Chapter IV


US patent policy generated enormous conflict in India not only in the area of increasing patent protection, but also on the issue of “bio-piracy”. US accusation against India of “piracy” is matched by India’s charge of “bio-piracy” against the US. Bio-piracy refers to the utilization of traditional knowledge or resources by industrialized nations to create profitable products without compensation. Just as US corporations complain that inadequate patent laws are leading to losses, developing nations claim that bio-piracy is robbing them of valuable resources. RAFI, a Canadian NGO, estimates that medicinal plants and microbials from the South contribute at least $30 billion a year to the North’s pharmaceutical industry.\footnote{RAFI, “Bioprospecting/Biopiracy and Indigenous Peoples”, RAFI Communique, November 1994, p. 1} India’s grievance is against patents granted in the US to foreign corporations utilizing resources originating from India. The argument is that traditional knowledge or resources are freely taken and are not protected by intellectual property rights, whereas products or processes derived from such resources can be patented. The Indian protest on the issue has been extremely strong as it has involved various cultural aspects. The US argues that it is not stealing Indian resources but rather creating innovative products.

To developing nations, where most traditional knowledge is located, patents utilizing such knowledge represent “biopiracy”, a theft of their resources.
and culture. On the other hand, for industrialized countries, who have the technology to produce such commodities, these patents are a means of rewarding and encouraging important inventions. Three criteria of novelty, non-obviousness and industrial applicability have been established to determine what is patentable but this has left unanswered the issue of traditional resources which cannot be incorporated under these standards. After all, traditional knowledge usually has no industrial applicability, is many times passed on orally and not written, and is not novel according to patent law. This has led to the debate on biopiracy where indigenous knowledge itself is not patentable but products created out of this knowledge are. IPR laws, in addition, are a product of national legislation giving rise to wide variations between countries. The issue of biopiracy has come into vogue recently but is the result of debates that have divided the North and the South for decades. The controversy has come into sharp focus because of industrialized nations interests in securing trade benefits for high technology industries and developing nations attempts to maintain a hold over resources that are used by these high technology industries. Developing nations protest that western IPR laws only recognize products created from these resources but do not recognize the contribution of farmers and communities in developing these resources. Patent laws thus allow for appropriation of their resources.

This chapter focuses on the “bio-piracy” conflict between the US and India. India and the US have engaged in this debate in relation to three patents that have been granted in the US. An emotionally charged outburst has arisen in India over these patents.
Definitions

Three specific terms used in this chapter need to be defined: bio-piracy, indigenous knowledge and genetic resources:

*Genetic Resources:* Plant genetic resources refer to the genetic information found in the chromosomes of plants. Plant genetic resources include genetic material from "all agricultural crops, fruit, nut and forest trees, forage crops, medicinal and ornamental plants, unexploited plants, wild relatives and ecosystem diversity." The Convention on Biological Diversity defines genetic resources as "genetic material of actual or potential value" and genetic material as "any material of plant, animal, microbial or other origin containing functional units of heredity."(Article 2 Use of Terms)

*Bio-piracy:* Plant genetic resources from developing nations have been appropriated by industrialized nations without compensation. Most developing nations have characterized this unidirectional and uncompensated appropriation as "bio-piracy". International law has not defined uncompensated extraction of plant genetic resources as piracy, therefore the characterization of such acts as piracy serves as a normative assertion by developing countries that they have an entitlement to their plant genetic resources.

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4 Odek, n. 2, p. 145
5 Ibid.
6 Ibid.
*Indigenous Knowledge*: The term is difficult to define. One working definition that has been formulated states, "The term 'indigenous knowledge' (IK) is used synonymously with 'traditional' and 'local knowledge' to differentiate the knowledge developed by a given community from the international knowledge system, sometimes also called the 'Western' system, generated through universities, governmentalist research centers and private industry. IK refers to the knowledge of the indigenous peoples as well as any other defined community."\(^7\) Sometimes indigenous knowledge is equated with "folk beliefs" or the "local". The Indigenous and Development Monitor states, "Indigenous knowledge systems relate to the ways members of a given community define and classify phenomena in the physical/natural, social, and ideational elements. Examples are local classifications of soils, knowledge of which local crop varieties grow in difficult environments, and traditional ways of treating human and animal diseases".\(^8\) It has also been defined as, "a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use".\(^9\)

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\(^8\) Ibid., p. 174

\(^9\) Quoted in Graham Dutfield, "Intellectual Property Rights and Traditional Knowledge", Draft, January 1999, p. 4
Basis of the Conflict

The conflict between the US and India on this issue is based on two factors that are examined in detail below. These are: 1) The common heritage principle over genetic resources and 2) The exclusion of indigenous knowledge from intellectual property law. The application of these norms has led India to accuse the US of promoting "bio-piracy". The conflict between the U.S. and India on "bio-piracy" is based on the following: 1) The appropriation of genetic resources from India by the United States without compensation; 2) The granting of patents to American companies in the United States on products or processes which have been derived from genetic resources or traditional knowledge originating from India; 3) The absence of property rights for genetic resources or indigenous knowledge.

The "Common Heritage" Principle

The principle of common heritage of mankind currently applies to areas and their natural resources outside the national jurisdiction of any state. Ambassador Pardo of Malta, who introduced the concept in the Law of the Sea negotiations, is regarded as the progenitor and propounder of the term although he was not the first to use it. The principle is found in several treaties and international instruments: the Declaration of Principles Governing the Sea-Bed and the Ocean Floor (1970); the Agreement Governing the Activities of States on the

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10 Simone Bilderbeek, ed., Biodiversity and International Law (Amsterdam, 1992), p. 86
Moon and other Celestial Bodies (1979); the UN Convention on the Law of the Sea (Part XI) 1982. 12

Although the scope of the principle of common heritage is uncertain, when applied to common areas, it implies: 1) the areas designated as common heritage shall not be appropriated 2) the use of the areas and their resources which fall under the common heritage regime will be governed and managed by an international authority 3) there will be active and equitable sharing of benefits derived from the exploitation of the common heritage area and its resources 4) the peaceful use of areas and resources concerned 5) the protection and preservation of given resources for the benefit and interests of mankind. 13

Almost from its inception, developing nations have viewed the common heritage of mankind "as a tool for the solution of the disparities existing between developing and developed states". 14 To developing nations it represents a crucial realignment of the world legal order through which both the burden and benefit of the management of our planetary environment cannot be left to the free sovereign will of the states. Developing nations have supported the concept as an important pillar of the NIEO (New International Economic Order). 15 Developing nations believed that through the principle of free exchange there would be scope for economic development. The idea that there are certain resources that belonged to.

12 Bilderbeek, n. 10, p. 86
13 Balsar, n. 11, p. xx-xxi
14 Ibid., p. 96
15 Ibid., p. 101
all human beings and could not be owned by one state or individual strongly
influenced the formulation of the common heritage principle.

"Common Heritage" and Genetic Resources

Genetic resources have been viewed for decades as "common heritage". Plant genetic resources have been available as a free good, the only cost being associated with their acquisition being the expenses of collection. There has long been universal consensus that, "The major food plants of the world are not owned by any one people and are quite literally a part of our human heritage from the past".16

The application of common heritage to genetic resources did not originate from an international agreement, but rather dates far back in history from the initial period of plant exploration and exchange. From the days of Columbus, plants and seeds were freely transferred across continents in what has been called "the Colombian exchange" by A W Crosby.17 Returning from his first voyage of exploration and conquest, Columbus brought with him seeds of the maize plant. Thus began a period of unprecedented transfer of resources across the world. The spread of plants has been a universal feature of history but the areas of greatest genetic diversity remained distinct until the establishment of contact between the Old and New Worlds. Plant genetic resources then became a part of the colonial era. In what Pat Roy Mooney called the "botanical chess game", plant germplasm

was appropriated and shifted across the continents as the European powers sought commercial hegemony. Thus, the principle of common heritage originated as a matter of practice in terms of genetic resources.

The conflict over patents utilizing resources originating from developing countries is rooted in historical factors determining the divide between developed and developing countries over genetic resources. Over 95% of the world’s genetic resources originate and are concentrated in developing countries. Developing nations are thus gene-rich whereas industrialized nations are gene-poor. The reason for this divide is a result of the period of glacialization that led to enormous losses in plants in the now industrial world. N. I. Valivov, the great Russian botanist, first detected the uneven distribution of resources. He identified areas of genetic diversity concentration which were termed “Valivov Centers of Genetic Diversity”. Valivov concluded that the following areas were the origin of the crops with which they were associated: the Mediterranean, the Near East, Afghanistan, Indo-Burma, Malaysia, Java, China, Guatemala-Mexico, the Peruvian Andes and Ethiopia. Although subsequent research has shown that the centers of diversity are not necessarily the source of origin of these crops, it is still evident that biodiversity resides in developing nations. Most of the world’s important food crops were domesticated in Asia, Africa and Latin America thousands of years ago. The crops that dominate the agricultural economies of the North -- corn, wheat, soybeans, potatoes -- have been introduced there by the South. Inspite of this origin, today only 14% of the germplasm in storage (excluding the IARCs) are

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18 Friends of the Earth, Traditional Centers of Genetic Diversity (Bedfordshire, 1995), p. 4
found in developing nations. This has occurred as industrialized nations have made free use of the genetic resources found in developing nations. They have also stored them in gene banks located in developed countries. Genetic resources, viewed as “common heritage” were placed in a category above the sovereign control of any nation. Therefore it was considered a resource to be utilized by all and owned by none. Developing nations since the 80’s have voiced the inequalities that this has caused.

This historical anomaly---where genetic resources originated from developing nations but were utilized by industrial nations---is the basis upon which the present debate over patents originates. The patent system in industrialized nations has been enlarged to encompass living resources and this has led to patents being granted on products/processes derived from these genetic resources. These genetic resources have been taken from gene banks or directly from developing nations. Developing nations are therefore angry that such resources are taken freely, but industrial applications derived from these resources can be privately owned through patents. The products developed from such resources can be acquired by developing nations only by paying royalties, whereas developed nations have taken these resources without any payment. Advanced nations, however, argue that such resources exist in nature and cannot be patented, but industrial applications of these resources are innovations and should be subject to property rights. The labor applied to the resources gives it value and therefore justifies patents. New developments in biotechnology have made possible greater use of such resources, making the issue more controversial today. In addition to the resource itself, developing nations argue that the knowledge embodied in the use
of these resources are freely taken by industrial nations. This "indigenous knowledge" represents years of labor employed by communities in developing nations, so it is unfair to say that the resource becomes valuable only when industrial corporations make industrial applications out of these resources. The controversy over "indigenous knowledge" and IPRs is the subject of enormous debate today.

**Gene Banks**

The institutionalization of the principle of common heritage in terms of genetic resources began with the establishment of gene banks. Gene banks are storehouses for plant genetic resources. The international system of gene banks functions under an institution known as the IBPGR (International Board for Plant Genetic Resources). Established in 1974, the IBPGR is housed at the FAO, but is an institution of the CGIAR (Consultative Group on International Agricultural Research). 20 The CGIAR was established in 1971 by the Ford and Rockefeller Foundations to coordinate the gene centers established in the 1960s in various developing nations. 21 These centers, known as International Agricultural Research Centers (IARCs), were established in various developing countries by advanced nations. Today the IBPGR has designated a network of mega-gene banks as global base collections. 22 These repositories now hold about 85% of the world's collected germplasm, and two-thirds of these banks are in the developing world. 23

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20 Ibid., pp. 163-4
21 Ibid., p. 160
22 H. Garrison Wilkes, "Plant Genetic Resources Over Ten Thousand Years: From A Handful of Seed to the Crop-Specific Mega-Gene Banks", in Jack Kloppenberg, Jr, ed, Seeds and Sovereignty: The Use and Control of Plant Genetic Resources (Durham, 1988), p. 80
23 Ibid.
IBPGR system was based on the principle of common heritage, justifying the free collection of plant genetic resources. In addition, the principle of “free availability” which mandates unrestricted exchange of banked germplasm was a foundation on which the system was constituted.24 Thus the principle of common heritage for plant genetic resources was institutionalized with the establishment of the IBPGR.

**India and the US under the Common Heritage Regime**

*India's Biological Wealth*: India is a land rich in biological resources. This factor is of great significance in determining the position of India on the issue. India's biological diversity is one of the most significant in the world. 45,000 wild species of plants and over 77,000 wild species of animals have been recorded so far.25 India is recognised as a country which is uniquely rich in all aspects of biological diversity from the ecosystem level to the species and genetic levels. As many as 33% of the flowering plants and 18% of all plants found in India are believed to be endemic i.e., found only in India.26 The Indian subcontinent is known as the Hindustan Centre of Origin of Crops and Plant Diversity, as termed by N.I. Valivov. At least 166 species of crops and 320 species wild relatives of crops are known to have originated here.27 This rich biological wealth of India naturally places India in a position where she wants to protect her resources.

*US Dependence on III World Germplasm*: In contrast with India, the United States is severely lacking in native genetic resources. The extent of US

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24 Kloppenberg, n. 17, p. 166
26 Ibid.
27 Ibid.
dependence on such genetic resources is illustrated by the statement of Dr. J.P. Kendrick, Jr. of the University of California, Davis. In 1977, he stated, "If we had to rely on the genetic resources now available in the United States for the genes and gene recombinants needed to minimise genetic vulnerability of all crops into the future, we would soon experience losses equal to or greater than those caused by southern corn leaf blight several years ago - at a rapidly accelerating rate across the entire crop spectrum". In the early 1970's the USDA presented a report which clearly revealed US dependence on genetic resources to protect its crops. The report noted, for example, that cucumbers now depend heavily upon introduction from Korea, Burma and India. Beans in the US contain disease resistance traits from Mexico, Spain, Turkey, Chile and El Salvador. Disease resistance in peas comes to North America from Peru, Iran, Turkey, Greece and Italy.

The United States, cognizant of this lack of resources, made a persistent effort from its early days to collect food and industrial crop germplasm. Through its systematic collection efforts, the US has been able to build its strength as the breadbasket of the world. However, the US needs genetic resources outside its territory to guard against pests and disease of its crops. Crop collection efforts of the US can be traced to the early 19th century. In 1818, US Secretary of Treasury directed all consular and naval offices abroad to collect seeds and plants that may be useful for American agriculture. The United States Department of Agriculture also played a major role in systematic plant collection efforts. By 1878, germplasm collection activity accounted for one-third of the USDA's annual budget. The USDA

28 Mooney, n. 19, p.3
29 Ibid., p.7
30 Ibid.
created the plant introduction office in 1898, thus formally institutionalising the global collection of plant genetic material.\textsuperscript{31} In what has been termed the "Golden Age of Plant Hunting" the USDA sponsored 50 expeditions to scour the world in search of new useful plant types in the first third of the 20\textsuperscript{th} century.\textsuperscript{32} As the following table indicates, the US has been able to gather resources from all over the world.\textsuperscript{33}

\begin{table}[h]
\centering
\begin{tabular}{|l|l|}
\hline
\textbf{CROP} & \textbf{MAIN SOURCES OF US GERM PLASM} \\
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Corn & Indigenous flints and dents, in situ development \\
Soybean & North and East China, Korea, Japan \\
Alfalfa & Chile, Germany, Russia, India, France, Peru, Egypt \\
Wheat & North Europe, India, Russia, Italy, Australia \\
Cotton & Mexico, Bahama Islands, Egypt \\
Tobacco & South America, West Indies \\
Sorghum & Egypt, Sudan, Natal, South Africa \\
Potatoes & Europe \\
Oranges & Arores, Brazil, in situ \\
Rice & Honduras, Japan, Philippines, Madagascar \\
Tomatoes & England, France, in situ \\
Peanuts & Spain, Brazil \\
Oats & Mexico, Uruguay, Russia, Australia \\
Barley & Mexico, Scotland, Germany, Russia, Balkans, Turkey \\
Sugar Beet & Europe \\
\hline
\end{tabular}
\caption{Source of US Germ Plasm*}
\end{table}


\footnotesize\begin{itemize}
\item \textsuperscript{31} Ibid.
\item \textsuperscript{32} Ibid, p.286
\item \textsuperscript{33} Ibid., Table 2.
\end{itemize}
US dependence on germplasm from developing countries, however, continues even today due to the need for genetic resources for biotechnology and for disease resistance. A State Department conference held in November 1981 known as the ‘Strategy Conference on Biological Diversity’, indicates the importance the US places on accessing germplasm from developing countries. Dr. Jim Murray of Chicago’s Policy Research Corporation stated at the conference, “The importance of biological diversity to the future of genetic engineering cannot be overemphasized. Germplasm is the fundamental resource....and developing countries will have an advantage in that they are the sources of a large percentage of the germplasm resources of the world.”34 He advised the US to negotiate with developing nations for access to the genetic resources.35

US, India and the International Genebanks

The genetic resource positions of US and India determine their relationship to the genebank system. Several authors have convincingly shown how the US benefited greatly from the system. To take just one example, Fowler and Mooney state, “The economic payoff to the North of access to CIMMYT (one of the IARCs) wheat germplasm is spectacular. The farmgate value of the US wheat crop in 1984, for example, was in excess of eight billion dollars. The American government’s own estimate is that CIMMYT material was responsible for almost two billion dollars of that value.”36

35 Mooney, n. 19, p. 286
36 Fowler and Mooney, n. 34, p. 183
India's experience with the genebank system is not as easy to judge. One of the IARCs, namely the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), was established in India in 1972. Indian germplasm has gone into many of the genebanks. The Green Revolution in India was spearheaded by HYV's (High Yielding Varieties) that were created at IRRI (an IARC in Philippines). Whether this was beneficial to India or not is still a point of debate. It is clear, however, that India began to understand that the genebanks actually caused a flow of resources from the South to the North. With evidence of this provided by several activists, India and other developing nations began to see the inequality of the system. In addition, the extension of patent protection in the US to products created from these resources, while considering the resources themselves to be "common heritage", was an anomaly that infuriated developing nations including India.

Intellectual Property Rights and Indigenous Knowledge

The "bio-piracy" debate also arises from the fact that indigenous knowledge is excluded from existing intellectual property systems. IPRs are available for products or processes that are derived from indigenous knowledge, but not for the original knowledge itself. Industrialized nations are able to take advantage of IPR laws for securing protection on industrial modifications of indigenous knowledge. Developing countries are at a disadvantage as they are rich in traditional knowledge but do not have the financial or technical capability to benefit from these resources. Developing nations accuse advanced nations of freely
appropriating traditional knowledge, and creating patentable products out of such knowledge. Industrialized countries dismiss the charge of "bio-piracy", claiming that they are not stealing any knowledge but rather spending huge amounts of money in researching and developing from this raw material. An analysis of the debate must begin with a study of why existing IPR laws are inapplicable to indigenous knowledge.

The aspect of IPR law that would be relevant here is biotechnology patent law. Patents are established to encourage innovation by granting a temporary monopoly to a new invention. Indigenous knowledge fails to meet the criteria set up for acquiring patents. Biotechnology patent law, however, provides scope for granting patents on industrial modifications of indigenous knowledge. It is common practice to grant patents for the development of processes to produce purified or synthesized compounds (chemicals or proteins) that have been isolated from natural sources.\(^{37}\) The following aspects of patent law establish this practice: 1) product of nature doctrine 2) novelty requirement 3) utility requirement 4) non-obviousness.

**Product of Nature Doctrine**

U.S. patent law does not contain a specific reference to the product of nature doctrine, but there is a longstanding prohibition against patenting products of nature. Indigenous knowledge, usually knowledge about the use of naturally occurring substances developed over generations, would be classified as

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unpatentable under the product of nature doctrine. However, industrial applications of indigenous knowledge could be patentable. A U.S. Congressional Research Report examining the issue states, "The first issue in determining whether traditional knowledge about the medicinal uses of plants and animals is patentable is whether it is the type of subject matter described by section 101. The central issue here is whether the traditional knowledge is merely the discovery of a product of nature. A patent applicant cannot obtain a patent for discovering a product of nature but may get patent protection for a process using the newly discovered product of nature. Unless a product which is the subject of a patent application is substantially different from the product as found in nature, that is, unless it is in a form not found in nature and thus the product of human invention, the product is unpatentable."38 Elaborating on the scope for patenting processes derived from traditional knowledge, the Report goes on to state, "A process producing a compound that is found in a product of nature could be patented if the process itself satisfied the requirements of U.S. law of being inventive, novel and useful, even though the product may not be patentable itself. A unique combination of known techniques may also constitute a patentable process. Even if there is a known process and a known product, and so the use of the known process to produce the known product actually yields a non-obvious result, the new use of the process is patentable."39

Novelty Requirement

39 Ibid., p. 55
Under U.S. patent law, an invention must be novel to be patentable. Novelty requires that the subject matter of the invention should not be known, used, patented or described in a printed publication. A substance can be considered novel even if it is available to the public, if the pure form of the substance is unavailable or the identity of the substance is previously unknown.40 Again this criterion acts as a bar to the patentability of native knowledge, but not as a bar on the patentability of a product isolated from natural substances.41 This is because the typical native remedy consists of the active substance in the form of a dilute, not a pure form of the substance.42 The Congressional Report reiterates, “The novelty requirements and related statutory bars alone would seem to bar patent protection for traditional knowledge. No individual applicant from the indigenous group could claim to have invented the subject matter himself, nor could he claim to be the first to invent, because the nature of traditional knowledge is that it has been passed on from generation to generation and that it may be known to more than one member of the group.”43

Nonobviousness Requirement

Section 103 of the U.S. Code provides that even if the invention is novel, it may not be patentable “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

40 Yano, n. 37, p. 460
41 Ibid.
42 Ibid.
43 Congressional Research Service Report, n. 38, p. 57
in the art to which the subject matter pertains." Prior art refers to the scope and content of existing sciences relevant to the invention. According to the CRS report, "Traditional knowledge presents unique problems in determining non-obviousness since it would be difficult to determine what the prior art might have been. Presumably the prior art would be knowledge that the indigenous people had prior to the invention, but since both prior art and claimed invention would be generations old, it would be difficult to determine at what point in time an indigenous group had acquired or developed a particular segment of knowledge." Non-obviousness would not prevent the isolation of the active ingredient from substances, as native people typically do not know the active substance.

**Utility Requirement**

In order to be patentable, an invention must be useful. In many cases this is interpreted as industrial utility. Traditional knowledge itself would not usually be considered useful under patent law, but a product or process developed from such knowledge may be thought to have utility. The interpretation of usefulness is defined by the needs of Western society, and does not include utility for indigenous communities.

Therefore, patent law precludes rewarding indigenous knowledge, but allows patents on industrial applications of this knowledge. This has led to the charge of "biopiracy". India and the US are two countries that have witnessed the

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45 Yano, n. 37, p. 456
46 Congressional Research Service, n. 38, p. 59
47 Yano, n. 37, pp. 460-61
most conflict on this issue. Three patents granted in the US have been the source of
the controversy. An examination of these cases clearly reveals the position of the
US and India on these issues.

Case Studies of the “Bio-piracy” Conflict Between the US and India

Neem, haldi and basmati are three substances found in India that have
been the source of the patent conflict between the US and India. A great deal of
confusion and misperception over these patents exists even today. It is clear,
however, that these patents have raised enormous controversy in India leading to
questions of sovereignty, nationalism and cultural factors. The relation of these
products to the cultural heritage of India raises issues beyond pure economic
analysis of the true impact of these patents. The three patents are analyzed in detail
below:

Neem

Neem is the most significant case in the issue of bio-piracy not only in
India but worldwide. It was the first patent case that raised large-scale protest.
Neem is a common tree in India that yields a variety of pesticidal, medicinal and
other uses.48 A patent issued in the United States utilizing neem became the target
of a public outcry against bio-piracy and the neem tree was the symbol of this
protest.

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(1997), p. 371
Known in Sanskrit as “sarva-roga nirvani” or the “curer of all ailments”, the neem tree has a variety of uses.\textsuperscript{49} Professor Heinrich Schumutterer, a zoologist from Germany, observed about neem, “It is such a versatile plant that many people doubt whether anywhere in the world there grows a tree more useful than the neem tree.”\textsuperscript{50} Various parts of the neem tree such as the branches, seeds, leaves and bark are commonly used by Indians all over the country. Farmers in India crush the neem seeds, soak them overnight in water and use the resulting solution as an effective pesticide. Scientists in India have documented the use of neem but it has not been widely patented in India due to the restrictions in Indian patent law.

Companies in industrialized nations have been quick to realize the industrial value of neem and capitalize on its market potential especially as an ecologically friendly bio-pesticide. The neem tree’s active substance, azadirachtine, is a selective insecticide, killing only certain species of pests, while sparing useful birds and insects.\textsuperscript{51} Over 53 patents have been granted in the US and Europe relating to neem.\textsuperscript{52} US corporations hold a majority of these patents. These patents cover industrial products or processes developed from neem and not neem itself in accordance with IPR laws that allow for patents on industrial inventions but not on a product of nature as such.

One specific patent relating to neem became the target of the bio-piracy protest that was launched in the mid-90s. The patent was one acquired in 1992 by

\textsuperscript{49} Ibid.
\textsuperscript{50} Antje Lehmann, “The Neem Tree: Ingredients for Ecological Insecticides”, \textit{Journal}, (Germany), (n.d.), p. 30
\textsuperscript{51} Ibid.
\textsuperscript{52} “What’s In a Neem?”, \textit{Down to Earth}, (March 15, 1996), p. 28

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W.R. Grace, a company based in the United States.\textsuperscript{53} The patent covered a method of extracting the active ingredient in neem, known as azadirachtin, and stabilizing it for longer shelf life. Over 200 organizations from 35 countries launched a legal battle against W.R.Grace's patent, granted on June 23, 1992 by the United States Patent and Trademark Office (USPTO).\textsuperscript{54} In September 1995, this global coalition led by Jeremy Rifkin of the Foundation of Economic Trends in Washington, D.C. and Vandana Shiva, a well-known activist in India, filed a petition in the USPTO requesting a re-examination of the patent. Other key petitioners included: Dr. M.D. Nanjundaswamy of Karnataka Rajya Ryota Sangha, a farmer's organization in India; Linda Bullard, Vice-President of the International Federation of Organic Agriculture Movements in Brussels; and Martin Khor, Director, Third World Network.\textsuperscript{55} The petition claimed that Indian farmers had been using neem as a pesticide for centuries and Indian scientists had documented the use of neem as far back as 1928 so there was nothing novel in Grace's patent. Rifkin, speaking of Grace's patent, stated, "Any chemist worth his salt could have come up with it."\textsuperscript{56}

The petition claimed that the patent is barred by prior art. According to the petition, "the patent should be overturned because the company's method of extracting stable compounds has been widely used prior to the patent's issuance and because the extraction methods have been previously described in printed publications. Although W R Grace's processes are more technical, they are mere

\textsuperscript{53} "Patents on Native Technology Challenged", \textit{Science}, (Washington, D.C.), vol. 269, (September 15, 1995), p. 1506

\textsuperscript{54} Ibid.

\textsuperscript{55} "More than 200 organizations from 35 nations challenge US patent on neem", \textit{Third World Resurgence}, (Malaysia) vol. 63 (November 1995), p. 22

\textsuperscript{56} "Grace's Patent On a Pesticide Enrages Indians", \textit{The Wall Street Journal}, (September 13, 1995)
extensions of the same processes that Indian villagers have been using for hundreds of years." The petition claimed that the patent was obvious. It stated that, "W R Grace merely appropriated the knowledge and wisdom generated by other individuals. Thus, even if there no references that make claims identical to those of W R Grace, the combined teachings of the prior art makes W R Grace's patent obvious."

W.R. Grace did not dispute the fact that the original knowledge of neem comes from India. Rather, their claim to an invention was that they had found a way to increase the shelf life of the pesticide from a few weeks to a few years. Grace's critical chemistry steps, according to the company, enabled packaging and wide distribution of the pesticide. The patent therefore was not on discovering the use of neem as a pesticide, but the invention of stabilizing it for longer storage. Grace acquired the product from Robert Larson, a timber exporter, who sold the rights to the pesticide to Grace in 1988. Grace began marketing the product as Margosan-O in 1992 and entered into a joint venture with an Indian company to produce storage stable neem pesticide.

With the filing of the petition in the US Patent Office against the patent, there were widespread debates worldwide on the issue of bio-piracy. The following chart sums up the arguments that were made for and against the patent:

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57 Third World Resurgence, n. 55, p. 23
58 Ibid., p. 24
Indian farmers have been using neem as a pesticide for centuries. There is nothing novel in the patent. Knowledge of neem is from India but the novelty of the invention is that it increases the shelf life of the neem pesticide.

The patent will lead to an increase in neem seed prices, will affect the availability of neem seed and drive small farmers of the land. The patent does not prevent Indian farmers from using neem the traditional way. The patent may help India by leading to export of neem. Grace only uses a small percentage of neem seed.

The patent will have to be granted in India after India changes its laws to conform with TRIPs. The patent does not give the company a monopoly on neem. Several others have patents relating to neem and even India has three.

The US Patent Office dismissed the petition noting that under US patent law Grace’s work was an invention and an improvement over what existed in nature. A Congressional Research Service Report for Congress entitled, “Biotechnology, Indigenous Peoples, and Intellectual Property Rights”, explaining the neem patent stated, “One example of the product of nature issue as it applies to traditional knowledge is the seed of the neem tree, including the species Azadirachta indica and melia azadirachta. Neem seeds have been used as a pesticide in India for hundreds of years. The neem seed itself is not patentable because it is a product of nature. Similarly, the mere knowledge that neem seeds are effective pesticides is not patentable by anyone. Also, the method of scattering ground neem seeds as a pesticide would not be a patentable process, because this process has been known and practiced for centuries and likely would be deemed obvious. However, patents have been granted for (1) extracts from pre-treated neem bark shown to be
effective against certain cancers (2) neem-seed extracted azadirachtin in a stable storage form and (3) azadirachtin-derived insecticides which have greater stability than the naturally occurring form of azadirachtin. Azadirachtin itself is a natural product found in the seeds of the neem tree and it is the significant active component. There is no patent on it, perhaps because everyone recognizes it as a product of nature. But, as mentioned above, a synthetic form of a naturally occurring compound may be patentable, because the synthetic form is not technically a product of nature, and the process by which the compound is synthesized may not be patentable. Thus, the laboratory-synthesized derivative of azadirachtin, which was more stable and easier to store and therefore more useful than the naturally occurring azadirachtin was considered patentable by the Patent and Trademark Office.  

It further added, “Although traditional knowledge inspired the research and development that led to these patented compositions and processes, they were considered sufficiently novel and different from the original product of nature and the traditional method of use to be patentable.”

The upholding of the patent by the USPTO led to further resentment and opposition among developing nations on the issue. In India, there was widespread protest against the theft of neem by US corporations. The bio-piracy debate was launched with the neem issue. Vandana Shiva asserts, “While it is repeatedly claimed that the neem itself or its parts cannot be patented, the patent claims in effect cannot exist without the neem or its properties. There is no product or process based on neem which does not depend on the intrinsic properties and

59 Congressional Research Service Report, n. 38, p. 54
60 Ibid., pp. 54-55
principles of neem itself."\textsuperscript{61} She claimed, "The free tree is no more free".\textsuperscript{62} In addition, there was also speculation on why Indian scientists had not been able to acquire such patents. V.P. Sharma, director Malaria Research Centre, Delhi, stated, "Part of the blame for foreign companies patenting neem products has to be taken by our own country. People have been using neem for centuries here but we (the scientists) have not been protecting the rights of our people over neem. It is not that our scientists never worked on it. But generally, our whole approach has been different. So far, the stress of our scientists has been wholly on research; commercial aspects have stood ignored or discouraged."\textsuperscript{63}

\textit{Haldi}

The haldi patent is a significant case in the "bio-piracy" conflict. Unlike the neem dispute, India was able to successfully challenge the haldi patent in the U.S. and get the patent revoked. The Indian government, under pressure from the public who was outraged at the neem debacle, was actively involved in challenging the patent. When the Indian government was able to win the case, it projected it as a major victory for India.

Haldi or turmeric is a plant in India with medicinal properties. Turmeric (curcuma longa) is a plant of the ginger family.\textsuperscript{64} The yellow powder or paste from the dried root of the turmeric plant is routinely applied to scrapes and cuts to help

\begin{footnotes}
\textsuperscript{61} Vandana Shiva, \textit{Intellectual Piracy and the Neem Patents}, (New Delhi, 1993), p. 10
\textsuperscript{62} Ibid., p. 6
\textsuperscript{63} Down to Earth, n. 52, p. 30
\end{footnotes}
wounds heal faster. It is also widely used in cooking in all Indian homes. Haldi is an important remedy in traditional Ayurvedic medicine since antiquity. Turmeric usage dates back to 4,000 years, to the Vedic culture in India, when turmeric was the principal spice and also had religious significance.

On March 28, 1995 two researchers from the University of Mississippi Medical Center acquired a patent (US Patent No. 5,401,504) on the process of using turmeric as a healing agent in the US.65 The patent holders, Mr. Suman K. Das and Mr. Hari Har Cohly, two Non-Resident Indians, said they were familiar with the traditional use of turmeric but that the patent was granted because they had clinically tested it and proven its effectiveness.66 The patent made the following claims67:

1. A method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient.

2. The method according to claim 1, wherein said turmeric is orally administered to said patient;

3. The method according to claim 1, wherein said turmeric is topically administered to said patient;

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4. The method according to claim 1, wherein said turmeric is both topically and orally administered to said patient;

5. The method according to claim 1, wherein said wound is a surgical wound;

6. The method according to claim 1, wherein said wound is a body ulcer.

The Council of Scientific and Industrial Research (CSIR), an Indian government scientific body, after getting information of the patent, was quick to inform the Indian public that they would challenge it. A CSIR spokesman explained to the Indian press in July 1996 that the patent would be challenged.\textsuperscript{68} CSIR’s intellectual property management division head, Mr. Subbaram, pointed out that the patent should not have been granted because the “invention” lacked novelty as its use as a traditional medicine was well known in India.\textsuperscript{69} On October 28, 1996, CSIR challenged the patent and filed for re-examination in the United States Patent Office, asking for complete cancellation of all six claims of the patent.\textsuperscript{70} CSIR gathered documents to prove that knowledge of the wound healing properties of haldi had been documented in India. It was pointed out that as far back as 1953 the wound healing properties of turmeric were reported in the Journal of the Indian Medical Association by scientists who had tested it in King George’s Medical College in India.\textsuperscript{71}

After CSIR presented the evidence, the US Patent Office ruled on August 13, 1997 that the invention was not patentable. All the six claims of the patent

\textsuperscript{68} Times of India, July 5, 1996
\textsuperscript{69} Ibid.
\textsuperscript{71} Times of India, July 5, 1996
were rejected by the US Patent Office under 35 U.S.C. 102 (b) and 35 U.S.C. 103 (a) of the US patent statute.72

The cancellation of the patent was perceived as a great achievement in India. The CSIR claimed, "This is a significant development of far-reaching consequences for the protection of the traditional knowledge base... which has been an emotional issue not only for the people of India, but also for those of other Third World countries".73 Pointing out the "far-reaching consequences", the CSIR elaborated that, "This appears to be the first case where the use of traditional knowledge base from a third world country, patented through a US patent, has been successfully challenged with the USPTO, leading to complete cancellation. Earlier efforts made by several interested groups to challenge the neem patent were not even entertained for admission by the US Patent Office. This success story strongly sends signals that if patent cases are fought on well-argued and well-supported techno-legal grounds, then there is nothing to fear about protecting our traditional knowledge base. This case also demonstrates that CSIR and other Indian institutions are now acquiring capabilities to fight the complex techno-legal issues of IPR, both defensively and aggressively, to meet the challenges under the WTO regime." According to Mashelkar, director-general of CSIR, "This success will enhance the confidence of the people and help remove fears about India's helplessness in preventing bio-piracy and appropriation of inventions based on traditional knowledge."74

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72 Rediff, n. 65.
73 Ibid.
74 Ibid.
The haldi case also evoked strong criticisms of the US patent system in India. Suman Sahai of the Delhi-based Gene Campaign declared that the government should use the turmeric case to “press the North to reform its own laws governing intellectual property rights, instead of pressuring the South to change its laws.”\textsuperscript{75} Vandana Shiva, an activist on the issue, claimed, “examples of bio-piracy make it clear that it is not just Indian patent laws that need to be changed. The American laws also need to be changed to fit into a fair and honest global Intellectual Property Rights system.”\textsuperscript{76} The specific aspects of the US patent law that were labeled as being faulty included the fact that the US discloses a patent only after it is granted, and the distinction between domestic prior art and foreign prior art in the US. The first provision means that in the US there is no scope for opposing patents before approval, as in India and other countries. This also makes it extremely difficult to gather information about the patents that would be granted. For example, there are still other patents on turmeric existing in the US. A recent search of relevant databases revealed nine patents relating to haldi.\textsuperscript{77} The second provision means that prior foreign activity can be used to invalidate a patent only when it is found in a printed publication (or some tangible form), or in another patent.\textsuperscript{78} Prior foreign knowledge, use and invention are all excluded from the prior art related to a U.S. patent application.\textsuperscript{79} However, prior knowledge, use or invention within the United States can be used as evidence to invalidate a

\textsuperscript{76} Ibid., p. 7
\textsuperscript{77} Pradesh, n. 64.
\textsuperscript{78} Kadijal, n. 48, p. 379.
\textsuperscript{79} Ibid.
Thus any attempt to file for re-examination of a patent on the grounds that there exists prior foreign knowledge must include printed evidence. The fact that much of traditional knowledge is passed on orally and is not recorded makes it difficult to fight such patents. The US patent system has also been criticized for being very expensive. The amount of money India had to spend on the case, for example, was pointed out as being unnecessary.

The United States Patent Office admitted that the turmeric patent was a mistake, but it was also quick to point out that the case revealed that there was a mechanism for correcting errors. Linda Lourie, legal counsel for the USPTO, stated that the turmeric patent was an embarrassment and a mistake. However, it showed that the USPTO can respond and that a re-examination process exists.

**Basmati**

The basmati case has raised an enormous amount of protest in India. While the opposition in the neem and haldi patents came mainly from non-governmental organizations, in the basmati case Indian industry is also involved. This is because basmati is a major export crop for India. The Indian government has also voiced its interest in ensuring that the patent is revoked. An inter-ministerial group composed of the Ministry of Commerce, Ministry of Agriculture, Industry, Department of Biotechnology, CSIR and Agricultural and Processed Food Products Export Development Authority (APEDA), was constituted as soon as the patent came to light to work out the modalities of defeating the patent.

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80 Ibid., p. 371
81 Interview with Linda Lourie, Attorney-Advisor, USPTO, January, 1999
82 Ibid.
83 *Hindustan Times*, March 1, 1998
Basmati meaning “queen of fragrance” or “fragrant earth” is a slender, aromatic, long grain rice grown in India and Pakistan. The earliest record of the word ‘Basmati’ is found in the classic love story from Punjab, Heer Ranjha, written by Waris Shah in 1766:

“The store rooms are full of the fragrant rice
These have been dehusked and winnowed
Basmati, Musafari and Begami are there
Harichand has turned these into Zarida”

Unlike haldi or neem, however, basmati is an important export commodity for India. Over 80% of the basmati grown in India is exported. India exports about half a million tons of basmati to the Middle East, Europe and the US, and 10% of India’s basmati exports go to the US. Basmati rice exports are valued at $ 200 million per year.

RiceTec, a company based in Texas, USA, acquired a patent on basmati on September 2, 1997 from the US Patent Office. Patent no. 5,663,484, was granted for “Basmati rice lines and grains”, and states, “The invention relates to novel rice lines and to plants and grains of these lines and to a method for breeding these lines. The invention also relates to a novel means for determining the cooking and starch properties of rice grains and its use in identifying desirable rice

RiceTec claimed to have created a superior variety of basmati. RiceTec's invention was developing a variety of basmati rice that could be grown in North, Central and South America, whereas until now basmati could only be grown in India and Pakistan.

Widespread protest followed in India against the granting of the basmati patent. Rice exporters became especially vociferous on the need to defeat the patent. Mr. Ramu Deora, President of Federation of Indian Export Organizations said, "India has been the largest exporter and grower of this rice for more than 50 years and the country has already suffered quite a lot on the overall exports front. This setback cannot be tolerated at all." (Asian Age, Calcutta, February 17, 1998).

All India Rice Exporters Association (AIREA) president Gurnam Arora pointed out the impact of the patent on exports in an interview with The Economic Times (March 9, 1998), "Though the next two-three months may be fine, in the long run India will definitely have serious problems in positioning its rice. If action is not taken at the appropriate time, matters will soon reach a point where Indian exports of $ 500 million high-value rice will just disappear." He further noted, "Basmati belongs to the nation." Rice exporters, farmers, NGOs and industry associations all voiced their opposition to the patent. Farmer's lobbies and other organizations held a huge demonstration in front of a US office in New Delhi in July 1998 against RiceTec's patent. Hundreds of angry farmers gathered in New Delhi to protest against the patent. "We have not done enough to protect our treasures of this country", said Jaya Jetley, general secretary of the Hind Mazdoor Kisan

http://www.uspto.org, Patent no. 5,663,484
Panchayat, who participated in the demonstration. (Dawn, April 4, 1998). ASSOCHAM chief Mr. Lakshman stated that the US patent violates the geographical clause under TRIPs (The Economic Times, Calcutta, February 19, 1998).

While the Indian government claims that it will file for re-examination and have the patent revoked, RiceTec has voiced surprise at the controversy the patent has generated in India. Robin Andrews, CEO and President of RiceTec speaking of the outburst in India said, "This whole flap is totally unnecessary, and has happened only, I believe, because of the laws we have in the United States which allow companies to protect their inventions. RiceTec invented a way to produce basmati rice in the United States comparable to the best basmati grown in India and Pakistan and we have received a patent to protect our breeding methods and seeds." He asserted that the patent does not give the company the right to call its rice "basmati" and that RiceTec did not use genetic transformation or biotechnology to create the rice.

India and Pakistan are attempting to launch a joint front against the patent. In their fight, however, they will face tough opposition from RiceTec which would try to dispute the argument that basmati applies specifically to a single variety of rice grown in India and Pakistan. RiceTec claims basmati is a generic term, whereas India says it is a term which is specific to rice grown in India and Pakistan. US Patent Office spokesperson Paula Coute explained that "There's more than one kind of basmati grown in India. We granted RiceTec a patent for a

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88 http://amseed.com/documents
89 Ibid.
‘cultivar’ of basmati rice” (The Economic Times, Calcutta, February 14, 1998). RiceTec’s strain had the same qualities as Basmati, but according to her, “it’s slightly different so we gave them a patent on the genetic improvement” (The Economic Times, Calcutta, February 14, 1998).

The Agricultural Products Export Development Authority (APEDA) of India are engaged in ten other cases involving Basmati rice. Of these India has won one in Greece where RiceTec has been barred from registering its produce under the trademarks Texmati, Kasmati and Jasmati. In fact the Basmati patent case came to light only in February 1998, when APEDA was gearing up to fight RiceTec’s trademark application in the UK. RiceTec’s strategy of patenting the rice is therefore part of its attempt to make a strong bid to capture the niche market of Basmati rice where India and Pakistan have had a monopoly. Basmati has been an important foreign exchange earner and in recent times has been doing particularly well in the world market. RiceTec’s motive is to penetrate the market through the proliferation of names around the word ‘mati’ and thus creating confusion in the world market, particularly in Europe. India’s position in the trademark cases will influence the patent issue.

The following table outlines positions of RiceTec and India on the basmati patent conflict:

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90 Shastri, n. 86, p. 66
91 Lexis-Nexis, Emerging Markets Datafile, Business India, April 20, 1998
92 Ibid.
93 Ibid.
94 Ibid.
India is keen on defeating the patent, but is not sure of the strategy to adopt. Various lobbies in India are exerting pressure on the government to take up the challenge. Vandana Shiva of the Research Foundation, a prominent NGO, filed a case in the Indian courts to compel the government to act on the issue. Several strategies have been suggested such as:

1. The case is a trademark issue and the strategy must be to prove that Basmati is not a generic term and ensure that RiceTec cannot call its rice Basmati

2. India should challenge the novelty of the patent

<table>
<thead>
<tr>
<th>RiceTec’s View</th>
<th>India’s View</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basmati is a generic term. Renowned Indian rice breeder Siddiq has also referred to it as such.</td>
<td>Basmati is not a generic term. It is a specific term referring only to rice from India and Pakistan. The reference to Siddiq’s article has been misconstrued by the US</td>
</tr>
<tr>
<td>Novelty resides in the patent because the rice is superior to regular Basmati and RiceTec has invented a means of growing this rice in America</td>
<td>Scientists in the ICAR and CSIR challenge the novelty of the patent</td>
</tr>
<tr>
<td>The patent does not give RiceTec the right to call its rice Basmati, but there is no restriction against using the term</td>
<td>RiceTec should not have the right to call its rice Basmati</td>
</tr>
<tr>
<td>RiceTec is a small company and there is no fear of dominating the market. The rice is labeled “American style” basmati rice so there is no confusion</td>
<td>RiceTec will be able to mislead consumers through use of terms like Basmati, Kasmati, and will be able to dominate the market</td>
</tr>
</tbody>
</table>
3. India must pass a bill on geographic appellations bill taking advantage of the clause in TRIPs to ensure that products like Basmati are treated like French Champagne (i.e., they are recognized as belonging to a particular region)

In the basmati case, the Indian government has been unable to chalk out a clear cut strategy of defeating the patent. Inspite of the enormous public opinion that exists in India and the consensus across political parties on the issue, the Indian government has not been able to take action. The legal intricacies of the case are daunting, yet the government must take advantage of the variety of farmer’s lobbies, industry concerns and non-governmental organizations that have reacted strongly against the patent. The United States is able to use legal technicalities to promote its view. But narrowing the issue only to legalities evades other serious concerns. The United States is adopting legal arguments to suit its interests, ignoring the inequalities that exist in its IPR regime. The Indian government must be pro-active in pointing out such inconsistencies while framing its position in cases of “bio-piracy”.

The Basmati patent has fueled enormous controversy in India. The fear has been raised that several products that originate from India such as Alphonso mangoes or Darjeeling tea may be subject to such patents in future. The Indian government has been criticized heavily for not protecting India’s interests. In addition, severe opposition against US patent laws have been voiced.

India's rich biological diversity and cultural heritage are factors that shape India's response to the issue of biopiracy. India's concern with development and economic growth have played a major role in the biopiracy debate. Cultural factors have also played a role. Each of the three products that have caused the conflict—
neem, haldi and basmati—have enormous significance in India. The rise of a nationalistic oriented political party in India has also fostered the feeling of Indian heritage and pride being insulted by such patents. Indian activists have been able to make a strong case that US patent policies are encouraging a theft of Indian resources and culture. Several influential lobbies in India are demanding that laws be implemented in India to prevent biopiracy and recognize "traditional knowledge".

The US position on the issue is strongly influenced by its biotechnology industry. US interests in maintaining a lead in the field have led demands for greater protection of biotechnological inventions. Access to genetic resources is an important consideration of the US biotechnology industry as these are the raw materials of the research. The demand for eco-friendly products has also fueled the quest for traditional knowledge and resources. The US wants to ensure that this industry can contribute to US competitiveness in the world economy and recognizes that resources or knowledge found in developing nations may be a valuable resource. The US does not view patents utilizing traditional knowledge or resources as biopiracy but rather as instruments to reward and encourage the development of important products. Research conducted on such resources by biotechnology companies may lead to cures for diseases like AIDS and other developments that would be beneficial for both developing and developed countries. The raw material for these may be found in developing nations so such patents should be allowed. US argues that such patents in no way restrict traditional uses of the products, nor cause any economic loss to developing nations.