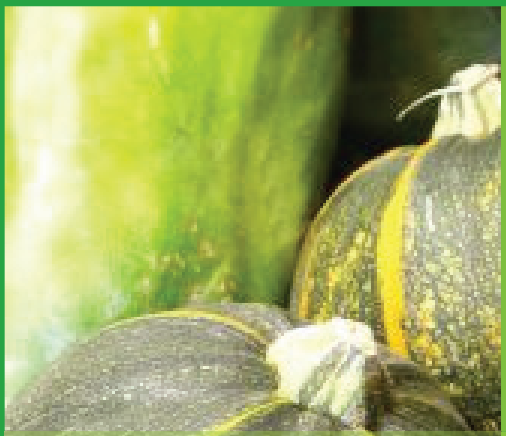

Fog in the Fields:

Demystifying the Law of Patents, Genetically Modified Organisms and Biopiracy

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Contents

PART I
Demystifying Patents

Demystifying Patents

Basic concepts

What is a patent?

A patent is a monopoly right with the sanction of law. It provides the right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent, usually 20 years from the filing date.[1]

What is a Process Patent?

A process patent gives one the owner exclusive right over the manufacturing process but not the product itself.[2] In other words, anyone can make and sell a particular product as long as they use a different process to produce it.

What is a Product patent?

A product patent thwarts others from manufacturing, selling, distributing or importing the patented product, even if it is being produced through different processes, without the authorization of the patent holder.[3]

What is free trade agreement?

Free trade is a market model in which the trade of goods and services between or within countries flows unhindered by government-imposed restrictions. Such government interventions generally increase costs of goods and services to both consumers and producers.

What is bilateral trade?

Bilateral trade or clearing trade is trade exclusively between two states, partic-

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1 Rangnekar, Dwijen. "No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime." Economic and Political weekly.2006

2 Joseph, Ammu. "Advent of patent Raj". **InfoChange News & Features.June 2005. available at http://www.infochangeindia.org/agenda2_01.jspa**

3 Ibid.

ularly, barter trade based on bilateral deals between governments, and without using hard currency for payment. Bilateral trade agreements often aim to keep trade deficits at minimum by keeping a clearing account where deficit would accumulate.

Are patents territorial in Nature?

Patents are granted and enforced under national laws and are therefore, territorial in nature. However, these national laws can be influenced by international treaties, which require members to incorporate the terms of the treaty into their national patent laws.[4] Patents are usually granted through a nation's patent office and the infringement is dealt with through the national courts.[5]

Conditions of patentability?

A patent application must satisfy the requirement of novelty, utility and non-obviousness in order to qualify for patenting.

Novelty

This requirement generally means that the information upon which the patent application is founded must not have been available to the public prior to the original application date.[6] Since the inventor is granted a patent for disclosing something new, it follows that if the invention has already been disclosed in literature available to the public, the applicant can disclose nothing new in return for the grant, and is either not entitled to be granted a patent, or if one has been granted, is liable to have it revoked.[7]

Non-obviousness

An invention must be sufficiently inventive, i.e. non-obvious to meet the patentability criteria.

Utility

The invention must be capable of being used in any kind of industry. Industry in

4 Ibid.

5 UNAIDS and WHO: 'Patent situation of HIV/AIDS-related drugs in 80 countries'. Geneva, 2000.

6 Dianne Nicol, "On the Legality of Gene Patents" (2005) 29 (3) Melbourne U. L. Rev. 809 at 822-823. (Hein online).

7 *Ibid.*

this sense is any physical activity of a technical character. States differ considerably in their treatment of industrial applicability.[8]

International and National Laws Relating to Patents

What is the GATT?

The General Agreement on Tariffs and Trade (typically abbreviated GATT) was a treaty and not an organization. It was the outcome of the failure of negotiating governments to create the Internation Trade organisation (ITO). The Bretton Woods Conference had introduced the idea for an organization to regulate trade as part of a larger plan for economic recovery after World War II. As governments negotiated the ITO, 15 negotiating states began parallel negotiations for the GATT as a way to attain early tariff reductions. Once the ITO failed in 1950, only the GATT agreement was left. The GATT's main objective was the reduction of barriers to international trade. This was achieved through the reduction of tariff barriers, quantitative restriction and subsidies on trade through a series of agreements. The functions of the GATT were taken over by the world Trade Organization which was established during the final round of negotiations in early 1990s.[9]

The history of the GATT can be divided into three phases: the first, from 1947 until the Torquay Round, largely concerned which commodities would be covered by the agreement and freezing existing tariff levels. A second phase, encompassing three rounds, from 1959 to 1979, focused on reducing tariffs. The third phase, consisting only of the Uruguay Round from 1986 to 1994, extended the agreement fully to new areas such as intellectual property, Services, capital, and agriculture. The WTO was born out of this round.[10]

What is the Paris Convention

Paris Convention for the protection of Industrial Property which was initially agreed in 1883. The Paris Convention sets out a range of basic rules relating to patents, and although the convention does not have direct legal effect, the principles of the convention are incorporated into all notable current patent systems. The most significant aspect of the convention is the provision of the right to claim priority; filing an application in any one member state of the Paris Convention

8 *Ibid.*
9 What is the WTO? (Official WTO site)
10 *Ibid.*

preserves the right for one year to file in any other member state, and receive the benefit of the original filing date. Because the right to a patent is intensely date-driven, this right is fundamental to modern patent usage.

What is the WTO?

The World Trade Organization (WTO) is an international organization dealing with the rules of trade between nations. As of October 2006 there were 149 member countries to the WTO.[11] In becoming Members of the WTO, countries undertake to adhere to the 18 specific agreements annexed to the Agreement establishing the WTO. They cannot choose to be party to some agreements but not others with the exception of a few "plurilateral" agreements that are not obligatory.[12]

What is TRIPS?

The TRIPS Agreement has been in force since 1995 and is to date the most comprehensive multilateral agreement on intellectual property. The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR), including those for patents.[13] In addition, the TRIPS Agreement also introduced detailed obligations for the enforcement of intellectual property rights. It introduced intellectual property law into the international trading system in a systematic and enforceable manner for the first time. It has the greatest impact on the pharmaceutical sector and access to medicines.

What is Doha Declaration?

The Doha Declaration on the TRIPS Agreement and Public Hea**lth** was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to medicines. Paragraph 4 - 6 outline the clauses relating to promotion of public health and access to medicines.[14]

11 WTO website: “Members and Observers” http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

12 WHO: “WTO and TRIPS Agreement”. see http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

13 Ibid.

14 Text of Doha Decleration

What is Compulsory Licensing?

A compulsory license is a government license that enables someone other than the patent holder to copy patented or copyrighted products and processes. Governments can issue them if a patent owner abuses their rights by, for example, failing to offer their product on the market, or offering it at a price that is too high for potential buyers to afford. Competitors can then produce the product or use the process under government license without fear of prosecution.[15]

What is Parallel Import?

Parallel importation is the cross-border importation of the more cheaply priced drugs from another country. Parallel importation is not limited under the World Trade Organization (WTO) agreement on intellectual property (TRIPS).

Explain the evolution of the Indian Patent Act?

The first patent enactment was the Act for Granting Exclusive Privileges to Inventors of 1856. This enactment provided for the protection of inventions in India. Later, a new enactment was introduced in 1859 modeled on the English Patent Act of 1852.[16] Under this Act, an inventor of a new product filed a specification of his invention to obtain the "exclusive privileges of making, selling and using the invention in India and authorizing others to do so for a term of 14 years from the time of filing such specification." For the purpose of providing protection for designs, the "Patents and Designs Protection Act" was passed in 1872. An amendment Act affording protection to inventors desirous of exhibiting their inventions at exhibitions was passed in 1883. Subsequently, in 1888 the laws passed in 1859, 1872 and 1883 were consolidated into a single Act.[17] The same was revised and replaced by the Indian Patents and Designs Act, 1911. This Act established for the first time in India a system of patent administration under the management of the Controller of Patents. In the period from 1911 to 1970 various amendments to this Act were introduced.[18] The 1970 Act was subsequently amended post TRIPS.

15 Bonita de Boer:; TRIPS, AIDS and Generic Drugs: Avert International website available at www.avert.org

16 Dr. Hedge, V.D. "East is not west: India and the Patent Regime." Combat Law; Volume 4 Issue 4,June-july 2005

17 Ibid.

18 Ibid

What are the three amendments?

India was obliged to amend its Patent Law in accordance with the TRIPS. India enacted the first amendment in 1999 (No 17 of 1999) adding, Chapter IVA, titled "exclusive marketing rights". The second amendment No 38 of 2002) was enacted on June 25, 2002 and the third amendment was enacted in 2005.[19]

What is patentable/non-patentable under Indian Law?

Similar to Article 27.3(b) of TRIPS, is sections 3(j)[20] of the Indian Patent Act, which excludes plants and animals, in whole or any part thereof, other than microorganisms but including seeds, varieties and species and biological processes for production or propagation of plants and animals, from the list of patentable inventions.

What is a pre-grant opposition?

A pre-grant opposition allows anyone to contest a patent application filed by a company at the Patent Office on grounds of known prior-art, invalid claim and lack of novelty.

19 Ibid.

20 *Supra* note 65, s. 3.

PART II

Genetically Modified Organisms and Farmers

Genetically Modified Organisms and Farmers

GMOs: What they are and What they Do!

What are GMOs and GE?

All plants and animals are made up of different kinds of cells. Every single cell within a living thing contains a set of instructions called genes. Genes determine many of the traits of living things, like how a plant looks, how well it can survive under certain conditions, and how it interacts with the environments. Plants and animals get their genes from their parents, which in the case of plants are the plant from which the pollen comes (father) and the plant which is pollinated and produces seeds (mother). This means that half the traits of a living this will come from its mother and the other half from its father.

Scientists have discovered methods which allow them to take a gene from one living thing and put it into an entirely different living thing, allowing it to take on a new trait. For example, a common trait that is added to crops is insect resistance from a bacterium called Bacillus thuringiensis (Bt). The methods used for altering genes are known as **Genetic Engineering (GE)**. The new and altered plants or animals are known as **Genetically Modified Organisms (GMOs)**.

More about GE Crops

Public research has been done on GE technology for the last 30 years; however, only 2 GE traits have resulted: herbicide resistance and insect resistance.[21] What is extremely important to note is that these traits DO NOT INCREASE YIELD![22] This is what the corporations that are marketing these products would like farmers to believe, but there isn't a single GE technology that has proven to increase a farmer's yield; therefore, it is untrue that GMOs can address the food security

21 Friends of the Earth Europe, "GMOs in Europe and the WTO – Questions and Answers," Accessed on 18 June 2008, <http://www.foeeurope.org/publications/2006/GMO_and_WTO_QA_Feb2006.pdf>.

22 Kavitha Kuruganti and K V Ramanjaneyulu, "Genetic Engineering in Indian Agriculture: An Introductory Handbook," Centre for Sustainable Agriculture, April 2007: 19.

problem that faces the world's developing countries. Moreover, GE foods do not have any more nutritional value than non-GE foods, and in fact may be less nutritious.[23]

Even with regard to the two traits that have achieved commercial use, there is not nearly enough known about the regulatory systems that control these genes and other genes related to them.[24] GE assumes that adding a trait has one simple result; however, single genes can play a role in a variety of traits of a plant or animal, so a great amount of research is needed to produce a single trait that is safe to the environment and produces food that is safe to eat. Such research has not been done. In fact, there is a considerable amount of research that suggests that GE crops and food are extremely unsafe for both human health and the environment, as seen in the below sections.

How do GE Crops and Foods Affect Human Health?

Genetics is not a simple science, and the systems that our cells use to regulate how genes work are far from being fully understood. Given how much is still unknown about gene regulation, it is not yet possible to adequately understand how GE foods will affect human health in the short and long term. Below is a list of the potential dangers to human health that have already been flagged by research scientists:

Increased Exposure to Chemicals

Herbicide resistant GE crops cause producers to be more dependent on agrochemicals to kill weeds. Agrochemicals are hazardous to human health, and are known to cause diseases of the central nervous system and the endocrine system, damage to skin and eyes, cancer, and other serious conditions.[25] Farmers are especially at risk in India, as most chemicals are applied manually by farmers, as opposed to by machines like in North America. People who consume the food that is produced are also at increased risk since they will be exposed to more chemical residues than they otherwise would have been.[26]

23 *Ibid.* at 20.
24 *Ibid.* at 14.
25 U.S. Environmental Protection Agency, "Pesticides: Health and Safety," Accessed on 16 June 2008, <http://www.epa.gov/opp00001/health/human.htm>.
26 Manju Sharma, K. S. Charak and T. V. Ramanaiah, "Agricultural biotechnology research in India: Status and policies," Current Science 84:3 (10 February 2003) 297.

Unexpected Allergic Reactions

Introducing a new gene into a crop from another source raises the possibility of creating new allergens or causing allergic reactions in consumers. Millions of Indians have life threatening food allergies, and there is no labelling scheme for GE foods, which means that there is a huge risk of unexpected allergic reactions to such foods.[27] Allergens in GE foods may transfer the gene to gut bacteria of humans, causing the allergen to be produced within the human body, prolonging the allergic reaction.[28]

Toxicity

Research has revealed the possibility for GE foods to contain higher levels of toxins or unknown proteins that could have dangerous effects on human health. Most plants produce some toxins, but produce them at such a low level that they are harmless to humans. However, the messy process of inserting a gene into a plant can disturb other genes sufficiently to cause them to produce the toxins at levels that may be dangerous to humans in the short or long term.[29]

Poor Nutritional Value

There is a concern that GE foods are less nutritious than non-GE foods, and will therefore lead to poorer human health. Similar to the concerns around toxins, there is concern that the process of inserting genes into plants will lead to a reduction in nutrients and minerals that are essential to human health. For example, a recent study revealed that GE soybeans produced less phytoestrogen compounds than non-GE soybeans. Phytoestrogen compounds are believed to protect against heart disease and cancer.[30]

Antibiotic-Resistant "Superbugs"

Among the most serious known dangers of GE crops and foods is the potential they have to lead to antibiotic resistant disease causing bacteria and viruses. In order to effectively transform a novel gene into a plant or animal cell, biotechnolo-

27 Deborah B. Whitman, "Genetically Modified Foods: Harmful or Helpful?" Accessed on 19 June 2008 <http://www.csa.com/discoveryguides/gmfood/overview.php>

28 *Supra* note 2 at 24.

29 GEO-PIE Project, "Issues Related to Genetic Engineering," Accessed on 18 June 2008, < http://www.geo-pie.cornell.edu/issues/issues.html#health> Cornell University.

30 A. Bakshi, "Potential Adverse Health Effects of Genetically Modified Crops," Journal of Toxicology and Environmental Health B-6 (2003) 211-225.

gists must use antibiotic resistant marker genes. The fear is that these antibiotic resistant genes may become incorporated into the genes of disease causing bacteria in the gut of humans or animals, or with disease casing bacteria and viruses in the environment.[31] If this occurred, pandemics could result.

How do GE Crops affect the Environment?

Harm to Other Plants and Animals

One of the major problems with GE crops, especially those that produce toxins to kill pests, are that they are harmful to more creatures than just the pests that damage the crops. A well studied example of this the in the monarch butterfly caterpillars that eat milkweed plants. Nature magazine published a study which showed that pollen from Bt corn blown onto milkweed plants in adjacent fields caused high mortality rates in monarch butterflies which fed on these plants.[32] Bt toxin is not specific to the pests it's meant to kill, so as the leading gene modification to crops worldwide, it poses a huge threat to a wide range of insects, and the fauna that feed on them.

"Superweeds"

GE crops with herbicide resistance genes have the potential to cross pollinate with weeds or to become weeds, making them extremely difficult or even impossible to kill with herbicides. Studies have shown that GE crops hybrids of canola and rapeseed may be able pass an herbicide resistance gene to their weedy relatives.[33]

Increased use of Herbicides

It is believed in the scientific community that the introduction of herbicide resistant GE crops will lead to a huge increase of chemical herbicide use.[34] Excessive herbicide use pollutes the environment, damaging wild plants, harming animals and insects, and contaminating the air and water.

31 *Ibid.*

32 D. Saxena, S. Flores & G. Stotzky, "Insecticidal Toxin in Root Exudates from Bt Corn." Nature (December 1999) 402-480.

33 Jennifer Thompson, "Genetically modified food crops for improving agricultural practice and their effects on human health," Trends in Food Science and Technology 14 (2003) 218.

34 J. Emberlin, B. Adams-Groom, and J. Tidmarsh, "A Report on the Dispersal of Maize Pollen," Soil Association (7 May 1999).

Unknown Effects

Genetics is an extremely complex and it is not yet known, and arguable not possible to know all of the possible negative effects GE crops might have on the environment.

GMOs Affect Farmers!!

Widespread Crop Failure

Unlike conventional crops, GE crops have identical genetics, so if a fungus, virus or pest develops that can attack this crop, it is quite possible that the entire crop will perish.[35]

Genetic Contamination

One of the major sources of concern surrounding GE is the fact that it is extremely difficult and impractical to try and contain GE crops to only the fields they are planted on. Pollen from GE crops can travel by wind and insects to adjacent fields, cross-pollinating with non-GE crops, contaminating them. All the other farmers in the vicinity of a GE plantation will essentially have no choice whether or not there are GE crops on their own fields.

GMOs being Forced on Farmers

Another anxiety faced by farmers in India is the banning of local crop varieties, and other pressure tactics to force GE seeds on farmers. This is being done to pave the way for transnational corporations to sell their seeds. The United Nations Committee on Economic, Social and Cultural Rights criticised the Indian government for this in April of this year. The UNCESCR stated that it:

> "…is deeply concerned that the extreme hardship being experienced by farmers has led to an increasing incidence of suicides by farmers over the past decade. The Committee is particularly concerned that the extreme poverty among small-hold farmers caused by the lack of land, access to credit and adequate rural infrastructures, has been exacerbated by the introduction of genetically modified seeds by multinational corporations and the ensuing escalation of prices of seeds, fertilisers and pesticides, particularly in the cotton industry."[36]

35 Turtle Mountain, "GMO – Genetically Modified Organisms," Accessed on 17 June 2008, <http://www.turtlemountain.com/health/gmo.html>.

36 United Nations Committee on Economic, Social and Cultural Rights, Item 29; E/C.12/IND/

Unexplained Decreases in Beneficial Plants and Animals

Small farms in India are among the most productive in the world, as they not only produce crops, but also herbal medicines, spices, and often serve as trapping grounds for fowl and small animals. GE crops have been produced in western countries, assuming that only one species would be living on the land. As such, these seeds and crops have properties that are harmful to the other living things that co-exist with traditional crops, and have beneficial uses for farming families.

Loss of Jobs

De-weeding represents a huge number of jobs in the agriculture industry. The addition of herbicide resistance to crops means that chemical pesticides will replace the labour that would traditionally remove the weeds. This affects women the most, as they represent the majority of de-weeders in India.[37]

De-Skilling of Farming Communities

Farmers have traditionally had a deep understanding of the land and ecosystems, and this has evolved over generations in pursuit of the best farming practices. There is evidence that shows that the introduction of GMOs will erode this knowledge of the land, as the technology completely ignores it, and replaces it with pesticides and toxins in the crops.[38]

Reduced Effectiveness of Pesticides

Often pests will evolve as pesticides evolve. As such, there is the concern that pests may evolve to become resistant to Bt or other crops.[39] This would be much more serious than resistance to a chemical pesticide, as within time GE crops are liable to take over non-GE crops, either due to commercial pressure or genetic contamination. The result of this could be widespread crop failure.

Illness among Farm Workers

There are a number of human health concerns associated with the use of GE crops and foods, as outlined above. Since farmers have the most direct contact with

CO/5; page 5&6.

37 *Supra* note 2 at 32.

38 *Supra* note 2 at 34

39 *Supra* note 15

these crops, and likely consume these foods in higher proportions than the general population, they are at the highest risk. For more information, see "**How do GE Crops and Foods affect Human Health**" above.

Bans by Trade Partners

Many state, district, and local governments worldwide have placed bans on the import of GMOs. If this trend continues, especially with the emerging organic food craze in North America and the serious potential for consumer backlash towards GMOs to resume in Europe, Indian farmers may be faced with a serious lack of demand for their produce.

Regulation of GMOs and GE in India and Abroad

The Law

GMOs in India are regulated by the 1989 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells ("The Rules"), which fall under the Environment Protection Act, 1986.

This act essentially gives the Genetic Engineering Approval Committee (GEAC) all power over the approval of the production, import and use of GE products in India. This includes the import of processed foods that contain genetically modified ingredients, GE produce, GE seeds and GE plants. Even after approving a product, the GEAC maintains the right to revoke the production, import and use of the product, if the person who was granted the approval does not follow the guidelines of the GEAC, if new information about its effects surfaces, or if the product is damaging to human health or the environment. Any aggrieved person may appeal an approval or revocation decision of the GEAC within 30 days.

The GEAC is also tasked with supervising GE in the country, and may with due notice, inspect any premise where GE products are being produced, used or stored.

Government Agencies

The Rules are to be administered by the Department of Biotechnology (DBT), Government of India. The Rules lay out the following agencies for the regulation of GE products:

Recombinant DNA Advisory Committee (IXDAC)

This committee reviews developments in Biotechnology at national and international levels and recommends suitable and appropriate safety regulations for India in recombinant research, use and applications.[40]

Review Committee on Genetic Manipulation (RCGM)

This committee is to monitor the safety related aspect of research projects and activities involving GMOs. The Review Committee on Genetic Manipulation must include representatives of (a) Department of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity.[41]

This committee lays out the guidelines for regulation of activities involving GMOs in research, use and applications, including industry, with the aim of ensuring environmental safety.[42]

Institutional Biosafety Committee (IBSC)

This committee is responsible for the preparation of on-site emergency plans, according to the manuals/ guidelines of the RCGM.[43]

Genetic Engineering Approval Committee (GEAC)

This committee is the approval body for activities involving large scale use of GMOs in research and industrial production, looking specifically at environmental issues. The Committee shall also be responsible for approval of proposals relating to release of GMOs into the environment, including experiment Field trials.[44]

State Biotechnology Co-ordination Committee (SBCC)

Wherever necessary, there are State Biotechnology Coordination Committees. Their function is to inspect, investigate and take punitive action in cases of violations of the statutory provisions. These Committees also review the safety and control measures in the various industries/institutions handling GMOs.[45]

40 Department of Biotechnology—Govt of India, "Rules Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells," Accessed on 16 June 2008 <http://www.dbtindia.nic.in/policy/rules.html>

41 *Ibid.*

42 *Ibid.*

43 *Ibid.*

44 *Ibid.*

45 *Ibid.*

District Level Committee (DLC)

Wherever necessary, there are District Level Biotechnology Committees, which monitor the safety regulations where GMOs are being used. The District Level Committees visit the installations engaged in activity involving GMOs and perform risk assessments as well as design emergency plans.[46]

GMO Regulation Elsewhere

European Union (EU)

Before any GE crops, food or feed is permitted to enter the European market, there must be an application made to the European Food Safety Authority (EFSA). This application consists of safety analyses, suggestions for labelling, samples of the product for testing, and any other relevant materials. The EFSA is composed of scientists, engineers and experts in the field, and they are given 6 months to decide whether or not the product should be permitted to enter into the market.[47] For the 9 year period between 1998 and 2007, there were no new GE crops permitted in Europe due to major public backlash over health and safety concerns, and it is unknown if the very few crops that have been approved in the last year will be successful, as 54% of Europeans think that GE foods are dangerous, and only 14% disagree.[48]

Australia and New Zealand

In Australia, there are two public departments that look after the regulation of GMOs: the Office of the Gene Technology Regulator (OGTR), and Food Standards Australia New Zealand (FSANZ). As in Europe the dealings with GMOs are quite strict, requiring comprehensive health and environmental analyses before a license may be granted for the import, export, production, use, etc…of a GMO. Additionally, it is a requirement that the government maintain a public record of the GMOs that have been approved in both countries. Violators of any of the regulations concerning GMOs, including smuggling of seeds, and planting of unauthorized GMOs, can face a prison sentence.[49]

46 *Ibid.*

47 GMO Compass, "The Long Road to Authorisation," Accessed on 18 June 2008, <http://www.gmo-compass.org/eng/regulation/regulatory_process/157.eu_gmo_authorisation_procedures.html>

48 Friends of the Earth Europe, "GMOs in Europe and the WTO—Questions and Answers," Accessed on 23 June 2008 <http://www.foeeurope.org/publications/2006/GMO_and_WTO_QA_Feb2006.pdf>

49 Biotechnology Australia—Govt of Australia, "Regulation of Biotechnology in Australia,"

Bans on GMOs

- Tasmania has a complete ban on GE crops, renewed this policy in June 2008
- In March of 2008, Romania placed a ban on GE maize, the only GE crop permitted to be commercially grown in Europe, and has made organic farming an official policy
- Hungary also still bans GE maize, despite the WTO threatening trades sanctions on all EU countries, and the EU as a whole if bans are permitted
- France, Poland, Austria, Luxembourg, Greece and other European countries are still fighting to be permitted to ban GMOs since the WTO ruled it to be against trade regulations in 2006
- Some states in Brazil have complete bans on GMOs

What YOU can Do!

1 Contact NGOs that deal with this subject matter, such as HRLN and Greenpeace, immediately with detailed information of the problem, so that it may be documented and legal action can be taken. HRLN has a specialized group dedicated to these issues, and uses the following strategies to seek improvements in the laws that affect farmers in India:

- Strategies HRLN—People's Patent Group:
- Using tools such as Public Interest Litigation and legal interventions
- Conducting policy oriented research
- Publishing policy papers and policy documents
- Organizing seminars for sharing knowledge and advocating on key policy issues
- Engaging with policy makers and other stakeholders to advocate and lobby for change

HRLN Contacts:

The people's patent group is situated in the HRLN head office in New Delhi office:

Accessed on 23 June 2008 <http://www.biotechnology.gov.au/index.cfm?event=object.showContent&objectID=D202AF67-BCD6-81AC-10F92E84B99F1D6C>

Tel: +91-11-24379855/56

Email: contact@hrln.org

File a Public Interest Litigation (PIL)

1 Members of civil society may file cases that in the High Courts, that are of concern to the public interest. From these, orders to make immediate changes may be handed down from the court. For more information on how to file a PIL, contact you nearest HRLN office.

PART III

Bio-piracy and the Loss of Biodiversity: A Threat to Farmers and Indigenous Communities

Bio-piracy and the Loss of Biodiversity: A Threat to Farmers and Indigenous Communities

Bio-Piracy

What is Bio-Piracy?

The term "bio-piracy" was first used in the early 1990s to call the practice of "bio-prospecting" into question.[50] Bio-prospecting, or the search for flora and fauna from which commercially valuable compounds could be obtained, has occurred for centuries. However, bio-piracy has been defined as derogatory bio-prospecting, or a form of exploitation of developing countries which are usually rich in biodiversity and "genetic wealth."[51] Bio-piracy can be defined as the appropriation of Intellectual Property Rights (IPRs) and exclusive monopoly control over the knowledge and genetic resources of farming and indigenous communities without compensation.[52] In other words, traditional bio-piracy occurs when the source of the traditional knowledge does not share in the financial benefits of a traditional knowledge-based product that is patented and commercialized.

What are the Problems Associated With Bio-Piracy?

Under the TRIPS Agreement, the international patent regime (based on a Western conception of intellectual property rights) treats traditional and indigenous knowledge as part of the public domain. Since the traditional knowledge of local communities are considered "public knowledge", indigenous groups and farmers face difficulty in proving the "novelty" aspect necessary to establish a patent under the existing patent regime. This leaves them vulnerable to exploitation by multinational agri-business firms. As a result of this "gene rush," the United Nations estimates that developing countries lose at least $US5 billion annually in

50 Chris Hamilton, "Biodiversity, Biopiracy and Benefits: What Allegations of Biopiracy Tell Us About Intellectual Property," 6:3 Developing World Bioethics (2006) 159.

51 *Ibid.* at 159.

52 *Ibid*.

unpaid royalties to multinational corporations that appropriate traditional knowledge.[53] The following paragraphs outline three different patent cases involving Indian traditional knowledge, and illustrate the growing problem of bio-piracy in a country rich in genetic resources.

Bio-Piracy Case Study #1: Neem Oil

One of the well-publicized case studies on bio-piracy in the world, the "Neem Campaign of India" was launched by civil society groups and Indian farmers. A patent was granted to W.R. Grace of New York by both the European Patent Office (EPO) and the U.S. Patent and Trademark Office (USPTO) for a method of controlling fungi and insects on plants through extracted Neem Oil. Unlike other fungicides/insecticides, the use of Neem Oil had considerably less side effects on plants and the environment. W.R. Grace was able to stabilize the Neem compound in order to give it a longer storage life and make it viable for large-scale commercial production as a fungicide/insecticide. A coalition of civil society groups (affectionately referred to as the "Neem Team") filed a legal opposition to the patent on the grounds that Neem Oil extracts were used in India for centuries to control fungal infections in plants. Presented with convincing evidence on the traditional use of Neem Oil in India as a fungicide/insecticide, the EPO Board of Appeal revoked the patent on the grounds of a lack of "novelty" and "inventive step."[54] This ruling was hailed by many to be the world's first successful legal challenge to a case of bio-piracy. While the case is widely recognized as a crucial victory for developing countries, it is important to note that the USPTO patent on Neem Oil remains valid. This case is also important for its use of traditional knowledge as a means of disproving "novelty" and "inventiveness" in a patent.

Bio-Piracy Case Study #2: Turmeric

The turmeric case marks the first time that a patent based on the traditional knowledge of a developing country was challenged successfully. For thousands of years, Turmeric has been grown in South India and used as an ingredient in Indian medicine. Unlike the Neem Oil case above, a patent was granted to two Indian nationals based in the U.S. (rather than a multinational corporation) by

53 Coenraad J. Visser, "Making Intellectual Property Laws Work for Traditional Knowledge," Poor People's Knowledge: Promoting Intellectual Property in Developing Countries, eds. J. Michael Finger & Philip Schuler (Washington: The World Bank, 2004) 213.

54 *Supra* note 1 at 166.

the USPTO on the use of turmeric as an antiseptic. The government of India and the Council for Scientific and Industrial Research (CSIR) challenged this patent, presenting evidence relating to the traditional use of Turmeric in wound healing.[55] Ultimately, the USPTO revoked the patent on the grounds of a "lack of novelty" because it had been practiced in India for centuries. While the first two case studies concerned traditional medicinal uses, the final case study focuses on a specific crop found in India.

Bio-Piracy Case Study #3: Basmati

Basmati rice is renowned throughout the world for its length and aroma. For centuries, basmati rice was grown exclusively in the Northwest region of India and Pakistan. In 1997, Rice Tec Inc., a Texas-based agri-business company, received patent to a number of rice lines that it had developed through cross-breeding to produce rice grains with characteristics similar to basmati rice. The patent consisted of 20 far-reaching claims including the planting, harvesting, collecting and breeding of the basmati rice line. The Research Foundation for Science Technology and Ecology (RFSTE) filed a Public Interest Litigation (PIL) in the Supreme Court of India to challenge the patent based on a lack of "novelty." The Supreme Court forced the USPTO to narrow down the patent to five claims, two of which have been amended for a narrower scope. However, the basic patent still remains in place, and this has an indirect economic impact on many Indian farmers. South Asian growers now face stiff competition in the marketplace from foreign-grown basmati strains bred exclusively as substitutes for the traditional varieties.[56] This shows that even in cases where a patent application is "read down" by a court, farmers in developing countries could still be adversely affected by bio-piracy.

Modern Bio-Piracy: A Threat to Biodiversity

The three case studies above illustrate the problems associated with traditional bio-piracy, where profits based on patents are not shared with the original users of the product/knowledge. In addition to the constant threat of traditional bio-piracy, farmers and indigenous communities must also face a new wave of "mod-

55 Abhinav Bhatt, "Bio-Piracy – A Discussion of Some Important Cases," The Singapore Law Gazette (August 2004) 14.

56 Philip Schuler, "Biopiracy and Commercialization of Ethnobotanical Knowledge," Poor People's Knowledge: Promoting Intellectual Property in Developing Countries, eds. J. Michael Finger & Philip Schuler (Washington: The World Bank, 2004) 171.

ern bio-piracy," which concerns the long-term effects associated with allowing multinational corporations to genetically modify, patent and control the number of seed varieties used by farmers around the world.[57] For centuries, farmers have contributed to the world's biodiversity by replanting seeds from hand-selected plants that displayed distinctive characteristics better suited to their particular environments.

What is Biodiversity?

Biological diversity (or biodiversity) is the "Variability among living organisms from all sources, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems."[58] Thus, biodiversity is manifested at three different levels: ecosystems, species and genes. The protection of biodiversity has been the subject of numerous international treaties and conventions.

What is the *UN Convention on Biological Diversity*?

The main objectives of the *UN Convention on Biological Diversity* (CBD) are: conservation of biodiversity, sustainable use of its resources, and a fair and equitable sharing of benefits arising out of the use of genetic resources and its associated knowledge. For example, Articles 3 and 15 of the CBD recognizes the sovereign rights of states over their generic resources, and gives them the authority to determine access to genetic resources through national legislation. In order for anyone to use these genetic resources or traditional knowledge, they must obtain Prior Informed Consent for access, and share any benefits with the host country. The terms under these Access and Benefit Sharing Agreements (ABAs) could include: benefit sharing, technology transfer and preferential location of R&D units in the country of origin.[59]

The CBD was passed in order to enable developing countries to better benefit from their genetic resources and traditional knowledge. However, developing countries are usually not in a position to exercise their Article 3 rights when they

57 David Conforto, "Traditional and Modern-Day Biopiracy: Redefining the Biopiracy Debate", 19:2 Journal of Environmental Law and Litigation (2004), 361.

58 United Nations Convention on Biological Diversity, 1992, Article 2.

59 Ghate Utkarsh, Madhav Gadgil, and P.R. Sheshagiri Rao, "Intellectual Property Rights on Biological Resources: Benefitting from Biodiversity and People's Knowledge" Current Science 77:10 (December 1999) 1420.

are threatened with bilateral trade sanctions. Though the Convention mandates the signatories to respect, preserve and maintain traditional knowledge, it is important to note that the United States has not yet ratified the CBD. Since American biotechnology firms are among the worse perpetrators of bio-piracy, their exclusion from the Convention undermines its influence and impact. Overall, the CBD has provided developing countries with little recourse in stemming the tide of bio-piracy committed against them.

The Indian government passed the *Biological Diversity Act* (BDA) in 2002 to implement the provisions of the CBD on a national level. Specifically, the BDA deals with access to genetic resources and the sharing of benefits from the use of such genetic resources. The BDA envisages a three-tier structure – a National Biodiversity Authority, State Biodiversity Boards and Local Biodiversity Management Committees – to regulate the access and utilization of these resources. Through a mechanism of Prior Informed Consent, any non-citizen who intends to obtain any biological resource, or knowledge associated with it, has to obtain approval from these authorities before access is permitted.

Perhaps the most important part of the CBD has been its recognition of biodiversity as a "genetic resource," or tangible system of property, that could possibly be subject to intellectual property laws.[60] This would have significant ramifications on the treatment of "genetic resources" in the future.

How Does the *Convention on Biological Diversity and Biological Diversity Act* Fit In With TRIPS?

Many scholars and civil society members alike believe that the CBD and TRIPS lie in fundamental contradiction with each other, and cannot co-exist. Both treaties provide legally binding provisions for a national government, and both appear to give conflicting directions. While TRIPS imposes private IPR rights on developing countries' biodiversity, the CBD recognizes the collective rights of local communities to the same.[61] Article 16.5 of the CBD is a key provision stipulating that IPRs should promote (and not run counter) to the objectives of the Convention. However, this has not been the case and TRIPS has taken primacy over the CBD and its goals to preserve biodiversity. Article 27.3(b) of the TRIPS Agree-

60 *Supra* note 1 at 162.
61 *Ibid.* at 163.

ment falls in line with U.S. jurisprudence and accepts the patentability of life, including plant genetic resources. As a signatory to the TRIPS Agreement, India amended its *1970 Patent Act* to allow for the production or propagation of genetically engineered plants (Genetically Modified Organisms or GMOs) to qualify as an "invention." Being a primarily agricultural economy, India now finds itself in a precarious situation regarding the patenting of seeds.

The Seed Wars

Historically, plant varieties were exempted from IPRs in deference to farmers' traditional practice of saving and exchanging seeds. In the developing world, the majority of farmers depend on farm-saved seeds as their primary seed source.[62] In countries like India, more than half the seed supply is ensured by saving and exchanging seeds, rather than splitting grain and seed production between farmer and breeder like they do in developed countries. Given the importance of seed exchange to the country's biodiversity, the Indian government passed the *Protection of Plant Variety and Farmers' Rights Act* (PPVFRA) in 2001.

The Protection of Plant Variety and Farmers' Rights Act

The PPVFRA served as India's "sui generis" ("of its own kind") plant variety protecting regime. Its purpose was to protect the contributions made to conserving, improving and providing genetic plant resources for the development of new plant varieties. Following this mandate, the Act recognized the rights of farmers to save, use, re-sow, exchange, share and sell farm produce or seeds that were registered. However, this protection did not extend to branded products, protected plant varieties and farmers' own varieties. As a result, the PPVFRA has been criticized for favouring formal sector plant breeders, and not local farmers. These criticisms were exacerbated in 2004, when the Indian government introduced a Bill that would place seeds under the purview of TRIPS and the intellectual property regime.

The 2004 Seed Bill

The Seed Bill would introduce compulsory registration of all seed producers, processors and traders with state authorities. Plant varieties could only be protected through patents. Once registered, it would become illegal for a farmer to plant any unlicensed varieties without infringing on patent rights, as is the case in the

62 Crucible II Group, "Seeding Solutions."

United States (i.e. the *Asgrow* decision) and the United Kingdom. The Seed Bill could also prohibit seed saving and seed exchange between farmers, with a fine as punishment for the barter and exchange of unregistered seeds. As a result, farmers have to re-plant any leftover seeds, leading to soil exhaustion and lower soil quality.[63] This essentially criminalizes farmers for maintaining biodiversity and traditional varieties, which violates their right to food. More importantly, it pushes local farmers to become dependent on patented seeds, which are usually "owned" by multinational agri-businesses. This leads to a cycle of dependency and debt that essentially drives many Indian farmers to poverty and suicide.

The Seed Bill does not comply with the farmers' rights outlined under the PPV-FRA. In fact, it has only offered a monopoly to private seed industries by creating loopholes in the *Biological Diversity Act* to allow for the patenting of seeds. By allowing for the ownership and control of seeds under an intellectual property regime, there are no guarantees that it would remain a resource that could be freely traded between farmers. Through bio-piracy, seeds that were once considered part of the "common heritage" when collected in the developing world are now protected by patents when sold back by commercial seed companies.[64] This has significant repercussions for all people, as total control over the seed sector means total control over food security and bio-safety. Given the importance of agriculture to India's economy and society, what steps can farmers take to preserve their livelihood, prevent bio-piracy and protect India's precious biodiversity?

Other Relevant International Legislation

Outside of the *Convention on Biological Diversity*, there are other international legislation dealing with bio-piracy and biodiversity. The 2001 *International Treaty on Plant Genetic Resources for Food and Agriculture* created a multilateral system for access and benefit-sharing related to 35 crop general and 29 forage species. The Treaty set conditions for facilitated access to plant genetic resources food and agriculture under national agriculture and rural development policies and programmes. This includes the obligation to promote or support farmers and local communities' efforts to conserve on-farm their plant genetic resources for food and agriculture.[65] In conjunction with the CBD, farmer groups can use the

63 *Supra* note 8 at 378.

64 *Supra* note 1 at 161.

65 *International Treaty on Plant Genetic Resources for Food and Agriculture, 2001*, Article 5(c), Accessed on 18 June 2008, <www.fao.org/ag/magazine/ITPGRe.pdf>

Treaty to lobby the Indian government to: 1) Protect traditional knowledge relevant to plant genetic resources for food and agriculture, 2) Receive a share of the benefits arising from the utilization of plant genetic resources, and 3) Participate in matters related to conservation and sustainable use of plant genetic resources.[66] Under Article 9.3, the Treaty (also known as the "International Seed Treaty") does not limit any rights of farmers to save, use, exchange and sell seeds, subject to national law.[67] One criticism of the Treaty is that the extent to which farmers can use, exchange, sell or breed seeds is open to interpretation. It is also unclear how the Treaty will be interpreted along with TRIPS and the intellectual property regime.

Another international legislation that farmers can use is Article 22.1 of the TRIPS Agreement itself, which deals with Geographical Indications (GIs). A Geographical Indication is defined as a good in a territory, region or locality where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.[68] Simply put, GIs can be used to protect products of a special region from bio-piracy. As a signatory to TRIPS, the Indian government also passed the *Geographical Indications of Goods (Registration and Protection) Act, 1999*, relating to GIs in India. Examples of possible Indian GIs include: Darjeeling Tea, Kancheepuram Silk Sarees, Alphonso Mangos, Nagpur Oranges, Kolhapuri Chappals, Bikaneri Bhujia and Agra Petha. Under the Act, anyone can apply to the Controller-General of Patents, Designs and Trademarks in order to register a GI, provided that there is no opposition to the claim. Registration under the Act is not compulsory, though it affords better legal protection to facilitate an action in instances where there is an infringement. Given the large number of potential GIs in India, the national government can use this provision to conserve the country's biodiversity, limit the number of authorized users and protect the rights of farmers to benefit off of GIs that they have been cultivating for generations.

The *International Treaty on Plant Genetic Resources for Food and Agriculture* and the *Geographical Indications of Goods (Registration and Protection) Act* are two pieces of international legislation that farmers can use in conjunction with the CBD to conserve local biodiversity. What is required is intensive capacity-

66 *International Treaty on Plant Genetic Resources for Food and Agriculture, 2001*, Article 9.2, Accessed on 18 June 2008, <www.fao.org/ag/magazine/ITPGRe.pdf>

67 *International Treaty on Plant Genetic Resources for Food and Agriculture, 2001*, Article 9.3, Accessed on 18 June 2008, <www.fao.org/ag/magazine/ITPGRe.pdf>

68 TRIPS, Article 22.1

building and educational programs to make farmers, forest dwellers, tribes and local communities aware of these laws.

What Can Be Done? Three Courses of Action

In addition to intensive capacity building and awareness among farmer and rural communities, there are other steps that can be taken by the Indian government to combat bio-piracy. According to Dr. Vandana Shiva, founder of Navdanya and an expert on GMOs, biosafety and biodiversity, there are three courses of action that can be taken.[69] First (and ideally), patents could be excluded on all life forms, including plant and animal genetic resources. In this way, bio-piracy can be used to question the nature of the intellectual property regime as a whole. If this is not possible, then patents could be excluded on Traditional and/or Indigenous Knowledge, as well products essentially derived from them. Like the first course of action, this calls into question the dominant intellectual property regime under TRIPS. The last possibility, and the most feasible of the three, still operates within the parameters of the dominant intellectual property regime. This would involve the disclosure of biological source/country of origin/associated knowledge, proof of informed consent of Traditional Knowledge holders and details of the benefit-sharing agreements.[70] Failure to provide such data could result in a refusal or nullification of a patent based on Traditional or Indigenous Knowledge.

However, there are also difficulties associated with implementing a system of disclosure and informed consent. Given the nature and scope of Traditional and Indigenous Knowledge, there are material challenges in defining what the benefits are, who should receive them and how they should be distributed.

Further, when a natural resource is patented, the Traditional Knowledge transfers to the hands of the patent holder and becomes monopolized. This monopolization drives up the price of the resource/knowledge, often preventing the originators from continued use. From the case study of Neem Oil above, the price of Neem seeds have risen from Rs 300 per tonne to more than Rs 8,000 per tonne over the past 20 years.[71] A re-forestation plan would help keep the inflation of a particular

69 Vandana Shiva, "Seeds of Dictatorship", Presented on February 14, 2005, 5.

70 Ashish Kothari & R.V. Anuradha, "Biodiversity and Intellectual Property Rights: Can the Two Co-Exist?" 2:2 Journal of International Wildlife & Policy (1999), 9.

71 Philip Schuler, "Biopiracy and Commercialization of Ethnobotanical Knowledge," Poor People's Knowledge: Promoting Intellectual Property in Developing Countries, eds. J. Michael Finger & Philip Schuler (Washington: The World Bank, 2004) 165.

natural resource in check, though it may not be enough for many farmers and rural communities. In many ways, the challenges associated with this strategy are based on the weaknesses of the dominant intellectual property regime. Perhaps what is needed is a new property paradigm.

Elements of a *Sui Generis* System for Protecting Indigenous/ Traditional Knowledge

According to many biodiversity scholars, the intellectual property regime is not adequate or appropriate to deal with issues related to Indigenous/Traditional Knowledge, which is held collectively, passed orally and evolved over time. These same scholars advocate the development of a *sui generis* ("of its own kind") regime specifically targeted at the nature and characteristics of IK/TK. Article 27.3(b) of TRIPS requires that signatories (including India) provide intellectual property protection either through patents or some "effective *sui generis* system" at the national level,[72] though the Agreement gives no details on the necessary elements of such a system. When establishing a *sui generis* system, certain questions need to answered, such as: How to define the subject matter of protection? What are the requirements for protection? What should be the nature of the rights to be conferred? Who are the title holders? How the rights should be enforced? So far, many governments have interpreted this *sui generis* option to pass Plant Variety Protection schemes (like the PPVFRA described above), access laws and comprehensive biodiversity laws.[73] However, these measures have not been enough to stem the growing threat of bio-piracy, and it is evident that a new *sui generis* scheme is needed to conserve biodiversity. Until such a system is created, the Indian government must work with farmers' groups and rural populations to properly document local resources and knowledge to protect against bio-piracy.

Documenting Local Knowledge and Genetic Resources

Over the past few years, the Indian national government has been developing a Traditional Knowledge Digital Library (TKDL) to document public domain traditional knowledge related to medicinal plants. This digital database would be available in patent offices all over the world so that examiners are aware of the "prior art" relating to a medicinal plant prior to awarding a patent. This docu-

72 TRIPS, Article 22.1

73 "GRAIN, "Signposts to *Sui Generis* Rights: Strategy Ideas for the 1999 TRIPS Review & Beyond," Accessed on 18 June 2008, < http://www.ukabc.org/suigen1.htm>.

mentation has also occurred on the local level, with NGOs and local community groups creating Community Biodiversity Registers (CBRs) and People's Biodiversity Registers (PBRs) to record Traditional and/or Indigenous Knowledge. These registers can combat against bio-piracy by recording local knowledge and resources in a way that is recognized by the dominant intellectual property regime. It would also save money, since the government and/or local groups do not have to waste expenses contesting patent applications based on bio-piracy. Rather than attempt to change the current intellectual property paradigm, these registers seek to operate within it. Another way to combat bio-piracy through the current IPR regime is to encourage a greater number of patent applications in India.

Patenting in India

Currently, India's share of world patents is only 0.25%, in comparison with Japan (25%) and the U.S. (12%).[74] This is unacceptable, especially given the amount of genetic material and expansive indigenous knowledge base that is present in India. Much like multi-national agri-businesses have used the patent system to conduct bio-piracy in India, farmers and local communities can also use the patent system to their advantage. In conjunction with the documentation of local knowledge and genetic resources, farmers' groups can file patents of their own to protect against future bio-piracy. If the knowledge or genetic resources has a localized distribution, custodianship could be entrusted to local the farmer communities.[75] If it is not distinct in terms of identity or ownership, then the benefits could be rewarded to a National Biodiversity Fund that could be used for conservation, or to file future patents.[76] Costs are a key barrier to this; the filing, acquiring and enforcing of a patent is far beyond the financial means of many indigenous populations. The responsibility lies with the Indian government to mitigate these expenses for farmers and local communities. In the long run, the country can save more money and conserve its precious biodiversity by taking action now, whether it is within or outside the framework of the dominant intellectual property regime.

74 Rajendra Dobhal, "Recognizing Biodiversity and Indigenous Knowledge System Under New Intellectual Property Regime," Current Science (1999) Accessed 12 June 2008. <www.ias.ac.in>.

75 Ghate Utkarsh, Madhav Gadgil, and P.R. Sheshagiri Rao, "Intellectual Property Rights on Biological Resources: Benefitting from Biodiversity and People's Knowledge" Current Science 77:10 (December 1999) 1422.

76 *Ibid*.