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INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY: THE INDUSTRIALIZATION OF NATURAL RESOURCES AND TRADITIONAL KNOWLEDGE

MARK RITCHIE,*
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Intellectual property rights ("IPRs") entitle the inventor or the corporation which files a claim on the inventor's behalf, the exclusive right to make, use, and sell a new product or process technology, usually for a period of seventeen to twenty years. Generally, IPRs take the form of patents, trademarks or copyrights and traditionally have fallen under the domain of national law. Individual countries throughout the world have adopted different IPR laws, in an attempt to balance the interests of industry's desire to capitalize on its investments in technological development with society's rights to benefit from the knowledge and the resources of its country. Under the new rules of the Uruguay Round of Gen-

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1 See 35 U.S.C. § 154(a)(2) (1994) (authorizing "issue of patent" granting 20 year monopoly to patent holder from date on which application for patent was filed in United States); see also Frank Emmert, Intellectual Property in the Uruguay Round: Negotiating Strategies of the Western Industrialized Countries, 11 Mich. J. Int'l L. 1317, 1364 (1990) (stating that patents generally are protected for 15-20 years depending on national laws).

eral Agreement on Tariffs and Trade ("GATT"), all member countries must conform their national IPR laws with certain provisions of the GATT agreement on Trade-Related Intellectual Property Rights ("TRIPs"). The GATT's TRIPs provisions will undoubtedly alter the manner in which plants, animals, and other biological resources are used for agricultural and pharmaceutical purposes. The TRIPs Agreement embraces an industrial model whereby the products of scientific research become the private property of its corporate sponsors. The new rules developed during the Uruguay Round are in conflict with many existing national laws and the traditions of many agricultural and indigenous communities, where knowledge of the nutritional and medicinal uses of plants and the results of plant breeding are shared as a community resource.

Part I of this Article will discuss how the TRIPs Agreement threatens national sovereignty, Third World development, and human health. Part II will examine two alternative legal regimes

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5 See Shayana Kadidal, Note, Plants, Poverty, and Pharmaceutical Patents, 103 YALE L.J. 223, 224-25 (1993) (discussing general impact of GATT and TRIPs on use of indigenous resources); see also Yano, supra note 2, at 476-78 (discussing general shortcomings of Convention of Biological Diversity).

6 See TRIPs, supra note 4, pmbl. The TRIPs agreement recognizes that intellectual property rights are private rights. Id.; see also Vandana Shiva, BIODIVERSITY and INTELLECTUAL PROPERTY RIGHTS, THE CASE AGAINST FREE TRADE 108, 115 (1993). The author, an Indian scholar, has noted that this wonderfully presumptuous TRIPs clause "excludes all kinds of knowledge, ideas, and innovations that take place in the intellectual commons—such as in villages among farmers, in forests among tribes, and even in universities among scientists." Id. "TRIPs is, therefore, a mechanism for the privatization of the intellectual commons, and a de-intellectualization of civil society, so that the mind becomes a corporate monopoly." Id.

7 See 35 U.S.C. § 101 (1994) (allowing patent holder to obtain patent by fulfilling certain requirements); see also Edgar, supra note 2, at 78-79 (noting that many Third World nations are unhappy with intellectual property harmonization provision in GATT agreement).

8 See Kadidal, supra note 5, at 224 (recognizing that benefits of plant breeding are shared by members of community); see also Yano, supra note 2, at 448-49 (same).
for managing biological resources and their possible conflict with the TRIPs Agreement. The two regimes, the Convention on Biological Diversity and the United Nations' Food and Agriculture Organization's "International Undertaking on Plant Genetic Resources," both recognize a less exclusively proprietary approach to the ownership and use of biological resources. In the coming decades, such conflicts will most likely be resolved through processes of geopolitical bargaining and growing civic participation in the construction of new international legal regimes.

I. HOW THE TRIPs AGREEMENT THREATENS THE PUBLIC INTEREST

A. Overruling national sovereignty

The GATT-TRIPs rules prohibit member countries from discriminating as to the "place of invention" or as to the "field of technology" when granting patents. These criteria limit a member country's future use of IPRs as tools for development. The Agreement requires member governments to protect "plant varieties either by patents or by an effective sui generis system or by any combination thereof." These provisions were so controversial during the Uruguay Round negotiations that the final agreement states that such provisions "be reviewed four years after the date of entry into force." Although the TRIPs Agreement provides a five to ten year grace period for countries in development, this may not be sufficient time to enable the creation of proper domestic development strategies.

For example, some countries have allowed patents on processes but not products, ensuring that domestic firms can develop products of social value, such as medicines and seeds through a process

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11 See Kadidal, supra note 5, at 231-32 (explaining methods of ownership of biological resources); Yano, supra note 2, at 446-47 (describing Convention on Biological Diversity as agreement among several states to work towards preserving biological diversity).
12 See TRIPs, supra note 4, at art. 27(1).
13 Id. art. 27(3)(b).
14 Id. (indicating that such provisions are subject to review in year 1999).
15 Id. arts. 65, 66.
16 See Carolyn S. Corn, Note, Pharmaceutical Patents in Brazil: Is Compulsory Licensing the Solution?, 9 B.U. Int'l L.J. 71, 77-78 (1991) (noting that many Latin American Coun-
of reverse engineering. While these firms may not copy the formulas of patented products, they may create their own formulas which produce identical results. Many countries also use “compulsory licensing” laws to ensure that companies do not withhold useful products from the public.

India, Argentina, and Brazil are examples of countries where the “compulsory licensing” policies have resulted in an improvement in public health. Thus, strong national opposition to the TRIPs rules has emerged in these countries. Historically, India has denied patents completely in the fields of pharmaceutical and agricultural products, on grounds that these products are essential to public welfare. Recently, the Indian Parliament refused to pass legislation to bring its national IPR laws into conformity with TRIPs. Argentina, on the other hand, has used its IPR laws to develop a strong pharmaceutical sector which has contributed extensively to its national economy and, thus, has developed as a powerful competitor in the global marketplace. Brazil is seeking to mirror Argentina's success with its IPR laws. In both Argentina and Brazil, their Congresses also have fought against

tries refuse granting patents for pharmaceutical products, although such countries usually grant process patents for pharmaceuticals).

17 Id. at 77 n.50.

18 See id. at 88-89 nn.158-60 (recognizing that Canada has had compulsory licensing of patents since 1923); see also New Study Underscores Need for Maintaining Strong Intellectual Property Protection Under GATT; Report Concludes that Proposed Special Exceptions for Generic Drug Industry Would Put U.S. Firms at Risk, Bus. WIRE, Oct. 23, 1995 [hereinafter New Study] (noting that Thailand, India, and Singapore force innovator companies to provide compulsory licenses for patented products to competitors if government deems that result is in best interest of consumers).

19 See Corn, supra note 16, at 81-85 (explaining opposition to TRIPs); see also Alan Guterman, International Intellectual Property: A Summary of Recent Developments and Issues for the Coming Decade, 8 SANTA CLARA COMP. & HIGH TECH. L.J. 335, 343 (1992) (providing Argentina, Brazil & India as examples of countries that have inadequate protection for pharmaceutical).

20 See Guterman, supra note 19, at 402 (discussing India's lack of patent protection for food, medicine and drugs).

21 See Corn, supra note 16, at 81-82 (noting that Brazil also refused to pass legislation to have laws conform with TRIPs); see also Sanjoy Hazarika, India Presses U.S. to Pass Biotic Treaty, N.Y. TIMES, Apr. 23, 1995, at A13 (noting India's resistance to clause in GATT relating to intellectual property rights).

22 See David Pilling, World Trade News: Argentines Spit Out Bitter Patents Pill - 'Pirates' Charter' Versus 'Abusive Prices', FIN. TIMES, June 14, 1995, at 8 (noting feeling of United States companies that Argentina should be in higher category of development).

23 See Corn, supra note 16, at 77-78. Current laws in Brazil would prevent such patents from being inadequately exploited by permitting the granting of a compulsory license to a third party whenever the patented invention is not being exploited in order to meet the demands of market. Id.
altering the national IPR laws to conform with the TRIPs Agreement.\footnote{See Argentine Patent Measure Heads for Veto by Menem, J. Com., Apr. 12, 1995, at A3 (reporting President Carlos Menem of Argentina will veto offensive parts of patent law regarding pharmaceutical); see also James Bruce, Vote on Patent Law Further Delayed in Brazil, J. Com., Apr. 28, 1995, at A3 (reporting on another postponement in vote on Brazilian patent law, preventing intellectual property protection). See generally Corn, supra note 16, at 80-85 (describing Brazil as global leader in opposition of patent protection).

\footnote{See, e.g., Kadidal, supra note 5, at 239 (explaining invention process in pharmaceutical industry); see Edgar, supra note 2, at 84-86 nn.59-61 (citing United States cases with different results, including Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) and Le Roy v. Tatham, 55 U.S. (14 How.) 156 (1852)).

\footnote{See Edgar, supra note 2, at 87-92 (discussing controversial United States patent of Indian tree).}

\footnote{Marcy Burstiner, A Seedy Business, MULTINAT'L MONITOR, Mar. 1988.}}

B. Patenting Plant Varieties

A patent enables a company or an inventor to monopolize the market for new plant varieties for the term of the patent, generally a period of seventeen to twenty years. In developing new products, the first step consists of removing plant samples from the field and transporting them to the laboratory. Next, scientists move a single gene from one spot to another within a cell. Irrespective of whether an actual variation results in the next generation, a "plant variety" is created which is deemed sufficiently "new" to qualify as a patentable invention.\footnote{Asgrow Seed Co. v. Winterboer, 115 S. Ct. 788, 791 (1995); see Neil Hamilton, Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources, 28 Tulsa L.J. 587, 632-41 (1993) (discussing Asgrow Seed Co. v. Winterboer).}

While most genetic engineering experiments do not produce worthwhile results, in a few cases, the variations have generated "desirable" traits which are able to be reproduced and marketed.\footnote{See Marcy Burstiner, A Seedy Business, MULTINAT'L MONITOR, Mar. 1988.} Monsanto, for example, expects to generate an additional $150 million annually by patenting and marketing just one of its new products: a variety of soybean designed to withstand intensive applications of the herbicide "Round-Up," also marketed by Monsanto.\footnote{See Edgar, supra note 2, at 87-92 (discussing controversial United States patent of Indian tree).}

Patent-holding companies will most likely use the GATT-TRIPs rules to ensure that their monopoly rights are upheld. In the United States, the Asgrow Seed Company, a subsidiary of the Upjohn Company, sued two Iowa farmers, Denny and Becky Winterboer, for harvesting and selling a variety of seed which had sexually reproduced in their field.\footnote{Asgrow Seed Co. v. Winterboer, 115 S. Ct. 788, 791 (1995); see Neil Hamilton, Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources, 28 Tulsa L.J. 587, 632-41 (1993) (discussing Asgrow Seed Co. v. Winterboer).} Initially, the district court
granted summary judgment for the seed company. 29 That decision was reversed by the Court of Appeals for the Federal Circuit. 30 Asgrow then appealed to the United States Supreme Court which, in January, 1995, issued an 8-1 ruling against the farmers. 31 Justice Stevens, the only dissenter, agreed with the earlier Court of Appeals ruling which allowed farmers to sell up to half of their crops for seed, even if the seeds were legally protected. 32

Competition to dominate the vast field of genetically engineered plant varieties has led to claims for “sweeping patents.” 33 For example, Agracetus, a subsidiary of W.R. Grace, has sought exclusive rights to all genetically engineered varieties of cotton and soybeans. 34 The patents originally were granted by the United States Patents and Trademarks Office (PTO) in 1992 35 and by the European Patent Convention in 1994. 36 Since then, however, the PTO has tentatively reversed the sweeping cotton patent after a challenge by the United States Department of Agriculture and an anonymous party. 37 The European patent also has been challenged on grounds that genetically engineered plants are neither

30 Asgrow Seed Co. v. Winterboer, 982 F.2d 486, 492 (Fed. Cir. 1992) (finding no crop limitation on amount of seed saved by farmer), aff’d, 115 S. Ct. 788 (1995). See Brief Amici Curiae of Rural Advancement Foundation International, Friends of the Earth, Seed Savers Exchange, et. al., October 1994 (asserting that Federal Circuit was correct not to limiting farmer’s rights to sell seeds to other farmers).
31 Winterboer, 115 S. Ct. at 795. The Court stated, “[w]e hold that a farmer . . . may sell for reproductive purposes only such seed as he has saved for the purpose or replanting his own acreage.” Id. at 796.
32 Id. at 797 (Stevens, J., Dissenting) (noting owner of personal property, even if patented, is free to dispose of property); see also Winterboer, 982 F.2d at 491-92 (noting § 2543 does not limit amount of seed farmer can save or sell).
33 See Edgar, supra note 2, at 77-78 (discussing effect of genetically engineered plants on patent system); Steve Lustgarden, Patently out of Control: Biotechnology, VEGETARIAN TIMES, Dec. 1, 1994; Rogers Worthington, Love Polyester? Here’s a Crop You Can Cotton To, CHI. TRIBUNE, Dec. 19, 1994.
34 See Neil D. Hamilton, Why Own the Farm if You Can Own the Farmer (and the Crop?)?: Contract Production and Intellectual Property Protection of Grain Crops, 73 NEB. L. REV. 48, 91 (1994) (describing Agracetus’ attempt to obtain exclusive rights to certain genetically engineered plants); Lustgarden, supra note 33; Worthington, supra note 33.
36 See “Species” Patent, supra note 35 at 1.
37 See Lustgarden, supra note 33; Worthington, supra note 33.
“novel” inventions nor “non-obvious” innovations, according to the criteria of European patent law.\textsuperscript{38}

C. Hindering Third World Development

In addition to threatening national sovereignty and the monopolization of plants and seeds, the GATT-TRIPs Agreement will hinder the Third World from attaining self-sufficiency in pharmaceutical production. Third World drug manufacturers will be discouraged from entering production, or be forced out of business altogether by pharmaceutical transnational corporations (“TNCs”). As legal protection has shifted in favor of TNCs, the importance of local production and development of home-based expertise and capital has been ignored. In order to debate candidly the desirability of international patent protection, both sides must acknowledge that intellectual property pirating fuels development.\textsuperscript{39} The TRIPs agreement, however, merely seeks to broaden the scope of anti-piracy enforcement, thus strengthening the potent powers granted to TNCs in the Uruguay Round by shifting the burden of proof in patent disputes on Third World manufacturers. Certain articles in the TRIPs Agreement, such as Article 34,\textsuperscript{40} place Third World firms at great risk and disadvantage when faced with patent suits by well-financed TNCs because they do not have the resources to defend themselves.\textsuperscript{41} The accused manufac-


\textsuperscript{39} See Stephan Kirchanski, \textit{Protection of U.S. Patents in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand}, 16 \textit{Loy. L.A. Int'l \\& Comp. L.J.} 569, 577 (1994) (suggesting that equation is two sided—stimulation of local “private economy and erroneous losses to developed nations”); \textit{cf} Edgar, \textit{supra} note 2, at 92-93 n.133 (stating that “[h]istory shows that strong patent protection is the best way to encourage innovations and hold costs down”); Reichman, \textit{supra} note 2, at 175 (suggesting that intellectual property pirating opens markets to “second comers who provide cheaper and better products through imitation and incremental innovation”).

\textsuperscript{40} See TRIPs, \textit{supra} note 4, art. 34(1). Article 34 states “if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.” \textit{Id.}

\textsuperscript{41} Office of the United States Trade Representative (USTR), \textit{Statement as to How the Uruguay Round Series: The Interests of United States Commerce}, 1994 WL 761806 (G.A.T.T.), Sept. 27, 1994 (stating that TRIPs Agreement does more to protect and enforce rights of creators of intellectual property, using as example assurance that TRIPs agreement gives 20 year patent in pharmaceutical).
turer must demonstrate that it has not violated process patents held by TNC's.

The TRIPs Agreement provides patent protection for twenty years beginning on the date of filing, and subsequently allows an additional twenty years of patent protection to the manufacturing process if that process is new.42 Once a product patent has expired, other manufacturers are free to manufacture that product.43 If the manufacturing process is still under protection however, the new entrant needs to develop an alternative production process.44 The burden of proof is on the secondary manufacturer to demonstrate that its new process is in fact unique.45 Due to this heavy burden and the fear of legal action, small firms may not be willing to enter the market.46 Without competition, present monopolies represented by TNCs, will become more powerful in the Third World pharmaceutical trade.47 This lack of competition will increase prices and lower customer service.48 In order for Article 34 to be fair, the burden of proof should rest on the well-financed accuser and not the accused Third World manufacturer.

The present system of imposing the burden of proof on the accused will severely limit the capacity of the indigenous pharmaceutical industry to compete with TNCs. Since the pharmaceutical industry requires huge capital investments and expensive

42 See TRIPs, supra note 4, art. 33; see also 35 U.S.C. § 154(c) (1994) (indicating that United States implemented patents in accordance with terms of GATT).


44 See generally Huft, supra note 38, at 1706-20 (discussing joint inventionship and possible bars to patentability).

45 See id. at 1718-25 (discussing publication as bar to patentability and invalidating potential patents not meeting "novelty" requirement of patents).

46 See Julie Shiver, Rap Music to Medical Formulas. Little Seems Safe From Duplication, L.A. TIMES, Apr. 11, 1994, at A1 (observing that in 1988, Brazilian pirating of patents resulted in United States imposing massive tariffs amounting to $30 million on Brazilian pharmaceutical imports).

47 See Jenifer Sachs, Wall Street Financing Health Care Resolution, INVESTMENT DEALERS' DIG., Oct. 3, 1994, at 14 (indicating that United States pharmaceutical industry is $60 billion industry).

product promotions, indigenous industries are unable to compete and create a market share for themselves.\textsuperscript{49}

The Third World already has paid a great price to comply with United States patent protections. The following problems need to be addressed:

1. Non-use of a patent.

   In many cases, TNCs will apply for a patent in a particular country, but will not actually set up manufacturing facilities in the host country. This results in the drug, but not the production process, being imported to that country. Such non-use practice reflects a North/South imbalance apparent in the fact that over eighty percent of Third World patents in Third World countries are owned by foreigners, mainly TNCs. Furthermore, over ninety-five percent of these foreign-held patents are not utilized in these countries.\textsuperscript{50} This kind of patent protection blocks local competition.

   Imported patented products are generally more expensive and negatively impact the trade balance in a developing country.\textsuperscript{51} Article 27 of the TRIPs agreement, which mandates equal patent protection for imported and locally manufactured products, will further exacerbate this imbalance.\textsuperscript{52} Consequently, the world community should reevaluate Article 27 and encourage local production to improve the balance of trade of Third World countries. Lo-

\textsuperscript{49} See First Bite for BASF, BASFAG, MPI. CHEMIST, Dec. 1994, at 3 (noting pharmaceutical companies that lack dollars for research and development to compete in global market); see also Douglas Olsen, To be Competitive Follow These Four Steps, REED PUB. U.S.A. RES. & DEV., Feb. 1994, at 25 (noting that United States industry is facing intense, global competition); Drugs, WEI Panelists Debate Effects of Cost Containment on Drug Innovation, Daily Rep. for Executives (BNA), at A144 (July 29, 1994) (stating that returns for pharmaceutical is skewed with only one-third earning return above and beyond research and development costs, while return of majority of new drugs does not even carry costs); New Study, supra note 18 (indicating that United States pharmaceutical industry members invest on average 15 years and $359 million to bring medicine to market, and total pharmaceutical research and development investment in 1994 topped $13 billion, rating higher than any other United States industry).


\textsuperscript{52} TRIPs, supra note 4, art. 27(1). The language of the article states that, "... patent shall be available and patent rights enjoyable without discrimination ... whether products are imported or locally produced." Id. See generally Owen T. Adikibi, The Multinational Corporation and Monopoly of Patents in Nigeria, 16 WORLD DEV. 511, 511-26 (1988) (examining effect of foreign monopoly of patent grants in Nigeria and implications for technology development in that country).
cal production would also facilitate the transfer of technology—the basic premise for awarding patent protection—and would provide an economic boost for third world economies.

2. Licensing and Process Agreements.

When TNCs license their production processes to Third World manufacturers, they often prohibit their licensees from exporting products. Such export limitation agreements are not considered "barriers to trade" under GATT, although they do serve to restrict access to many markets. Moreover, efficient Third World manufacturers who improve products through creative innovation will never realize the profits of their labor. These producers usually are required to grant all patent rights back to the parent company to assure that the legal benefits remain with the First World corporate owners. Further, many process agreements ban the establishment of research and development facilities by the licensee, charge excessive royalties, or force the Third World firm to purchase inputs from the patent holder. Thus, these agreements hinder the development of indigenous industries, and transfer wealth out of Third World countries.

3. Transfer Pricing.

In order to maximize further profits and to avoid paying taxes to Third World governments, pharmaceutical TNCs will sell products, patented and otherwise, to their subsidiaries at prices that are anywhere from 87% to 2900% higher than those found in open markets. This allows subsidiaries to show a net loss on their accounts and evade taxes in host countries. At the same time, subsidiaries will purchase ingredients, such as sugar, from their parent company at excessive prices. This price manipulation has a negative impact on the balance of trade, increasing the trade deficit of developing Third World countries. Every patent creates a

53 See generally Adikibi, supra note 52, at 511-26 (discussing effect of foreign monopoly of patent grants in certain countries).
55 See generally Gary Gerreff, The Pharmaceutical Industry and Dependency in the Third World 193-98 (1983) (showing relative wholesale prices for various drugs in different countries based upon national law and policy, as indicators of state's capacity to influence economic development).
twenty-year monopoly. Abolishing patents' monopoly power would free indigenous firms to purchase products from open markets and relieve the pressures of price manipulation.

Without the patent protection of the TRIPs agreement, TNCs would be more willing to set up equitable joint ventures with indigenous firms. TNCs would gain access to new markets and local companies would receive more sophisticated technologies and products which might not otherwise be available.


Lastly, the GATT-TRIPs Agreement not only shields TNCs from competition by lower cost local industries but also turns the tables by helping biotechnology companies compete in the world marketplace against agricultural exports vital to many national economies. Biologically engineered synthetic substitutes for sugar, cocoa, and plant oils are already taking over large segments of the global markets for these commodities, upon which many impoverished African and Latin American nations depend.56

D. Harming health

GATT-TRIPs provisions also will permit pharmaceutical TNCs to create monopolies resulting in extremely high prices of medicines in Third World countries. Low-income consumers will have to pay higher prices for essential medicines. Many lifesaving medicines will simply be unavailable due to the problem of non-use of patents previously described in this Article.57

56 See Achim Seiler, Biotechnology and Third World Countries: Economic Interests, Technical Options and Socio-Economic Impact, PUGWASH MEETING NO. 208, July 23-29 1995, at 5 (noting that cell culture methods, enzyme techniques, genetic engineering, and other new technological research is aimed at developing bio-synthetic plant compounds for both food and non-food integrated industrial production systems as substitutes for agricultural exports important to developing countries' employment and balance of trade).

57 See TRIPs, supra note 4, art. 31 (a)-(b). In theory, article 31 of the TRIPs agreement allows a nation to deal with a worst case scenario of non-use: that a patent holder will not produce enough of a vital drug. Id. Article 31 allows for other use of the subject matter of a patent without the authorization of the right holder provided that such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder. Id. This requirement may be waived by a member in the case of a national emergency or other circumstances of extreme urgency. Id. However, the qualification that the right holder shall be paid adequate renumeration in the circumstances of each case, taking into account the economic value of the authorization, means that nations may have the will and the means, but not the funds to break a medical patent. Id. In addition, they cannot use article 31 to derogate from a patent they find untenable due to the high price of the patented product. Id. art. 31 (h).
Argentina is a powerful example of price impact. Nearly all pharmaceuticals marketed by Argentinean drug firms now are sold at prices ranging from fifteen to eighty percent lower than global corporation prices. Compared to fifteen years ago, the Argentinean industry has made tremendous progress. Through local market loyalty and efficient production, Argentinean firms now can provide low cost pharmaceuticals to the public. In addition, Argentina has developed a small export market for pharmaceuticals. The Argentinean pharmaceutical industry had created a strong presence by locally producing and marketing drugs to the public at prices much lower than those of the TNCs. Argentinean producers were able to accomplish this feat by defying and ignoring international patent systems created and promoted by European nations and the United States. This has allowed Argentineans to compete with transnational pharmaceutical firms, thus forcing the transnational corporations to provide their products at competitive prices. The following are some price differentials in pharmaceutical products between the Argentinean and US markets:

58 See Challu, supra note 51, at 107; see also Calum Simms, Argentine President Vetoes Patent Measure, N.Y. Times, Apr. 19, 1995, at A5 (discussing loss of $300 million per year from sale of pharmaceutical in Argentina by United States pharmaceutical industry).

59 See Daniel Chudnovsky, The Challenge by Domestic Enterprises to the Transnational Corporations Domination: A Case Study of the Argentine Pharmaceutical Industry, 7 World Dev. 45, 45-58 (1979) (noting that, given decrease in innovation of large transnational corporations operating in pharmaceutical field, domestic firms have been able to challenge domination of pharmaceutical industry by foreign enterprises).

60 See Kirchanski, supra, note 39, at 580 n.69. There is empirical evidence which supports the correlation between the internal level of creation of patentable inventions and the level of development in a country and the degree to which a country respects or violates intellectual property rights. Id. at 597. The economic development of an extremely underdeveloped country is indifferent to intellectual property protection. Id. at 605-06. More advanced countries become the greatest pirates of intellectual property because they can profit from the intellectual property but are not yet in a position to benefit from the protection of intellectual property. Id. at 596-97. Contra GATT Uruguay Round Trade Agreements: Before the Subcomm. on Trade of the House Ways & Means Comm., 103d Cong., 2d Sess. (1994) (statement of Gerald J. Mosshinghoff, President, Pharmaceutical Manuf. Ass'n). Mosshinghoff asserts that piracy by developing countries costs international pharmaceutical industry as much as $5 billion annually. Id.; Ruth L. Gana, U.S. Science Policy and the International Transfer of Technology, 3 J. Transnat'l & Pol'y. 205, 235 (1994). Gana notes that the traditional Western position is that the Third World benefits from infringing United States' intellectual property. Id.
<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>US Market (US$)</th>
<th>Argentinean Market (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Foreign or Licenses</td>
<td>Domestic Producers</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>106.82  14.20</td>
<td>13.15</td>
</tr>
<tr>
<td>Ketoconazole</td>
<td>240.05  36.10</td>
<td>26.65</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>84.23   21.95</td>
<td>11.76</td>
</tr>
</tbody>
</table>

India has had a similar experience. Using its compulsory licensing clause, India allowed the development of a national pharmaceutical industry. The indigenous industry has proved capable of producing many essential drugs for its people at affordable prices. Such successful practice, however, would no longer be possible under the Uruguay Round. In fact, the independence of the Indian pharmaceutical industry already has been seriously undermined through unilateral trade measures taken by the United States, largely provoked by the intervention of the United States pharmaceutical industry. As a result of these trade measures, India has changed its patent laws to conform with most United States demands. Consequently, Indian manufacturers

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61 See Challu, supra note 51, at 107.
63 See Guterman, supra note 62, at 126 (noting government intervention in pharmaceutical marketing designed to lower cost in developing countries).
65 See Omnibus Trade & Competition Act of 1988, 7 U.S.C. § 1691 (1988) (hereinafter Omnibus Trade Act). The Omnibus Trade Act's Super 301 provision, actually § 310 of Omnibus Trade Act, allows the United States Trade Representative to undertake trade investigations and identify nations that enact trade practices against the United States which are "unreasonable" or "unjustifiable." 19 U.S.C. § 2411 (1988). The identified countries are obliged to alter those practices or suffer a loss of trade with the United States. Id.
66 See Hazarika, supra note 21, at A13 ("India finally agreed to fall into line with American policy on the issue after opening its economy to foreign investment."); see also India to Accept Drug Patents, 8 J. PROPRIETARY RTS. 33 (1993) (discussing India's conformity with United States intellectual property laws); Rao in a Bind: India, ECONOMIST, Apr. 1, 1995, at 30 (discussing internal governmental tension concerning GATT plant patent provisions); Sandy Tolan, Against the Grain Multinational Corporations Peddling Patented Seeds and Chemical Pesticides are Poised to Revolutionize India's Ancient Agricultural System, L.A. TIMES, July 10, 1994, at 18 (reporting ramifications of India's conformity with GATT patent provisions). But see Trade-India: Government Gets Cold Feet on Patents Bill, INT'L PRESS SERVICE, Nov. 28, 1995 (suggesting potential delay in voting to conform India's patent laws with GATT requirements).
will no longer be able to provide affordable drugs to Indian consumers.

Compare the result of domestic patent laws through a price comparison between products available in the Indian and Pakistani markets:

<table>
<thead>
<tr>
<th>Drug</th>
<th>India (Indian Rs.)</th>
<th>Pakistan (Indian Rs.)</th>
<th>US (Indian Rs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin</td>
<td>51.00</td>
<td>234.63</td>
<td>305.21</td>
</tr>
<tr>
<td>Ketoconazole</td>
<td>43.00</td>
<td>221.96</td>
<td>673.67</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>29.30</td>
<td>260.40</td>
<td>744.65</td>
</tr>
</tbody>
</table>

In short, it is obvious that patents, in general, benefit the TNCs and stifle the growth of industry and health in Third World countries. This is particularly true in the pharmaceutical industry, where access to vital drugs is limited.

II. Alternative Regimes

A. Convention on Biological Diversity

In June 1992, more than 150 countries, with the United States as a notable exception, signed the United Nations Convention on Biological Diversity. The Convention stated their commitment to "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources." These goals are to be achieved by ensuring "appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding." The Convention's emphasis on IPRs has


69 Id. at 2, art. 1.
been placed in perspective, namely by ensuring "that such rights are supportive of and do not run counter to its objectives."70

The Clinton Administration met with biotechnology industry representatives71 before signing the Convention in June 1994. At that time, the Administration published an Interpretive Statement72 which redefined the IPR provisions of the Convention.73 In redefining the IPRs, the United States appears to demand that IPR protection under the Convention on Biological Diversity be consistent with the GATT.

The real world relationship between biodiversity and IPRs has resulted in a new "gold rush" known as bioprospecting. Seeking new plants to use for the creation of new products, ethnobotanists travel to indigenous communities, sometimes offering compensation in the form of gifts or shares in future royalties earned once a product is patented and marketed. Driven by possible future riches, these explorers inadvertently disrupt the indigenous communities.74 Once disrupted, it may be difficult or impossible for that human community to restore the traditional balance between itself and the ecosystem. In 1994, FAO Assistant Director-Gen-

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70 Id. at 39, art. 16(5) (summarizing article 16 of Convention which provides that participating countries are obligated to ensure swift access to new technologies relevant to conservation of biological diversity).

71 Id. at 36 (statement of Lisa Conte, Shaman Pharmaceutical) (stating that Shaman Pharmaceutical Company is not bank and that it could be as long as ten years before firm can reap rewards of new drug).

72 See Administrative Statement from the President of the United States transmitting the Convention on Biological Diversity, 103rd Congress, 1st Sess., Treaty Doc. 103-20, USGPO (1993). The President announced that the United States will sign Convention on Biological Diversity. Id.

73 Id. The President declared United States patent law provisions an adequate and effective protection of IPRs; the United States will not recognize patent laws which restrict patenting nor allow compulsory licensing arrangements. Id. The President also warned that the United States will "strongly resist any actions taken by Parties to the Convention that lead to inadequate levels of protection of intellectual property rights, and will continue to pursue a vigorous policy with respect to the adequate and effective protection of intellectual property rights in negotiations on bilateral and multilateral trade agreements." Id.; see Eduardo Lachica, GATT Negotiations Near Well-Balanced Accord on Intellectual Property, ASIAN WALL ST. J., Oct. 18, 1993, at 11. "The American pharmaceutical industry . . . wants to shorten the transition periods to be granted to developing countries. Under the current draft, . . . [even] the poorest [countries] . . . would have a grace period of 10 years." Id.

eral Obaidullah Khana referred to such bioprospecting as "biopiracy."  

The emphasis on finding and isolating plants with the most marketable traits has lead to the decline of other plant species, since only new techno-varieties are being cultivated. In the United States alone, a survey of seed banks showed that some varieties of non-commercial crops such as chufas, martynia, and rampion have been lost entirely.  

The privatization of patented genetic resources accelerates the trend toward monocultural cropping. In India, for example, peasant producers now cultivate some 50,000 varieties of rice, which have developed through traditional farming practices over the millennia. Such astonishing variety arose from subtle differences in the soil and in the climatic conditions, occurring due to mutation, evolution, and the deliberate application of cultural preferences. The GATT-TRIPs rules, however, would prohibit these farmers from harvesting and reusing the seed of any rice variety which has been patented. Also, lack of access to seed stocks will cause the abandonment of India's biologically diverse agriculture, necessary to sustain healthy diversity in surrounding ecosystems.

A further possible problem is that an engineered organism may produce unanticipated harmful impacts on other species. For example, scientists at Oregon State University have engineered a variety of bacteria known to reside in the soil and contribute to

75 See FAO Official Blasts Western 'BioPiracy', REUTERS WORLD SERV., June 6, 1994. Various suggestions have been made as to what contractual and legislative safeguards may prevent such exploitation, and even turn bioprospecting into a source of needed resources on the national and local levels. Id.


78 See generally id. at 54-90 (1990). The authors describe the development of crop diversity through thousands of years of traditional agriculture. Id. The authors also explain the threats that the seed industry and genetic engineering pose to this diversity. Id.

79 See generally Steven Lohr, New Varieties of Hardy Rice Hold Promise, N.Y. TIMES, Aug. 14, 1984, at C1 (discussing process of developing varieties of rice and benefits derived from production).

80 See Hamilton, supra note 28, at 657 n.222 (citing United States Department of Agriculture report by R.D. Plowman, Administrator of Agricultural Research Service, discussing 140 important rice occasions showing all ancestry traces to 22 introductions in southern rice belt and 23 in western rice belt).
the decomposing of plant material. This enables the soil to efficiently convert agricultural wastes to ethanol fuel. Although the project was successful in meeting this goal, in the late stages of testing the scientists discovered that the new product also destroyed much of a beneficial fungus essential to the recycling of nitrogen through plant roots. This result could lead to decertification throughout the range of the product.

B. Food and Agriculture Organization’s International Undertaking on Plant Genetic Resources

During the 1970s and 1980s, developing nations expressed concern about the free flow of plant genetic resource materials, or germplasm, from the South to the North. The question was posed: why are patented seeds of southern origin bringing in tremendous profits to multinational seed companies without compensation for the developing world? In the culmination of the “Seed Wars” of the 1980s, Third World leaders managed to express their concerns in an international arena via the United Nations Food and Agriculture Organization (“FAO”). In 1983, the FAO established the Global System for the Conservation and Utilization of Plant Genetic Resources. This organization includes a legally non-binding set of guidelines called the “International Undertaking on Plant Genetic Resources” (“Undertaking”) and an inter-
governmental Commission on Plant Genetic Resources. The Commission was created to monitor the implementation of the Undertaking and more generally, to discuss the use, control, and conservation of plant genetic resources. Each country possesses one vote.

The purpose of the Undertaking is to "ensure that plant genetic resources of economic or social interest, particularly for agriculture, will be explored, preserved, evaluated, and made available for plant breeding and for scientific purposes." The underlying notion is based upon the common heritage principle, namely that "plant genetic resources are a heritage of mankind and consequently should be available without restriction." This principle is extended to include not only native plant materials, but also farmer-developed varieties and new products of biotechnology.

The guarantee of access without restriction has caused eight industrialized countries to register reservations; the United States and Canada still do not adhere to the Undertaking.

Two annexes to the Undertaking were adopted in 1989, and a third was adopted in 1991. A fourth annex presently is being negotiated. One annex addressing Farmers' Rights recognizes the right of farmers to be compensated for developing and conserving plant genetic resources. For instance, it is well known that over generations, Andean potato farmers developed frost-resistant


88 See Report of the Conference of the FAO, supra note 10, para. 385. The FAO's new interpretation of the Undertaking provides that the objective of the agreed interpretation is to achieve greater acceptance of the Undertaking and to strengthen the conservation, use, and availability of germplasm. Id. Such efforts will be accomplished by recognizing and legitimizing the rights to be compensated of germplasm donors and donors of funds and technology through the parallel recognition of plant breeders' rights and farmers' rights. Id. The FAO is using the agreed interpretation to lay the base for an equitable and solid global system. Id.

89 Id. art. 1, para. 385.

90 Id. art. 2, para. 385; see Hamilton, supra note 28, at 601 (stating that Undertaking was left open to apply to all genetic stocks including "special generic stocks" which include specially bred proprietary lines of seed breeders).

91 Interpretation of the International Undertaking on Plant Genetic Resources, Food and Agriculture Organization of the United Nations, 25th Sess., U.N. Doc. C/89/24 (Nov. 11-30, 1989) [hereinafter Interpretation of International Undertaking]. The Conference recognizes certain farmers' rights, such as that plant genetic resources are a common heritage of mankind to be preserved and to be freely available for use. Id. Also, plant genetic resources are indispensable for the genetic improvement of cultivated plants and are in danger of erosion and loss, and there is a need to continue the conservation, development, and use of the plant genetic resources in all countries. Id.

92 See Margaret A. Boulware, An Overview of Intellectual Property, 16 HOUS. J. INT'L L. 441, 499 (1994) (stating that Andean group consists of Bolivia, Columbia, Ecuador, Peru,
varieties for growing in flat bottomlands where frost is common, and that Chiapan\textsuperscript{93} farmers have bred at least a dozen varieties of corn which were heavily utilized by local farmers. Farmers' Rights have emerged in part as a mechanism for equitably sharing the benefits of utilizing plant genetic resources acquired by seed breeders in the North with the people from whom the resources were obtained.\textsuperscript{94} Likewise, the rights of local communities have been acknowledged and are a major focus in the Convention on Biological Diversity, which emerged during the 1992 Earth Summit in Rio de Janeiro, extended to include indigenous communities.\textsuperscript{95} Despite such recognition in the Biodiversity Convention, the definition and implementation of Farmers' Rights is still a source of tension surrounding the use and control of plant genetic resources.\textsuperscript{96}

The Plant Breeders' Rights annex acknowledges the significant contributions of plant breeders, including those who work for private entities such as Pioneer Hi-Bred and Northrup King, and their work in international agricultural research. Plant breeders were concerned that Farmers' Rights could represent a wholesale transfer of wealth from the North to the South.\textsuperscript{97} This annex acknowledges that the rights of plant breeders are not incompatible

\textsuperscript{93} Chiapas is a state in southern Mexico.

\textsuperscript{94} See Hamilton, supra note 28, at 601. "The concept of farmers' rights was developed as a counterbalance to breeders' rights, and preservation of plant genetic resources by the indigenous farmers of a country of origin." \textit{Id.}

\textsuperscript{95} Convention on Biodiversity, supra note 9, art. 8, para. j. The Biodiversity Convention states that contracting parties will "... respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices. ..." \textit{Id.}

\textsuperscript{96} See Neil D. Hamilton, \textit{Why Own the Farm If You Can Own the Farmer (and the Crop)?: Contract Production and Intellectual Property Protection of Grain Crops}, 73 Neb. L. Rev. 48, 102 (1994). The United States refused to sign the Biodiversity treaty, for unlike TRIPs, it failed to provide for plant patents or "breeders' rights." \textit{Id.}

\textsuperscript{97} See James Odek, \textit{Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources}, 2 J. Intell. Prop. L. 141, 144 (1994). Developed countries have pursued heavily funded biotechnological research programs, and developing countries feel the "escalating flow" of genetic materials and data from "gene rich but technology poor countries of the South to gene-poor but technology-rich countries of the North." \textit{Id.} For example, in the United States, plant genetic resources from the "South" contribute $500 million per year to the wheat crop. \textit{Id.}
with Farmers' Rights and allows for legal protection of patented seed varieties.\(^9\) Quantifying the South's contribution to seed development, and determining how to collect and distribute compensation, however, remain unresolved issues. With the exception of the FAO undertaking and the Biodiversity Convention, Farmers' Rights and Indigenous Communities' Rights have not achieved overt recognition in other international dealings, such as trade agreements like the GATT. Because the GATT strengthens the intellectual property rights of the plant breeding industry, many Southern nations have questioned the commitment of the North to the Undertaking.\(^9\)

The third annex, adopted in 1991, reaffirmed the concept of "common heritage," however the concept was made subject to the sovereign rights of nations over their plant genetic resources.\(^10\) Thus, nation states have the right to determine how to preserve, protect, and be compensated for innovation utilizing their native plant genetic resources. The annex recognizes that countries of origin have legal ownership of the plant genetic resources found within their borders, and thus have the right to control the use of and access to these materials.\(^11\) The Biodiversity Convention's preamble endorses this concept, affirming that "[s]tates have sovereign rights over their own biological resources."\(^12\)

A fourth revision to the Undertaking is currently underway, and will occur in three stages. Stage I will integrate the annexes and harmonize the Undertaking with the Biodiversity Convention. Many developing countries have suggested that the Undertaking adhere strictly to the Biodiversity Convention. The United States has suggested that, while this would be beneficial, the North may not be able to guarantee compensation. At the First Extraordinary Session of the FAO Commission which occurred in

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98 See Interpretation of the International Undertaking, supra note 91 (recognizing farmers' rights are to be preserved).
100 Id. (discussing purpose of patents and intellectual property rights in preventing exploitation of commercial ideas without fair compensation to originators).
101 See Odek, supra note 97, at 150-59 (providing summary of argument concerning access to plant genetic resources).
102 See generally Kadidal, supra note 5, at 223 (discussing patents in pharmaceutical markets). But see Odek, supra note 97, at 177 (proposing vesting proprietary rights to plant genetic resources in customary groups and communities).
November 1994, United States spokesperson Henry Shands stated that, "[t]he international community cannot be in a position to ensure benefits. We can support but cannot necessarily ensure benefits."103

Stage II of the fourth revision will discuss how to enforce Farmers’ Rights and ensure equitable access to plant genetic resources. Finally, Stage III will consider making the Undertaking a legally binding agreement, such as a protocol to the Biodiversity Convention. A great deal of germplasm utilized by plant breeders of the North originated in the South, therefore, developing nations have a key role to play in ensuring the fourth revision addresses their concerns about access to and control over their native plants.

In the fourth revision, representatives of developing countries are seeking regulation of access to plant genetic resources through an international forum such as the Biodiversity Convention. Such a clarification and realization of Farmers’ Rights and technology transfer will encourage the conservation and sustainable use of plant genetic resources for food and agriculture.

Since the undertaking relies on the “common heritage” principle, it is necessary to ensure the rights of farmers and indigenous communities, both of which have traditionally understood the value and utility of plant genetic resources.104 Specifically, these communities should somehow receive compensation for their knowledge of plant genetic properties. The conservation of biodiverse resources and numerous products—primarily therapeutic or medicinal—has resulted from this knowledge and has brought significant uncompensated profit to multinational pharmaceutical companies located in the North.105

103 See PRG Undertaking Gets First Reading, South-North Development Monitor, Nov. 15, 1994.

104 See Shiraz Sidhva, World Trade News: Patents Plans ‘Sow Seeds of Destruction’ - Warnings of the Consequences of Copyright Draft, FIN. TIMES, July 23, 1993, at 6 (arguing multinational corporations are appropriating seeds and plant varieties which have traditionally belonged to developing nations).

105 See id. (stating that cancer drug, Vincristine, was developed in Madagascar, but country derives no benefit from Vincristine’s million-dollar market); see also Odek, supra note 97, at 145-47 (providing examples of unidirectional and uncompensated appropriation of plant genetic resources which raise issues of “secondary use” of inventive steps). See generally Richard E. Shultes, The Future of Plants as Sources of New Biodynamic Compounds in Plants in the Development of Modern Medicine 103, 105 (Tony Swain ed., 1972) (stating that 25% of all United States prescriptions in 1967 were for drugs whose principle agents were higher plants).
The Undertaking and related events have provided nongovernmental organizations (NGOs) a unique opportunity to respond in a manner that empowers citizens, indigenous communities, and farmers throughout the world. Many NGOs, including the Rural Advancement Foundation International (RAFI) and Genetic Resources Action International (GRAIN), have already participated in meetings with the FAO Commission. For example, prior to the 1992 Rio Earth Summit, the Keystone Symposia brought together governmental, nongovernmental, and academic participants to explore the question of preserving the world’s plant genetic resources. This group of forty-one individuals from twenty-two countries concluded that the current situation calls for a Global Initiative for the Security and Sustainable Use of Plant Genetic Resources. Likewise, the Crucible Group, made up of intergovernmental officials, NGOs, and industry representatives, has been working to identify the trends, concerns, and opportunities related to intellectual property issues relevant to plant breeding and plant genetic resources.

In June 1996, government officials and NGOs met in Leipzig, Germany for the Fourth International Technical Conference on Plant Genetic Resources. Two major documents were discussed: the First Report on the State of the World’s Plant Genetic Resources (Report), and the Global Plan of Action (GPA). The Report is a critical assessment of the status of the world’s plant genetic resources, and the multilateral institutional capacity to preserve and develop these resources. The GPA is a combination of recommended programs, priorities, and projects to conserve and to develop plant genetic resources. Envisioned as a major component of the FAO’s contribution to the implementation of the Biodiversity Convention, the GPA also addresses means of compensating developing countries for their native germplasm and promotes on-

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107 See generally THE CRUCIBLE GROUP, PEOPLE, PLANTS AND PATENTS (1994) (examining major issues regarding intellectual property and implications on plant life and environment in general). The Crucible Group constitutes the widest cross-section of sociopolitical perspectives and agricultural experience that has ever been assembled to hammer out ideas and recommendations on the subject of intellectual property. Id. It includes grassroots organizers working with small-scale or subsistence farmers, agricultural research scientists and science managers, intellectual property specialists, trade diplomats, and agricultural policy analysts, from both South and North and both government and industry. Id.
farm use and development of genetic resources. In order to facilitate NGO participation in this process, the FAO has established the International Conference and Programme for Plant Genetic Resources (ICPPGR), which will coordinate activities and develop a range of initiatives and agreements designed to generate consensus and commitment for implementing the Leipzig conference results.

CONCLUSION

The FAO's International Undertaking on Plant Genetic Resources and the Convention on Biological Diversity establish important principles regarding the protection of biodiversity while recognizing the vast commercial value of germplasm. The recent expansion of international trade agreements, however, establishing a global regime of intellectual property rights, creates incentives which may destroy biodiversity, while undercutting social and economic development opportunities as well as cultural diversity. Presently, countries are under pressure to change their IPR laws to conform with the TRIPs agreement of the GATT. Such rules will supersede national laws and allow privatization of the world's knowledge and resources. The ability of companies to gain monopolies over formerly freely available community resources, including seeds, plants, and even micro-organisms, may have devastating effects on both human communities and the protection of biodiversity.

108 See Pesticide Action Network, Preparations for Plant Genetic Resources Action Plan, PANUPS, May 8, 1995 [hereinafter Preparations for Plant Genetic Resources]; see also Sidhva, supra note 104, at 6 (stating that developing nations' rights to native germplasm, such as rice technology developed in China and palm oil research in Mayaysia, must be protected). See generally Vandana Shiva, The Violence of the Green Revolution 186-87 (1991) (illustrating difference between germplasm as "product" and germplasm as "raw material" in value-added context).
