."[41] Because of this potential to increase crop growth in so many areas, there has been commercial interest in licensing the SbMATE patent. For example, both Dow Chemical and Oji Paper, Japan's second largest paper products producer, have sought to license SbMATE.[42]

While the SbMATE gene has enormous commercial potential,[43] widespread commercial use is years away.[44] In the meantime, there is a lingering concern that such biological patents will "threaten[] the ability of developing countries to build their own industries, and feed and treat their people."[45] Opponents of patents like SbMATE argue that developing countries must pay a high price for patented products that are reintroduced into their countries while simultaneously being unable to use "intellectual property framework to protect against the piracy of their own indigenous and local resources and knowledge."[46]

Defenders of Tanzania's rights to the SbMATE gene are upset that, while the SC283 line of sorghum was used to isolate the SbMATE gene, no rights to the gene or related patents were conferred to Tanzania.[47] The SC283 variety of sorghum is not the only aluminum tolerant variety of sorghum; there are aluminum tolerant sorghums from other areas of Africa as well,[48] such as the Nigerian SC566-14 line mentioned in the

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[38] U.S. Patent '809.

[39] *Id.*; WIPO Patent 144,257.

[40] U.S. Patent '809; Hammond, *supra* note 4, at 12.

[41] U.S. Patent '809.

[42] Patents on Tanzania's Sorghum Raise Legal, Ethical Questions, http://www.twnside.org.sg/title2/susagri/2010/susagri113.htm; Hammond, *supra* note 4, at 4.

[43] *Id*. at 4.

[44] *Id.* at 12.

[45] Sue Mayer, *Are Gene Patents in the Public Interest?,* BioITWorld.com (Nov. 12, 2002), http://www.bio-itworld.com/archive/111202/insights_public.html.

[46] Lara Ewins *as quoted in* IKECHI MGBEOJI, GLOBAL BIOPIRACY 150 (2006).

[47] *See, e.g.*, Hammond, *supra* note 4, at 15; Patents on Tanzanian Sorghum raise legal, ethical questions http://www.twnside.org.sg/title2/wto.info/2010/twninfo100102.htm.

[48] Hammond, *supra* note 4, at 13; Krishna Ramanujan, *Cloned Gene Being Used to Develop Aluminum Tolerant Crops*, Kochian Says at AAAS, ChronicleOnline, Feb. 22, 2010, http://www.news.cornell.edu/stories/Feb10/aaasKochian.html; Lynn M. Gourley et al., *Genetic Aspects of*

research paper.[49] Some critics further argue that genes from sorghum varieties originating from Ethiopia, Sudan, and Uganda are also "encompassed" by the U.S. patent.[50] Still, the possible "theft" of Tanzania's rights to the SbMATE is written about the most.[51]

II. GENERAL PROBLEM OF DEVELOPED COUNTRIES & COMPANIES PATENTING "INVENTIONS" INDIGENOUS TO DEVELOPING COUNTRIES

A. Historical Perspective

The term "biopiracy" is somewhat ambiguous. The term is most often used today to describe "when multinational corporations profit from the medicinal and agricultural uses of plants known to indigenous or native societies and fail to compensate those communities,"[52] but the term can also apply when more developed nations or societies are the "pirates," or when profiting occurs from new uses of non-indigenous plants.[53] Currently, biopiracy is most likely to occur when "knowledge is patented by 'expatriate scientists and resident inventors with access to industrial country patent offices,'" although biopiracy can occur in many other ways as well.[54]

The World Intellectual Property Organization (WIPO) considers biopiracy to be both a trade abuse and a threat to biodiversity.[55] There is a concern that taking a country's indigenous plants without its permission undermines its statehood, as "the undoubted powers of states to regulate access to and the use of plant life forms within their domains has always remained an inherent aspect of statehood."[56] The number of "takings" involved underscores the seriousness of the problem. For example, one study found that by 1996 the base compound in most of the top 150 plant-derived

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Aluminum Tolerance in Sorghum, 123 Plant And Soil 211 (noting that "most sorghum cultivars are not tolerant to high concentrations of [aluminum]").

[49] Jurandir V. Malgalhaes et al., *Comparative Mapping of a Major Aluminum Tolerance Gene in Sorghum and Other Species in the Poaceae*, 167 Genetics 1905, 1906 (2004).

[50] *Hammond*, supra note 4, at 13.

[51] *See, e.g.*, Hammond, *supra* note 4, at 13; Mike Mande & Abduel Elinaza, *US, Brazil Seek Patent to Tanzania Sorghum*, THE EAST AFRICAN (Feb. 15, 2010), http://www.theeastafrican.co.ke/news/-/2558/861208/-/pv8ocdz/-/index.html; Riaz K. Tyob, *Patents on Tanzania's Sorghum Raise Legal, Ethical Questions*, THIRD WORLD NETWORK (Jan. 18, 2010), http://www.twnside.org.sg/title2/susagri/2010/susagri113.htm.

[52] Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 221 (2008). Authors have also used a similar term, "bioprospecting," to refer to when genetic and biological information that was previously known by indigenous people in its naturally-occuring form, is used to benefit "the creation of new pharmaceuticals, cosmetics, biotechnology, and crop production." Vincent M. Smolczynski, Note, *"Willful Patent Filing": A Criminal Procedure Protecting Traditional Knowledge*, 85 CHI.-KENT L. REV. 1171, 1171 (2010).

[53] MARCELIN TONYE MAHOP, INTELLECTUAL PROPERTY, COMMUNITY RIGHTS AND HUMAN RIGHTS 19 (2010).

[54] Vincent M. Smolczynski, *"Willful Patent Filing": A Criminal Procedure Protecting Traditional Knowledge*, 85 CHI.-KENT L. REV. 1171, 1176−77 (2010).

[55] Dwyer, *supra* note 52, at 243.

[56] IKECHI MGBEOJI, GLOBAL BIOPIRACY 104 (2006).

pharmaceuticals corresponded with traditional medical knowledge.[57] Furthermore, there is a very real concern that biopiracy "delegitimizes the profound intellectual input of local farmers onto the improvement of plants."[58]

Accusations of "biopiracy patents" are not new.[59] The following examples of natural rubber, rosy periwinkle, and the Enola Bean Patent demonstrate how the term biopiracy is applied to different types of situations and has evolved throughout history.[60] These are only a few examples of the larger cultural clash that can result over the exploitation of non-indigenous plant material. At its core, biopiracy "encapsulates a strong moral and ethical dimension, which is entrenched on the demise of cultural linkages between communities and their assets, from which communities have contributed in nurturing and sustaining their assets."[61]

Natural Rubber

Authors often use the story of natural rubber as a famous example of possible biopiracy, although the alleged taking does not include the taking of traditional knowledge.[62] In the mid–1800s natural rubber was produced primarily from wild trees in the Amazon basin.[63] During the Industrial Revolution, the value of this raw rubber grew as demand for it in Europe and North America rapidly increased.[64] By 1876, Brazil controlled ninety-five percent of the global trade,[65] and its Amazon River cities became "the centers of an extremely lucrative, near-global monopoly."[66]

To overcome the Brazilian monopoly, the British Royal Botanical Gardens sent a botanist to collect Amazon seeds.[67] The botanist collected over 70,000 rubber tree seeds,[68] which were used to establish rubber plantations in the British colony of Ceylon and other plantations in South East Asia.[69] These British plantations "broke" the Brazilian monopoly on natural rubber,[70] which eventually collapsed.[71] This rubber "piracy" is still remembered in some parts of Brazil today.[72]

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[57] Francesca Grifo et al., *The Origins of Prescription Drugs, in* BIODIVERSITY AND HUMAN HEALTH 131, 135–37 (Francesco Grifo & Joshua Rosenthal eds., 1997).

[58] *Id.*

[59] MAHOP, *supra* note 53, at 20.

[60] For more thorough descriptions of historical examples of "biopiracy" and different perspectives of these examples *see, e.g.*, IKECHI MGBEOJI, GLOBAL BIOPIRACY (2006); DANIEL F. ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES (2010); POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES (J. Michael Finger & Philip Schuler eds., 2004).

[61] MAHOP, *supra* note 53, at 20.

[62] John Tustin, *Traditional Knowledge and Intellectual Property in Brazilian Biodiversity Law*, 14 TEX. INTELL. PROP L.J. 131, 133 (2006).

[63] *Id.*

[64] *Id.*

[65] IKECHI MGBEOJI, GLOBAL BIOPIRACY, 104 (2006).

[66] Tustin, *supra* note 62, at 133.

[67] *Id.*

[68] IKECHI MGBEOJI, GLOBAL BIOPIRACY, 105 (2006).

[69] Tustin, *supra* note 62, at 133.

[70] *Id.*

[71] IKECHI MGBEOJI, GLOBAL BIOPIRACY, 104 (2006).

[72] *Id.*

Rosy Periwinkle

The story of rosy periwinkle (Catharanthus roseus) is another example of alleged biopiracy. The plant is found in Madagascar, and is the source of the two powerful cancer fighting drugs vincristine and vinblastine.[73] Both drugs were isolated, tested, and marketed by Eli Lilly beginning in the 1950s and, eventually, vincristine generated substantial profits for the company. [74] Madagascar did not profit from the development or sale of either of the drugs, while many authors have argued it should have.[75]

However, there is another perspective on the rosy periwinkle biopiracy story. Despite concerns about the improper treatment of Madagascar, it is not clear if rosy periwinkle is native to Madagascar or just first described there.[76] Furthermore, while rosy periwinkle may have originated in Madagascar, it was naturalized in other parts of the world long before Eli Lilly studied it, and the first specimens used by Eli Lilly actually came from India.[77] Today the rosy periwinkle is truly an international plant, as it is cultivated on all six continents and is integrated into folk healing traditions in countries as diverse as England, Vietnam, and Dominica.[78]

Also, while "indigenous and peasant communities strongly suggested bioactivity," the flower's use as the source of a cancer drug was previously unknown and was expensive for Eli Lilly to discover.[79] Therefore, while numerous authors once argued that Madagascar was unfairly denied revenues from Eli Lilly's drugs, the rosy periwinkle story is now considered, "a weak case for those who argue that the pharmaceutical industry has reaped great profits by exploiting the ethnobotanical knowledge of particular nations . . . ."[80]

The Enola Bean Patent

A more recent example of possible biopiracy is the Enola bean. The alleged "theft" of an indigenous resource began when an American executive, Larry Proctor, traveled to Mexico and brought back a bag of yellow colored beans.[81] In April of 1999, after two years of a selective breeding program using the beans, Proctor obtained a patent on the resulting beans.[82] Proctor stated that these patented beans had a distinctively yellow color that held true across generations, and he named them Enola beans after his

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[73] Dwyer, *supra* note 52, at 226.
[74] MICHAEL F. BROWN, WHO OWNS NATIVE CULTURE? 135−38 (2003).
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *Id.* at 137.
[81] Dwyer, *supra* note 52, at 228.
[82] *Id.*

wife.[83] While it was admitted that the Enola bean is a descendent from the traditional Mexican bean Mayacoba,[84] it was argued that the Enola bean is unique.[85]

In Mexico, farmers have grown yellow colored beans since the Aztecs, and agronomists registered the Mayacoba bean as a variety of the yellow bean in 1978.[86] By the time of the Enola patent, Mexican farmers were exporting yellow beans, including Mayacoba, to the U.S., and annual sales in the U.S. were reported at about $50 million dollars.[87]

After the Enola bean patent was issued, Proctor monitored imports of Mexican yellow beans.[88] He believed that Mexican farmers were possibly infringing on the Enola patent by selling yellow beans to companies in the United States, and he stated that Mexican farmers were likely raising Enola beans and selling them as Mayacoba.[89] At the request of his company, U.S. Customs officials stopped bean shipments from Mexico to search for any beans with the same color as Enola beans.[90]

Proctor also monitored U.S. sales of yellow beans. He filed suit against sixteen small U.S. bean seed companies that sold Mexican yellow beans for infringing on the Enola patent, also accusing them of illegally growing and selling Enola beans.[91] Furthermore, he charged licensing fees of up to six cents a pound for the right to sell yellow beans in the United States.[92] All of these actions had a large effect on the Mexican yellow bean industry.[93] After the Enola bean patent was issued, Mexican export sales of yellow beans dropped over ninety percent, which had a severe economic impact on farmers in northern Mexico.[94]

The Enola bean patent was most controversial because a number of organizations believed that the patent was improvidently granted.[95] These organizations maintained that despite its consistent yellow coloration, the Enola bean failed to meet the basic patent

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[83] Danielle Goldberg, *Jack and the Enola Bean*, http://www1.american.edu/TED/enola-bean.htm (last visited Jan. 17, 2011).

[84] Dwyer, *supra* note 52, at 228.

[85] U.S. Patent No. 08/749,449 (filed Nov. 15, 1996). http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=enola.TI.&OS=TTL/enola&RS=TTL/enola.

[86] Philip Schuler, *Biopiracy and Commercialization of Ethnobotanical Knowledge, in* POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 159, 174−75 (J. Michael Finger & Philip Schuler eds., 2004).

[87] *Id.*

[88] *Id.* at 175.

[89] *Id.*

[90] *Id.*

[91] Dwyer, *supra* note 52, at 228; Danielle Goldberg, *Jack and the Enola Bean*, http://www1.american.edu/TED/enola-bean.htm (last visited Jan. 17, 2011).

[92] Philip Schuler, *Biopiracy and Commercialization of Ethnobotanical Knowledge, in* POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 159, 175 (J. Michael Finger & Philip Schuler eds., 2004).

[93] *Id.*

[94] Vincent M. Smolczynski, *"Willful Patent Filing": A Criminal Procedure Protecting Traditional Knowledge*, 85 CHI.-KENT L. REV. 1171, 1172 (2010); Danielle Goldberg, *Jack and the Enola Bean*, http://www1.american.edu/TED/enola-bean.htm.

[95] BROWN, *supra* note 74, at 106−07.

requirement of novelty over Mexican yellow beans and, therefore, the Enola bean was unpatentable.[96]

Less than a year after the Enola bean patent was issued, the Colombia-based International Center for Tropical Agriculture (CIAT), with support from the Food and Agriculture Association, filed a request for reexamination of the Enola bean patent.[97] CIAT claimed it that maintained "some 260 bean samples with yellow seeds, and six accessions [that were] 'substantially identical' to claims made in Proctor's patent."[98] After several years of re-examinations, the U.S. Patent and Trademark Association revoked the Enola Patent in April of 2008.[99] Despite the ultimate invalidation of the Enola bean patent, opponents of the patent believe that the invalidation took too long to occur, and allowed "the owner of a flagrantly unjust patent to legally monopolize markets and destroy competition for close to half the 20-year patent term."[100] This inability of the U.S. patent system to quickly invalidate an improvidently granted patent is often cited as a failure of the U.S. patent system, and a concern for future "biopiracy patents."[101] Perhaps because the Enola bean patent is so often cited as a "biopiracy," a few authors have wrote adamant defenses of the Enola bean patent while its validity was being determined.[102]

B. Acquiring a U.S. Patent

Patent law in the United States is grounded in the United States Constitution, which gives 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 respecting Writings and Discoveries."[103]

A patent grant gives the owner the right to exclude others "from making, using, offering to sell, or selling the invention within the United States, or importing the invention into the United States."[104] In other words, the United States provides the inventor the right to exclude others from the invention for a limited period of time, so that the inventor has an economic incentive to disclose her invention; furthermore, in

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[96] ETC Group, *Hollow Victory: Enola Bean Patent Smashed At Last (Maybe)* (April 29, 2008), http://www.etcgroup.org/en/node/683.

[97] *Id.*

[98] Philip Schuler, *Biopiracy and Commercialization of Ethnobotanical Knowledge, in* POOR PEOPLE'S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 159, 175–76 (J. Michael Finger & Philip Schuler eds., 2004). *See also* Press Release, International Center for Tropical Agriculture, U.S. Patent Office Rejects Company's Patent Protection for Bean Commonly Grown by Latin American Farmers (May 2008), http://webapp.ciat.cgiar.org/newsroom/release_31.htm.

[99] ETC Group, *Hollow Victory: Enola Bean Patent Smashed At Last (Maybe)* (April 29, 2008), http://www.etcgroup.org/en/node/683.

[100] *Id.*

[101] *See, e.g., id.*

[102] *See* Carol Nottenburg, *Enola Bean Patent Controversy*, Harvest Choice (July 14, 2009), *available at* http://harvestchoice.org/technology/intellectual_property/commentaries (defending the Enola bean patent as novel and non-obvious under United States patent law at the time of patenting, and criticizing CIAT).

[103] U.S. Const. art. 1 § 8, cl. 8.

[104] 35 U.S.C. § 271(a) (2006).

exchange for a patent, the inventor provides the public with the knowledge of how to create the invention in her patent application.[105]

Section 101 of the Patent Act defines patentable subject matter as:

> 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 therefore, subject to the conditions and requirements of this title. [106]

The Supreme Court has determined that the wide language of this section means that "Congress plainly contemplated that the patent laws be given wide scope." [107] While the patent laws do give "a wide scope" as to what is patentable, there are limits, and the court has provided three specific exceptions.[108] Laws of nature, physical phenomena, and abstract ideas are not patentable.[109] The Court has noted that while these exceptions are not clearly stated in the text, "these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years."[110]

Determinations of patentability can be subtle and sometimes appear contradictory. For instance, while discoveries that are "only some of the handiwork of nature" have been held not patentable,[111] a bacterium was held patentable because it had "markedly different characteristics from any found in nature" and had "the potential for significant utility."[112] Even if a discovery meets the requirements of § 101 of the Patent Act, in order for it "to receive patent protection, [it] must be novel, § 102, nonobvious, § 103, and fully and particularly described, § 112."[113] These requirements are thought to "serve a critical role in adjusting the tension . . . between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by statutory design." [114]

Still, the United States' patent law has been criticized for impeding progress by not sufficiently recognizing already existing traditional knowledge known in other countries. United States patent law explicitly prohibits the patenting of an invention when another inventor has already "patented or described [the invention] in a printed publication in this or a foreign country," however, United States patent laws only prohibit the patenting of an "invention known or used by others *in this country.*"[115] Therefore, United States patent law does not explicitly prohibit the patenting of an invention known or used by others in a foreign country and, subsequently, has been criticized for not

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[105] Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).
[106] 35 U.S.C. § 101
[107] *Id.*
[108] *Id.*
[109] *Id.* at 309.
[110] Bilski v. Kappos, 130 U.S. 3218, 3225 (2010).
[111] Funk Bros. Seed Co. v. Kalo Inoculant Co. 333 U.S. 127 (1948).
[112] Diamond v. Chakrabarty, 447 U.S. 309, 310 (1980).
[113] Bilski v. Kappos, 130 U.S. 3229 (2010).
[114] *Id.*
[115] 35 U.S.C. § 102 (a). "[I]n this country" means only in the United States and does not include WTO or NAFTA countries. Manual of Patent Examining Procedure § 706.02 (c).

recognizing other countries' traditional knowledge that has not been published.[116] Still, the United States has policy reasons for using this language.[117] However, this omission of non-recorded knowledge of inventions known in other countries is different from what most other countries require.[118] Additionally, arguments that controversial patents are valid because previous knowledge of the invention in a foreign country was not published incite further criticism of United States patent law.[119]

As outlined below, United States patents for genes, plants, and seeds are also controversial,[120] but U.S. patent law has developed in such a way that all three are currently patentable in at least some form. However, as outlined below, there have been challenges to the future patentability of genes, plants, and seeds, and such challenges have implications for future controversies that are similar to the SbMATE controversy.

U.S. Plant Patents

The United States Plant Patent Act of 1930[121] introduced a type of patent specifically for plants known as a "plant patent."[122] These patents protect developers of new varieties of asexual propagated plants,[123] such as apple trees and rose bushes.[124] Because plant patents can only be issued for asexually-propagated plants, they are limited in scope. Furthermore, the patent rights derived from such patents are limited to "plants that are asexually reproduced *from the patentee's plants* . . . [so that] independent creation *is* a valid defense."[125] Allowing independent creation as a valid defense against patent infringement is an unusual limitation on the rights of the patent holder, as most patent holders can pursue infringement actions against anyone who uses the patented invention, even if the alleged infringer created the invention independently.

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[116] *See, e.g.,* John Reid, *Biopiracy: The Struggle for Traditional Knowledge Rights*, 34 AM. INDIAN L. REV. 77, 82 (2010).

[117] Namely, there are practical concerns about trying to prove activities outside the United States. R. Carl Moy, *Patent Harmonization, Protectionism and Legislation*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 777, 784 n.24 (1992).

[118] Jean Jin, *Of Pirates and Patents*, ILL. B.L.J. (Oct. 20, 2007), http://www.law.illinois.edu/bljournal/post/2007/10/20/Of-Pirates-and-Patents.aspx.

[119] *See, e.g.,* Gillian N. Rattray, *The Enola Bean Patent Controversy: Biopiracy, Novelty and Fish-and-Chips*, 2002 DUKE L. & TECH. REV. 008, ¶ 6 (Jun. 3, 2002), http://www.law.duke.edu/journals/dltr/articles/2002dltr0008.html (describing how this was one of the defenses raised in the Enola Bean patent controversy).

[120] *See, e.g., Are Gene Patents in the Public Interest*, BioITWorld.com, http://www.bio-itworld.com/archive/111202/insights_public.html (last visited Jan. 17, 2011).

[121] 46 Stat. 376 (1930), *codified as amended* 35 U.S.C. § 161-164.

[122] BiOS, *Can IP Rights Protect Plants?,* http://www.patentlens.net/daisy/bios/124#plant_patents.

[123] 35 U.S.C § 1616. Plant Patents are the same as regular U.S. patents except that the utility requirement is replaced by a distinctiveness requirement, 35 U.S.C. § 161, and "a plant patent cannot be declared invalid if its description is as complete as reasonably possible, 35 U.S.C. § 162." Kathryn Garforth, *Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms*, *in* PATENTING LIVES 27, 40 n.66 (Johanna Gibson ed., 2008).

[124] Colorado State University, *Transgenic Crops: Introduction and Resource Guide*, http://cls.casa.colostate.edu/TransgenicCrops/patent.html (last visited Jan. 17, 2011).

[125] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 120 (4th ed. 2007).

In 1970, the United States Plant Variety Protection Act[126] ("PVPA") established plant variety protection certificates issued by the United States Department of Agriculture.[127] These certificates give developers of new varieties of seed-propagated plants patent-like rights, although they cannot be granted for first generation hybrid plants.[128] The certificates confer to a breeder the right to prevent others from selling, reproducing, importing, or exporting a plant, and the right to stop others from producing a hybrid or different variety of the plant.[129] They provide protection for slightly longer than a patent; plant variety protection certificates provide protection for twenty years from the date of issuance, instead of the standard patent protection term of twenty years from the date of filing.[130] The certificates are limited in scope because there is an exception from infringement liability for experimentation using a protected variety.[131] Also, farmers may legally save seeds from protected varieties and use these seeds in the production of crops without infringement.[132]

In 1985 in *Ex parte Hibberd*,[133] the Board of Patent Appeals and Interferences held that a variety of maize was patentable, despite initial rejections that the subject matter was beyond the scope of 35 U.S.C. § 101 and ought to be protected under the Plant Patent Act or the Plant Variety Protection Act.[134] Since this case was decided, it has been cited for the proposition that utility patents can be issued on plants, in spite of other intellectual property protections available to inventors of such plants by the Plant Patent Act and the Plant Variety Protection Act.[135]

Subsequently, in 2001, in *J.E.M. Ag Supply v. Pioneer Hi-Bred International*,[136] the Supreme Court affirmed the patentability of sexually reproducing hybrid plants, even if they are not genetically modified.[137] In *J.E.M,* the Supreme Court also held that breeders had the right to obtain "dual protection" for new breeds of plants under both the PVPA and the Patent Act.[138]

These cases are significant. They increased the methods of protection available for some types of plants, and gave some inventors a range of options not generally available to patent holders. While most inventions can only be protected by a single patent, transgenic plant holders can chose to apply for multiple patents or to not use any patents.

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[126] 7 U.S.C. §§ 2321−2582.

[127] 7 U.S.C. § 2482.

[128] 7 U.S.C. § 2402.

[129] 7 U.S.C. § 2483 (a) (1).

[130] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 120 (4th ed. 2007).

[131] *Id.* at 119.

[132] *Id.*

[133] 227 U.S.P.Q. (BNA) 443 (1985).

[134] 227 U.S.P.Q. (BNA) 443−44 (1985); Kathryn Garforth, *Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms*, *in* PATENTING LIVES 27, 39−40 (Johanna Gibson ed., 2008).

[135] North Carolina State University Libraries, *Utility Patents Applied to Plants,* http://www.lib.ncsu.edu/guides/plantintellprop/utilitypatentforplants.html (last visited Nov. 12, 2010).

[136] 534 U.S. 124, 125 (2001).

[137] Kathryn Garforth, *Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms*, *in* PATENTING LIVES 27, 40 (Johanna Gibson ed., 2008).

[138] 534 U.S. 124 (2001).

Generally, inventors prefer to protect transgenic plants with utility patents because "the utility patent can apply to the method used to engineer a plant, the genetic sequences that are inserted, and the plant that results."[139] In contrast, plant patents protect "only a single plant or genome"[140] and do not provide protection against independently created plants.[141] Also, while plant patents and plant variety protection certificates can prevent only the unlawful proliferation of a variety and cannot prevent the use of plant materials for breeding purposes, utility patents can both prevent seed increases by reproduction of the same variety and protect breeders from unauthorized use of protected plant varieties for breeding and research.[142] The same plant may be protected by both a utility patent and a plant patent,[143] and a plant variety protection certificate.[144]

U.S. Gene Patents

Patents on genes are not generally allowed until a DNA product has been isolated and purified.[145] Patents on such isolated and purified products prevent others from "mak[ing], us[ing], offer[ing] to sell, or sell[ing] [patented genes] within the United States, or import[ing] [patented genes] into the United States."[146] Biotechnology companies argue that genes, plants and seeds should be patentable so that companies will have enough confidence to invest the time and money necessary to develop such products.[147]

Still, a recent district court ruling held patents for isolated DNA containing breast cancer susceptibility genes invalid.[148] This district court noted that "[i]n light of DNA's unique qualities as a physical embodiment of information, none of the structural differences . . . between native . . . DNA and the isolated . . . DNA claimed in the patents-in-suit render the claimed DNA 'markedly different,'"[149] and that "the time may come

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[139] Colorado State University, *Transgenic Crops: Introduction and Resource Guide,* http://cls.casa.colostate.edu/TransgenicCrops/patent.html (last visited Jan. 17, 2011).

[140] BiOS, *Can IP Rights Protect Plants?,* http://www.patentlens.net/daisy/bios/1234#plant_patents.

[141] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 120 (4th ed. 2007).

[142] Brian D. Wright, Plant Genetic Engineering and Intellectual Property Protection 1, Agricultural Biotechnology in California Series, Publication 8186 (2006).

[143] BiOS, *Can IP Rights Protect Plants?,* http://www.patentlens.net/daisy/bios/1234#plant_patents.

[144] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 120 (4th ed. 2007).

[145] *See* Parke-Davis & Co. v. H. K. Mulford & Co., 189 F. 95 (S.D.N.Y. 1911), *aff'd* 196 F. 496 (2d Cir. 1912) (stating that a purified substance from a living creature can be patented even though "it is of course possible logically to call this a purification of the principle"). Note that the Association for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) case currently on appeal before the Federal Circuit challenges the assumption that this case stands for the establishment "that the purification of a natural product necessarily renders it patentable." *Id.*

[146] *See* 35 U.S.C. § 271(a) (2006) (describing the protection provided by patents generally).

[147] Sue Mayer, *Are Gene Patents in the Public Interest?*, BioITWorld.com (Nov. 12, 2002), http://www.bio-itworld.com/archive/111202/insights_public.html.

[148] Association for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[149] Association for Molecular Pathology 702 F. Supp. 2d 229.

when the use of DNA for molecular and diagnostic purposes may not require purification."[150] The district court further noted that "Supreme Court precedent has established that products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product."[151]

This decision has led to questions about other patents on human genes, which has led to doubt about a larger number of U.S. patents, as over 40,000 patents on 2,000 human genes are said to exist.[152] The language of the decision also questions the patentability of other types of genes, as much of the logic regarding the patentability of human genes applies to the patentability of genes in general.[153]

The district court's decision has been criticized for relying on older cases and failing to cite relevant Federal Circuit cases.[154] However, the decision may be indicative of a new trend. Soon after the decision, the Department of Justice submitted a friend-of-the-court brief that contradicted the long-standing stance of the PTO and stated that genes should not be eligible for patents because they are a product of nature.[155]

Ultimately, the patentability of genes remains a controversial subject.[156] Despite its brief, the government suggested that changing gene patent laws "would have limited impact on the biotechnology industry because man-made manipulations of DNA, like methods to create genetically modified crops . . . could still be patented."[157]

C. International Patent Law

International patent law has been significantly influenced by the U.S. Supreme Court decision in *Diamond v. Chakrabarty*,[158] which held that a live, human-made micro-organism is patentable subject matter.[159] International gene and plant patenting has also been affected by international trade and patent harmonization agreements, such as the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), the *General Agreement on Trade and Tariffs* (GATT), and the *North American Free Trade*

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[150] *Id.*

[151] *Id.* at 222.

[152] John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent,* N.Y. TIMES, March 29, 2010 at B1, http://www.nytimes.com/2010/03/30/business/30gene.html; Sharon Begley, *In Surprise Ruling Court, Declares Two Gene Patents Invalid*, NEWSWEEK, Mar. 29, 2010, http://www.newsweek.com/blogs/the-human-condition/2010/03/29/in-surprise-ruling-court-declares-two-gene-patents-invalid.html.

[153] *See* Association for Molecular Pathology 702 F. Supp. 2d 229.

[154] *Association of Molecular Pathology v. USPTO- The Case Law*, The Patentability Blog (April 21, 2010), http://patentability.blogspot.com/2010/04/association-for-molecular-pathology-v.html.

[155] Andrew Pollack, *U.S. Says Genes Should Not Be Eligible for Patents*, N.Y. Times, Oct. 29, 2010 at B1. http://www.nytimes.com/2010/10/30/business/30drug.html?src=me&ref=homepage.

[156] Joe Devanny, *Should Genes be Patented?,* International Debate Education Association (April 14, 2009), http://www.idebate.org/debatabase/topic_details.php?topicID=32; Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access,* 76 UMKC L. REV. 295 (2007).

[157] Andrew Pollack, *U.S. Says Genes Should Not Be Eligible for Patents,* N.Y. Times, Oct. 29, 2010 at B1.

[158] *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH LAW J. 123, 125 (2002), http://www.ncbi.nlm.nih.gov/pubmed/14748275.

[159] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

Agreement (NAFTA).[160] In both the developed and developing countries that signed these agreements, "genes . . . are considered patentable material if they meet general patent criteria and are demonstrated to be new creations (e.g., artificial genes) or are isolated from nature and identified . . . and shown to have a particular function and use."[161]

While TRIPS does not require plant patents, it specifically requires the protection of plant varieties "either by patents or by an effective *sui generis* system or by any combination thereof."[162] The term "*sui generis*" is not well defined and its meaning is debated.[163] It is generally thought that it "enables member countries to design their own system of protection for plant varieties" if they do not issue plant patents; however, it is not clear what is sufficient to qualify as a "*sui generis* system."[164]

The TRIPS agreement also did not define "invention." The United Nations has noted that this exclusion allows WTO "member countries relatively free to draw the line between patentable 'discoveries' and actual inventions in the patent field,"[165] thereby preserving some autonomy for WTO member countries as they implement their patent laws.

Still, many WTO member countries have changed their patent laws to conform to the TRIPS agreement because, as member countries, they are bound to adhere to TRIPS.[166] For example, prior to joining TRIPS, the Indian patent system followed the 1970 Indian Patent Act, which prevented patent claims for "substances intended for use, or capable as being used as food or medicine or drug."[167] This patent exception was broad and the Indian Patent Act defined food as "any article of nourishment."[168] However, the India patent system changed after India joined WIPO and had to comply with the TRIPS agreement. Patents are now granted for seeds, plants, micro-organisms, cells and even [genetically modified] organisms and animals."[169] Similarly, it is argued that prior to Australia, Canada, and Ireland joining WIPO, attempts by agribusiness to introduce legislation similar to TRIPS were rebuffed in all three countries.[170]

In fact, Australian patent laws have changed to such an extent that, like the U.S, Australia now allows inventors to patent individual plant varieties.[171] While plant varieties are not patentable in many European countries, a plant characterized by a

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[160] *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing,* 10 HEALTH LAW J. 123, 125 (2002); IKECHI MGBEOJI, GLOBAL BIOPIRACY 121 (2006).

[161] *Id.* at 125−26.

[162] World Trade Organization, TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Part II Section 5: Patents, Article 27, (italics added) http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5 (last visited Jan. 17, 2011).

[163] BiOS, *Can IP Rights Protect Plants?,* http://www.patentlens.net/daisy/bios/1234#plant_patents (last visited Jan. 17, 2011).

[164] *Id.*

[165] IKECHI MGBEOJI, GLOBAL BIOPIRACY 130 (2006).

[166] BiOS, *Can IP Rights Protect Plants?,* http://www.patentlens.net/daisy/bios/1234#plant_patents.

[167] VANDANA SHIVA, PROTECT OR PLUNDER? 138 (2001).

[168] *Id.*

[169] Vanada Shiva, *The Indian Seed Act Patents, Sowing the Seeds of Dictators,* CounterCurrents.Org (Feb. 15, 2005), *http://www.countercurrents.org/gl-shiva150205.htm.*

[170] IKECHI MGBEOJI, GLOBAL BIOPIRACY 130 (2006).

[171] *Id.*

particularly gene, instead of by its genome, is patentable in most of Europe.[172] Furthermore, in much of Europe, transgenic plants are patentable only if they are not restricted to a specific plant variety but represent a broader plant grouping.[173] In the past, developing countries have responded with attempts "to restrict and even prohibit the patenting of plants."[174]

The issuance of intellectual property rights over genetic material in native species has been defended for two reasons. It has been argued that:

> [i]n addition to more fairly distributing the gains from recombinant genetic products based on those species, it . . . also gives[s] developing countries an incentive to protect rainforests and other genetically rich areas . . . the granting of property rights over a resource can be expected to lead to more efficient use of a resource.[175]

In 1993, the landmark Convention for Biological Diversity (CBD) Treaty went into force, which attempted to address global biodiversity conservation.[176] The CBD Treaty is dedicated to the objectives of conservation of biological diversity, sustainable use of the components of biological diversity, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.[177] This third objective acknowledges the concerns of developing countries, and the CBD Treaty "recognizes the sovereign rights of states to determine through national legislation the conditions for access to the biological resources in their territories."[178]

Recently, developing countries have attempted to alter the TRIPS patent requirements in order to address biopiracy concerns, although these attempts are unlikely to be successful.[179] One recently proposed amendment suggested a requirement that patent applications that "use or are based upon genetic resources or traditional knowledge

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[172] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 121 (4th ed. 2007).

[173] *Id.*

[174] Chika B. Onwuekwe, *Plant Genetic Resources and the Associated Traditional Knowledge: Does the Distinction Between Higher and Lower Life Forms Mater?*, *in* PATENTING LIVES 139, 149 (Johanna Gibson ed., 2008).

[175] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 125 (4th ed. 2007).

[176] MAHOP, *supra* note 53, at 42. Many countries signed the CBD Treaty, although the United States is one of the few countries that has only signed, and not ratified the treaty. Convention on Biological Diversity, List of Parties, http://www.cbd.int/convention/parties/list/ (last visited Jan. 17, 2011).

[177] Convention on Biological Diversity, About the Convention (Jan 4, 2010), http://www.cbd.int/convention/about.shtml.

[178] MAHOP, *supra* note 53, at 45.

[179] Cynthia M. Ho, Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies, 39 U. MICH. J.L. REFORM 433, 487–88 (2006). It should also be noted that at least some developed countries are also attempting to address biopiracy claims through their current patent regimes. For example, in 2005 the European Patent Office revoked for the first time a patent "whose subject matter and claims were based essentially on traditional knowledge originating in a biodiversity country." Fritz Dolder, *Traditional Knowledge and Patenting: The Experience of the Neemfungicide and the Hoodia Cases*, 26 Biotech. L. Rep. 583, 583–87 (2007).

disclose the source, as well as the country of source."[180] Another proposed amendment to TRIPS would require that patent applications "must include evidence of prior informed consent of any materials used from another country and satisfaction of the [Convention of Biological Diversity] mandate that access to genetic resources be subject to prior informed consent . . . ."[181] Neither of these amendments is likely to be successful for many reasons, including the fact that amendments to TRIPS require broad consensus among WTO members, and that such proposals have little support among Western countries.[182]

Developing countries have attempted more local reform as well. Against a movement toward broader international intellectual property regimes, developing countries have implemented national systems to regulate use of their own indigenous plants and knowledge. For example, in 1999 the Indian government created an online database of documented traditional knowledge in response to concerns that traditional knowledge was being "misappropriated in the form of patents on non-original innovations."[183] The government specifically cites concerns about patents on inventions that use Indian plants such as basmati rice, hoodia, and kava, and the government's desire to prevent such "bio-prospecting" patents in the future.[184] It is hoped the database will break "the format and language barrier and mak[e traditional knowledge] accessible to patent examiners at International Patent Offices for the purpose of carrying out search and examination."[185]

SbMATE and the African Perspective

In spite of the ongoing controversy regarding the patentability of genes and plants, at least some of the claims in the SbMATE patent are likely to remain valid even

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[180] Cynthia M. Ho, Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies, 39 U. MICH. J.L. REFORM 433, 487–88 (2006).

[181] *Id.*

[182] *Id*. at 490–98.

[183] Council of Scientific & Industrial Research (CSIR), Traditional Knowledge Digital Library, About TKL http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng; Government of India, Press Information Bureau, Known Instances of Patenting on the UES of Medicinal Plants in India (May 6, 2010), http://pib.nic.in/release/release.asp?relid=61511.

[184] Council of Scientific & Industrial Research (CSIR), Traditional Knowledge Digital Library, Bio-piracy of Traditional Knowledge, http://www.tkdl.res.in/tkdl/langdefault/common/Biopiracy.asp?GL=Eng (last visited Jan. 17, 2011). In particular, the controversy surrounding the patenting of a type basmati rice has been written about by many authors. *See, e.g., TED Case Studies: Basmati*, American University, http://www1.american.edu/TED/basmati.htm (last visited Apr. 8, 2011); Sumathi Subbiah, *Reaping What They Sow: The Basmati Rice Controversy and Strategies for Protecting Traditional Knowledge*, 27 B.C. INT'L & COMP. L. REV. 529, 549–555 (2004). Critics of the patent alleged that some of the claims contained within it could "easily apply to ninety percent of all basmati grown anywhere in the world." *Id.* at 522. The controversy is infamous partly because the patent resulted in the Indian government and a coalition of NGOs bringing challenges at both the USPTO and the FTC. The PTO challenges eventually resulted in most of the basmati patent claims being rejected or withdrawn. However the outcome of the FTC's ruling was more controversial because it allowed the use of the term "basmati" for rice grown in the United States.

[185] Council of Scientific & Industrial Research (CSIR), Traditional Knowledge Digital Library, Bio-piracy of Traditional Knowledge, http://www.tkdl.res.in/tkdl/langdefault/common/Biopiracy.asp?GL=Eng (last visited Jan. 17, 2011).

if gene patents and general plant patents are held invalid. The SbMATE patent claims include not only isolated and recombinant DNA sequences and a transgenic seed and plant, but also a method of producing the genetically transformed plant.[186] Such transgenic organisms and methods for their production are unlikely to be invalidated as unpatentable subject matter.[187]

The continued patentability of transgenic organisms and methods of their production is discouraging to many Africans. Africans are concerned that biopiracy is costing Africa a lot of benefits.[188] There is a general sentiment that "the existing system of intellectual property rights and patents does not accommodate non-western systems of knowledge ownership and access."[189] There is also a concern that the system treats "knowledge as a commodity owned by an individual or company with the goal of trade." Furthermore, there is concern among "scholars, activists, and indigenous peoples [] that the patent system has not been sensitive to the dignity, rights and worldviews of indigenous and traditional people."[190]

Western intellectual property protections have been criticized because developing countries must pay a high price for patented products that are reintroduced into their countries while simultaneously being unable to use the "intellectual property framework to protect against the piracy of their own indigenous and local resources and knowledge."[191] Patents are accused of reflecting "the arrogance of Western civilization."[192] Another complaint is that the "creativity, ingenuity and invention which an efficient patent system should nurture and encourage is being undermined by patents that are creating patent thickets so dense that they are adding costs to medical and scientific research and, in some instances, hindering it all together."[193]

In 2000, in response to such concerns and in accordance with the CBD Treaty, the African Union formally endorsed legislation that sought to protect biological resources "including agricultural genetic resources by requiring, among other things, that 'any access to any biological resources . . . shall be subject to application' and refused to recognize any patent for life forms of biological processes."[194] This legislation, known as the Law on the Rights of Local Communities, Farmers, Breeders and Access, attempts to

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[186] U.S. Patent '809.

[187] Jacqueline Wright Bonilla, Guest Post: What Ultimately Matters In Deciding the "Gene Patenting" Issue, PATENTLYO, http://www.patentlyo.com/patent/2010/11/guest-post-what-ultimately-matters-in-deciding-the-genepatentingissue.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+typepad%2FANlN+%28Dennis+Crouch%27s+Patently-O%29 (last visited Jan. 17, 2011).

[188] Science in Africa, Focus on Biopiracy in Africa (Sep. 2002), http://www.scienceinafrica.co.za/2002/september/biopiracy.htm.

[189] *Id.*

[190] IKECHI MGBEOJI, GLOBAL BIOPIRACY 121 (2006).

[191] Lara Ewins *as quoted in* IKECHI MGBEOJI, GLOBAL BIOPIRACY 150 (2006).

[192] VANDANA SHIVA, PROTECT OR PLUNDER? 7 (2001).

[193] Luigi Palombi, *The Genetic Sequence Right: A Sui Generis Alternative to the Patenting of Biological Materials*, *in* PATENTING LIVES 75, 90−91 (Johanna Gibson ed., 2008).

[194] AU Model Law on Rights of Local Communities, Farmers, Breeders and Access, http://www.farmersrights.org/database/african_union.html (last visited Jan. 17, 2011); *Regional or National Measures*, Convention on Biological Diversity, http://www.cbd.int/abs/measures/group.shtml?code=afr-au (last visited Jan. 17, 2011).

"provide[] a framework for the recognition of the innovative and creative efforts of African societies." [195]

The law still exists as a model law, although it has not been formally adopted.[196] This type of model law is unlikely to be adopted in African countries, such as Tanzania, because they are members of the World Trade Organization[197] and, therefore, must adhere to minimum intellectual property standards under TRIPS.[198]

Still, there is an ongoing concern that patents that claim living organisms and genes, such as the SbMATE patent, are patents for discoveries of nature, and as such should not be patentable.[199] It is argued that the TRIPS requirement of a minimum, uniformly applicable intellectual property standard, "is a reflection of the trends in economic globalization, which promotes a private profit oriented approach within an economic and proprietary framework" that will result in "dire consequences for countries in the South."[200] Additionally, critics argue that the TRIPS requirement "of patenting of life forms and biodiversity will erode the sovereign power of [] Third World [countries]", such as Tanzania, "to their resources and will generate ethical problems to the patenting of life." [201]

III. THE "INTERNATIONAL SEED TREATY"

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA),[202] popularly known as the International Seed Treaty, and hereinafter referred to as such, went into force in June of 2004.[203] Its aims include:

> [R]ecognizing the enormous contributions of farmers to the diversity of crops that feed the world; establishing a global system to provide farmers,

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[195] Adejoke Oyewunmi, *The Rights of Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, *in* PATENTING LIVES 53, 70 (Johanna Gibson ed., 2008).

[196] AU Model Law on Rights of Local Communities, Farmers, Breeders and Access, http://www.farmersrights.org/database/african_union.html (last visited Jan. 17, 2011); http://www.cbd.int/abs/measures/group.shtml?code=afr-au; Adejoke Oyewunmi, *The Rights of Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, *in* PATENTING LIVES 53, 70 (Johanna Gibson ed., 2008).

[197] World Trade Organization, Members and Observers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Jan. 17, 2011).

[198] World Trade Organization, Frequently Asked Questions About TRIPS, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Jan. 17, 2011).

[199] IKECHI MGBEOJI, GLOBAL BIOPIRACY 301 (2006); VANDANA SHIVA, PROTECT OR PLUNDER? 8 (2001) (discussing concerns about the patenting of animals and cells).

[200] Adejoke Oyewunmi, *The Rights of Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, *in* PATENTING LIVES 53, 57 (Johanna Gibson ed., 2008). *See also* Feifei Jiang, *The Problem with Patents: Traditional Knowledge and International IP Law*, Harvard International Review, Fall 2008, http://www.entrepreneur.com/tradejournals/article/191331092.html (arguing that TRIPS has protected "large pharmaceutical countries to the detriment of developing nations").

[201] VANDANA SHIVA, PROTECT OR PLUNDER? 7 (2001).

[202] International Treaty on Plant Genetic Resources for Food and Agriculture, June 24, 2004, http://www.planttreaty.org/texts_en.htm.

[203] Food and Agricultural Organization, Fact Sheet No.8, History of the Treaty, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs08_en.pdf (last visited Jan. 17, 2011).

> plant breeders and scientists with access to plant genetic materials; [and] ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.[204]

The International Seed Treaty was fostered by the Food and Agricultural Organization (FAO) of the United Nations, and the Treaty remains under its control.[205] The FAO encouraged the Treaty because of "unease about intellectual property regimes that reward formal breeders while ignoring the contributions . . . of farmers to the development and conservation of the very plant genetic sources on which breeders depend."[206] The FAO maintains that genetic resources have a lot of value and that in the last thirty years more than three-quarters of increased crop productivity is the result of breeding.[207]

The Treaty provides "a strong and elaborate shape to the concept of farmers' rights." Furthermore, the Treaty is consistent with the theory that "the ownership approach is simply contrary to communities' traditional ways of life, which promote the common ownership of their [traditional knowledge] associated with their seeds . . . ."[208]

The Treaty sets up a Multilateral System from which resources can be obtained for use and conservation in research, breeding, and training.[209] If a commercial product is developed using resources from the multilateral system and may not be used without restriction by others for further research and breeding, the Treaty provides for payment of an equitable share of the resulting monetary benefits.[210] If a product is developed that others may use without restriction, payment is considered voluntary.[211]

Much of the Treaty is about the germoplasm collection of Consultative Group on International Agricultural Research (CGIAR)'s Future Harvest Centers. This germoplasm collection is thought to contain about 560,000 accessions of crop diversity and is considered invaluable because it contains diverse farmers' landraces[212] and local varieties, and they are held in trust for the international community.[213] The treaty calls upon International Agricultural Research Centers (IARCs) of CGIAR to "sign

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[204] International Treaty on Plant Genetic Resources for Food and Agriculture, June 24, 2004, http://www.planttreaty.org/texts_en.htm.

[205] Food and Agricultural Organization, Fact Sheet No.8, History of the Treaty, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs08_en.pdf (last visited Jan. 17, 2011).

[206] *Id.*

[207] Food and Agricultural Organization, Fact Sheet No.2, The Value of Plant Genetic Resources, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs02_en.pdf (last visited Jan. 17, 2011).

[208] MAHOP, *supra* note 53, at 41.

[209] Food and Agricultural Organization, Frequently Asked Questions, http://www.planttreaty.org /faq_en.htm (last visited Jan. 17, 2011).

[210] *Id.*

[211] *Id.*

[212] Landraces "refers to particular kinds of old seed strains and varieties that are farmer selected in areas where local subsistence agriculture has prevailed." Dave's Garden, Definition of Landraces (last visited Nov. 18, 2010), http://davesgarden.com/guides/terms/go/2247/. Landraces are considered "highly adapted to specific locales or groups." *Id.* Still, the exact definition of landraces is controversial and will mean different things to different people. A.C. Zeven, *Landraces: A Review of Definitions and Classifications*, 127 Eyphytica 129−34 (1998).

[213] Food and Agricultural Organization, Fact Sheet No.9, The Treaty and CGIAR, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs09_en.pdf (last visited Jan. 17, 2011).

agreements with the Governing Body with regard to such [] collections."[214] A large amount of this material and other regional collections are placed into the International Network.[215]

Sorghum is included under the list of Food Crops covered by the treaty.[216] It is listed as a food crop that falls under the Multilateral System, which "include[s] all plant genetic resources for food and agriculture . . . that are under the management and control of the Contracting Parties and in the public domain."[217] The Treaty further states that "Contracting Parties also agree to encourage natural and legal persons within their jurisdiction who hold plant genetic resources for food and agriculture listed in [the Treaty] to include such plant genetic resources . . . in the Multilateral System.[218]

The International Seed Treaty came into effect on June 29, 2004, and there are now 127 parties to the Treaty.[219] Of the countries involved in the SbMATE controversy, Brazil was the first to sign the Treaty on June 10, 2002 and further ratified it on May 22, 2006.[220] The United States of America was second to sign on November 1, 2002.[221] Tanzania did not accede to the International Seed Treaty until April 30, 2004.[222]

The International Seed Treaty has been criticized because it does not clarify what enforcement procedures will be used to ensure that farmers' rights will be respected[223] or even how benefits from the commercial use of the genetic materials will be shared.[224] The treaty itself advocates arbitration between contracting parties for the settlement of disputes.[225]

IV. ANALYSIS TO DETERMINE IF THE UNITED STATES DID VIOLATE THE INTERNATIONAL SEED TREATY

Defenders of Tanzania's right to the SbMATE patent contend that the patent and attempts to license the patent contradict the goals of the treaty.[226] Indeed one of the aims

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[214] The International Treaty on Plant Genetic Resources for Food and Agriculture art 15,

[215] Food and Agricultural Organization, Fact Sheet No.9, The Treaty and CGIAR, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs09_en.pdf (last visited Jan. 17, 2011).

[216] The International Treaty on Plant Genetic Resources for Food and Agriculture, Annex 1, Food Crops, Nov. 4, 2002.

[217] The International Treaty on Plant Genetic Resources for Food and Agriculture art 11.2, Nov. 4, 20002.

[218] The International Treaty on Plant Genetic Resources for Food and Agriculture art 11.3, Nov. 4, 2002.

[219] Food and Agricultural Organization, The International Treaty on Plant Genetic Resources for Food and Agriculture, Members, http://www.fao.org/Legal/treaties/033s-e.htm (last visited Jan. 17, 2011).

[220] *Id.*

[221] *Id.*

[222] Food and Agricultural Organization, List of Contracting Parties, The International Treaty on Plant Genetic Resources for Food and Agriculture, http://www.fao.org/Legal/treaties/033s-e.htm (last visited Jan. 17, 2011).

[223] KAMALESH ADHIKARI, SAWTEE, POLICY BRIEF NO. 18, FARMERS' RIGHTS, 5−6 (2009), http://www.iaahp.net/uploads/media/PB_FarmersRights_Tunisia_2009.pdf.

[224] 3D→THREE, BACKGROUNDER NO. 2 IN THE THREAD SERIES, SEEDS OF HUNGER: INTELLECTUAL PROPERTY RIGHTS ON SEEDS AND THE HUMAN RIGHTS RESPONSE 13 (May 2009).

[225] The International Treaty on Plant Genetic Resources for Food and Agriculture art 22, Nov. 4, 2002.

[226] Hammond, *supra* note 4, at 13.

of the treaty is stated to be "ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated."[227]

However, as has been noted by other authors, it is difficult to claim that the SbMATE patent directly violated the International Seed Treaty. The SC283 sorghum strain used in the invention of the SbMATE patent is available at a center, the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), under the label of Msumbiji or SB117.[228] This center supplies germoplasm under agreement with the FAO's International Seed Treaty,[229] so any material acquired through the center would be subject to the International Seed Treaty's rules. Therefore, if the researchers who invented the SbMATE patent innovation had used SC283 sorghum from the center, they would have broken the Treaty's requirement that "recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated."[230] The SbMATE patent would also have violated Article 12.3.d that "recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components . . . ."[231]

However, the ICRISAT center is unlikely to have been the source of the material used to obtain the SbMATE patent. Instead, Texas A & M is thought to have held samples of SC283 long before the International Seed Treaty was ratified, and there is no evidence that the Texas A & M sorghum line came from any Center subject to the International Seed Treaty.[232] Hence statements that "governments . . . ignore [the International Seed Treaty] provisions, pillag[e] the coffers of CGIAR and sell[] them to Dow Chemical and other wealthy country concerns" [233] are inaccurate and misleading exaggerations.

While the International Seed Treaty predates both the U.S. patent and the PCT application, neither falls under the authority of the International Seed Treaty, for neither encompasses material covered by the Treaty. However, it is worth noting that while the SbMATE patent and the PCT application may not directly violate the Treaty, they do appear to create the type of problem that the International Seed Treaty was designed to address.

As earlier noted, the FAO encouraged the Treaty because of "unease about intellectual property regimes that reward formal breeders while ignoring the contributions . . . of farmers to the development and conservation of the very plant genetic sources on

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[227] The International Treaty on Plant Genetic Resources for Food and Agriculture, Texts of the Treaty, http://www.planttreaty.org/texts_en.htm (last visited Jan. 17, 2011).

[228] International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), Sorghum Germoplasm Collection, http://www.icrisat.org/what-we-do/crops/sorghum/Project1/pfirst.asp (last visited Nov. 13, 2010) (listing Msumbiji in the germoplasm collection).

[229] Genebank Activities, Access to Germoplasm, International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), http://www.icrisat.org/gene-bank-activities.htm (last visited Nov. 13, 2010).

[230] The International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 4, 2002.

[231] The International Treaty on Plant Genetic Resources for Food and Agriculture art 12.3.d, Nov. 4, 2002.

[232] Gavin Lingiah, *Genetically Modified Aluminum Tolerant Sorghum: A Case of Study of Alleged "Biopiracy": A Briefing Paper for NGOs* (July 2010) (unpublished Briefing Paper) 10−11, http://www.lingiah.com/SbMATE.pdf.

[233] Hammond, *supra* note 4, at 12.

which breeders depend."[234] While statements such as, "permitting the SbMATE patent to stand and for the private sector to profit from it, would signal a new open hunting season on privatization of the vast collection of farmers' varieties of food crops held by the CGIAR" are inaccurate, they do demonstrate how farmers in developing countries feel misled and unprotected by the Treaty.

There is a sentiment that "the genius of African farms is locked up in the vaults of the CGIAR,"[235] and that while the International Seed Treaty may not protect the plants used by Tanzanian farmers from being used to make the SbMATE patent, it should. At its center, biopiracy "encapsulates a strong moral and ethical dimension, which is entrenched on the demise of cultural linkages between communities and their assets, from which communities have contributed in nurturing and sustaining their assets."[236] Therefore, even if the SbMATE patent is proven not to violate the International Seed Treaty, concerns about the SbMATE patent are likely to continue.

V. CONCLUSIONS

A. Outlook

Ethical concerns about patents, as well as concerns about the threat of patents to biodiversity,[237] are likely to continue in spite of the International Seed Treaty. Similar to the plant lines used in the SbMATE patent, any plant lines that have already been acquired will not be covered under the International Seed Treaty.[238] Therefore, it is likely that there are other germoplasms that are listed among the 560,000 accessions of crop diversity available in CGIAR[239] that were also acquired outside of the CGIAR regime and may be patented despite the International Seed Treaty.

In spite of these problems, the International Seed Treaty has been credited with "providing access to, as well as the conservation and sustainable use of, plant genetic resources on the one hand and the fair and equitable sharing of benefits derived from their use on the other."[240] Presumably the Treaty will become more important over time, as plants subject to the Treaty are used to develop further innovations in agriculture and medicine.

In the meantime, there are other proposed improvements to intellectual property systems intended to provide additional protection for developing countries' genetic resources.[241] For example, there are suggestions for developing more *sui generis* systems

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[234] Food and Agricultural Organization, Fact Sheet No.8, History of the Treaty, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs08_en.pdf (last visited Jan. 17, 2011).

[235] Hammond, *supra* note 4, at 15.

[236] MAHOP, *supra* note 53, at 20.

[237] VANDANA SHIVA, PROTECT OR PLUNDER? 42 (2001).

[238] International Treaty on Plant Genetic Resources for Food and Agriculture, June 24, 2004, http://www.planttreaty.org/texts_en.htm.

[239] Food and Agricultural Organization, Fact Sheet No.9, The Treaty and CIGAR, ftp://ftp.fao.org/ag/agp/planttreaty/factsheets/fs09_en.pdf (last visited Jan. 17, 2011).

[240] Adejoke Oyewunmi, *The Rights of Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, *in* PATENTING LIVES 53, 67 (Johanna Gibson ed., 2008).

[241] Santiago P. Soplin & Manuel Ruiz Muller, *The Development of an International Regime on Access to Genetic Resources and Fair and Equitable Benefit Sharing in the Context of New Technological*

of intellectual property, which are thought to be a more "fair" way to protect genetic sequence rights.[242] Another proposed improvement is having more developing countries adopt the Indian Traditional Knowledge Digital Library model, which lists online the known uses of indigenous plants by developing countries, to prevent the issuance of new patents for previously known uses of plants.[243]

In addition to the protection provided by proposed improvements to intellectual property laws, it is hoped that over time intellectual property systems in both developing and developed countries will become more advanced so that they provide better and more clear protection of genetic resources in general.[244] It is also hoped that intellectual property systems will be more effective at protecting developing countries' rights, after there is an increased understanding in developing countries of how intellectual property systems work and more people are taught how to use such systems to their advantage.[245]

B. Lessons Learned

As the historical examples of "biopiracy" have shown, determinations of biopiracy are not easy, and intellectual property systems are generally not well suited for making such determinations. In fact, patent systems in particular are not usually designed to address problems of "theft" of indigenous resources, and systems that are designed to address such concerns are often distinct from intellectual property systems.[246] When alleged "biopiracy patents" occur, generally the problem is a failure to create

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Developments, Initiative PREVENTION OF BIOPIRACY, April 2009, http://www.biopirateria.org/documentos/Serie%20Iniciativa%2010.pdf (last visited Nov. 19, 2010).

[242] Luigi Palombi, *The Genetic Sequence Right: A Sui Generis Alternative to the Patenting of Biological Materials*, *in* PATENTING LIVES 75, 92 (Johanna Gibson ed., 2008).

[243] Council of Scientific & Industrial Research (CSIR), Traditional Knowledge Digital Library, Bio-piracy of Traditional Knowledge, http://www.tkdl.res.in/tkdl/langdefault/common/Biopiracy.asp?GL=Eng (last visited Jan. 17, 2011).

[244] *See, e.g.*, Feifei Jiang, *The Problem with Patents: Traditional Knowledge and International IP Law*, Harvard International Review (Fall 2008), http://www.entrepreneur.com/tradejournals/article/191331092.html.

[245] *Id.*

[246] Attempts to create patent systems that do not permit patenting of living things, such as the legislation by the African Union that prevented the patenting of any "life forms and biological processes," are not monitoring "theft" of indigenous resources. *See Regional or National Measures*, Convention on Biological Diversity, Part III, http://www.cbd.int/abs/measures/group.shtml?code=afr-au (last visited Jan. 17, 2011) (expressly excluding patents of life forms and biological processes). Instead, these systems make blanket restrictions concerning what is patentable and, therefore, exclude material from being used in patent systems. Some entities, such as the African Union, do choose to monitor theft by requiring application for the use of any biological resources and to preserve some form of intellectual property protection by "Community Intellectual Rights," "Farmers' Rights," and "Plant Breeders' Rights." *Id.* at Part III, IV, V, and VI. Still, the African Union legislation is only a model law, and has not been enacted. Adejoke Oyewunmi, *The Rights of Development, African Countries and the Patenting of Living Organisms: A Human Rights Dilemma*, *in* PATENTING LIVES 53, 70 (Johanna Gibson ed., 2008). Attempts to regulate the use of indigenous resources without directly interfering with intellectual property systems, such as the Indian government's database of indigenous knowledge, appear more likely to be successful because they are less likely to interfere with TRIPS legislation. *See* Council of Scientific & Industrial Research (CSIR), Traditional Knowledge Digital Library, About TKL http://www.tkdl.res.in

protections against the taking of indigenous material, the failure to adequately publicize traditional knowledge,[247] or the failure to properly reward cultures for the use of their indigenous material. The problem is usually not that an intellectual property system granted a patent *per se*. For example, while the United States patent system may be criticized for allowing patents on inventions that are known, but not described in published material in foreign countries, generally in objectionable cases such knowledge is either known in the United States, published somewhere or fails to meet the non-obvious requirement.[248] Therefore, most biopiracy analysis should be determined without implicating intellectual property systems, particularly patent systems, and should instead focus primarily on the original "taking" and use of indigenous material.

For example, in the case of the possible biopiracy of Brazilian natural rubber, no intellectual property rights were involved, let alone patent rights.[249] Still, many authors have argued that the rubber was "biopirated." In the case of the Enola beans, a patent was issued in spite of biopiracy concerns, although it was eventually invalidated[250] because the beans were considered obvious; intellectual property law does not reward inventions that are simply "takings."[251] Finally, in the case of the rosy periwinkle the "invention" was not taken directly from an indigenous country and was in fact novel, so the patent should be valid.[252] Although the SbMATE patent involves a more obvious "taking" from an indigenous country than the rosy periwinkle did, the "invention" is also treated as a "novel" invention, and as such is considered patentable.

While there are increasingly greater protections for developing countries' resources, disagreements similar to the SbMATE controversy will continue. Intellectual property law, particularly in the United States, has accepted genetically modified plants as novel and patentable inventions.[253] While genetically modified plants may use traits from other plants, patents are granted to incentivize the work and skill that is required to create genetically modified plants and to incentivize the release of information to the public about how to create the genetically modified plant.[254] Researchers already have

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/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng (last visited Jan. 17, 2011) (the Indian government' database of indigenous knowledge, which describes its goal of preventing the patenting of indigenous knowledge).

[247] This statement presumes a burden exists for publicizing traditional knowledge, which is debatable. However, it should also be noted that when additional evidence of traditional knowledge has been brought before the USPTO in controversies such as the Basmati and Enola Bean patent controversies, patent claims thought to encompass traditional knowledge have been withdrawn and rejected, albeit slowly. *See* Sumathi Subbiah, *Reaping What They Sow: The Basmati Rice Controversy and Strategies for Protecting Traditional Knowledge*, 27 B.C. INT'L & COMP. L. REV. 529, 549–555 (2004); Lorna Dwyer, *Biopiracy, Trade, and Sustainable Development*, 19 COLO. J. INT'L ENVTL. L. & POL'Y 219, 221 (2008).

[248] An example is the Enola bean patent, which was defended as valid because the invention was not published or known in this country. In spite of this defense, the patent was held invalid for failing to be non-obvious.

[249] Tustin, *supra* note 62, at 133.

[250] ETC Group, Hollow Victory: Enola Bean Patent Smashed At Last (Maybe) (April 29, 2008), http://www.etcgroup.org/en/node/683.

[251] *Id.*

[252] *Id.*

[253] Colorado State University, *Transgenic Crops: Introduction and Resource Guide,* http://cls.casa.colostate.edu/TransgenicCrops/patent.html (last visited Jan. 17, 2011).

[254] *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 118-20 (4th ed. 2007) (discussing plant patents).

strains of many plants from around the world and will undoubtedly use these plants to create genetically modified plants. Countries such as the United States will continue to grant patents on these genetically modified plants as long as such patents conform to patent laws.

International intellectual property systems have largely followed the U.S. example that living organisms are patentable.[255] Like all other countries, developing countries are required to adopt WIPO intellectual property protection requirements if they wish to join the WTO.[256] For better or worse, this mandate limits how developing countries may approach intellectual property.

While patent laws may change so that patents can no longer be granted for genes and for some types of plants, patents that cover genetically modified plants, such as the SbMATE patent, are likely to continue. There are undoubtedly critics who believe that plants should never be patentable, critics who believe that intellectual property laws should not incentivize the creation of genetically modified plants, and critics who believe that patents should never be obtained on inventions that use material from a foreign country without the foreign country's permission. However, most patent laws are created to incentivize broad innovation and are not designed to meet these particular objectives.

Furthermore, the International Seed Treaty was not designed to completely address any of these concerns. The Treaty was never designed to encompass or address all past takings, and it is not clear where in history "the biopiracy clock" should start. Since plants such as the rosy periwinkle now exist throughout the globe,[257] tracing their "theft" is impossible. Indeed, it is almost equally impossible to determine when all the strains of plants like SC283 sorghum were taken from their indigenous countries. Moreover, any intellectual property system that does address these concerns will appear radically different from the system currently in place.

Under current intellectual property law, the SbMATE patent represents American ingenuity, and not the "looting" of a Tanzanian resource. While the use of the SC283 sorghum line must appear to some Tanzanians much like the theft of the Elgin marbles from Greece, there is no complete system in place to compensate developing countries for any use of their indigenous plants in the creation of new patentable inventions. The International Seed Treaty attempts to remedy these problems in the future and reward those farmer cultures that developed useful plants like SC283 sorghum. It does not seek to correct all past "takings." Therefore, the International Seed Treaty does not address potential problems caused by the SbMATE patent. In addition, for the foreseeable future patents accused of being "biopiracy patents," such as the SbMATE patent, are likely to remain valid.

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[255] History of a Gene Patent: Tracing the Development and Application of Commercial BRACA Testing, 10 Health Law J. 125, University of Cambridge (2002), http://www.ncbi.nlm.nih.gov/pubmed/14748275.

[256] BiOS, Can IP Rights Protect Plants?, http://www.patentlens.net/daisy/bios/1234#plant_patents (last visited Jan. 17, 2011).

[257] BROWN, *supra* note 74, at 135−38.