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## Gene Hunters in Search of "Disease Genes" Collect Human DNA from Remote Island Populations

**Issue:** In recent months, RAFI has learned that scientists and their corporate partners are collecting DNA samples from remote island populations in the South Atlantic, Micronesia and the east China sea. These are just a few examples of the people who are being targeted in the race to identify, patent and commercialize human disease genes.

**Impact:** Genomic companies and scientists are committing acts of genetic biopiracy and, in the process, violating the fundamental human rights of the people from whom DNA samples are taken.

**Action:** In response to these and other acts of biopiracy, indigenous peoples of the Pacific have called for a life-forms patent-free zone. RAFI calls on the Council for International Organizations of Medical Sciences, the World Health Organization and other inter-governmental bodies that address regulations governing human genetic research to reconvene and address urgently issues of patenting, commercialization, and expropriation of human genetic material. RAFI is launching a campaign to take the issue of life patenting to the International Court of Justice at the Hague.

### Introduction--The Gene Rush

Previous issues of the *RAF Communique* have reported on the astonishing growth of the new "genomic industry"—private companies that are racing to identify and commercialize human genes and their products. (See "Gene Boutiques Stake Claim to Human Genome," May/June 1994 and "The Patenting of Human Genetic Material," January/February 1994). In the closing years of the 20th Century, there is a silent but reckless "goldrush" underway with incalculable stakes for humankind. A handful of genomic companies and their pharmaceutical partners are rushing to privatize human genes and their products. The commodity they seek to exploit is not gold, but biological information. The raw material they need is human DNA: the blueprint of human life.<sup>1</sup>

### One-Stop Shopping for Genes

"Bio-informatics" is a new word in the English vocabulary that describes the business of the

genomic companies. It refers to the use of proprietary, high-tech computer methods for collecting, editing, analyzing and storing DNA sequence information. Incyte Pharmaceuticals, for example, a genomic company based in California, describes itself as both a biotech company and a software company, with the ability to collect vast volumes of biological information in a proprietary database. Access to their private genome database is sold to giant pharmaceutical companies such as Upjohn and Pfizer. Incyte calls it "one-stop shopping for genes."<sup>2</sup>

### The Language of Genomics: Commodification of Life

One genomic company whimsically refers to human DNA as "the most complex computer program of all time."<sup>3</sup> The genetic make-up of a human being is referred to as "our biological machinery." In the world of commercial biotechnology, human life is

reduced to nothing more than an industrial commodity. This practice is legally enforced when corporations receive patents on human genes and their products.

RAFI's search of patent databases reveals that more than 100 human cell lines are currently the subject of patent claims in the United States. Nobody knows for sure how many human genes have been patented, but one company estimates that the U.S. Patent and Trademark Office has issued more than 1,250 patents on human gene sequences.<sup>4</sup>

The technological breakthroughs are being made at an astonishing rate. Incyte claims that it has already identified 35,000 unique genes—roughly one-third of the human genome. The company claims that it has the capacity to process 3,000 genes per day. In 1994 alone, Incyte quadrupled its sequencing capacity. By the end of 1995, Incyte expects that its proprietary database will "contain sequences for a broad spectrum of cell and tissue types, and a representation of most human genes."<sup>5</sup> In 1994, Incyte announced that it had applied for patents on over 40,000 cDNA templates. The company's vice-president told *Bio/Technology Magazine* "...we want to protect all our sequences as far as possible."

### **Staking Claim to Human Disease Genes**

One of the hottest new techniques for identification of the so-called "disease genes" is the use of "positional cloning." Scientists believe that it will accelerate the process of identifying disease genes within the next few years.<sup>6</sup> This approach does not depend on large-scale sequencing of random DNA fragments with unspecified correlation to disease. Instead, the positional cloning method begins with direct genetic analysis of families who are affected by a specific disease. In other words, to find disease genes, scientists must have access to DNA from "well-characterized" populations of individuals who are "carriers" of an inherited trait—be it breast cancer, baldness, obesity, Type II diabetes or asthma. By analyzing inheritance patterns of DNA markers from individuals who are affected by a particular disease, it is easier to isolate the most likely location of the disease gene. This is followed by rapid mapping of the implicated region and intensive analysis to pinpoint abnormalities in the gene sequence.

### **Gene Hunters in Search of "Disease Genes" Collect Human DNA From Remote Island Populations**

In recent months, RAFI has learned that scientists and their corporate partners are collecting DNA samples from remote island populations in the South Atlantic, Micronesia and the East China Sea. These are just a few examples of the people who are being targeted in the race to identify and patent human disease genes. Kevin Kinsella, the CEO of Sequana Therapeutics explains the excitement surrounding the race to discover the so-called "disease genes" to the San Diego Union-Tribune:

*"Of all the tools in the armamentarium of modern gene discovery, none is potentially more powerful than that of having the disease gene in hand...We can now find the genes for the common complex disorders that affect the majority of people in Western countries."*<sup>7</sup> —Kevin Kinsella, CEO, Sequana Therapeutics

While the emotional appeal of Mr. Kinsella's statement is undeniable, the issue is far more complex and controversial. No matter how socially desirable the goal may seem at first glance, genomic companies and scientists are committing acts of genetic biopiracy and, in the process, violating the fundamental human rights of the people from whom DNA samples are taken. In all likelihood, the people who are targeted by scientists and corporate gene hunters are giving DNA samples (blood, hair, tissue) willingly, under standard regulations of "informed consent." Most of them do so with a general understanding that they are making a contribution to science that may someday improve the human condition. They are NOT informed that products derived from their DNA, or information gleaned from it, will be patented and commercialized, nor that they will lose control of their genetic material once it is removed from their bodies. Consider the following case study:

### **In Search of the Asthma Gene**

In September, 1994 Sequana Therapeutics, a genomic company based in California, announced that DNA samples extracted from nearly all of the 300 inhabitants of an isolated island in the South Atlantic may give the company the information they need to locate, identify and eventually patent the gene or genes that predispose people to

asthma.<sup>8</sup> The company obtained the DNA samples through its collaboration with the Samuel Lunenfeld Research Institute of Mount Sinai Hospital in Toronto, one of Canada's premier biomedical research facilities. The blood samples were collected in 1993 by Canadian scientists associated with the Institute. The genetics of asthma research is supported by Zeneca pharmaceutical corporation.

The people of Tristan da Cunha, virtually all of whom are descendants of the island's seven original families, exhibit one of the highest incidences of asthma in the world (30% of the population suffers from asthma and another 20% are asthma prone.) Two or three of the island's original settlers were known to have suffered from asthma. For researchers who are hoping to identify the gene or genes that cause asthma, the isolated and closely-related population of Tristan da Cunha provides the ideal target for genetic research.

Tristan da Cunha is a tiny, isolated island of 117 sq. km. located halfway between Brazil and South Africa. It was settled by British settlers and ship-wrecked sailors in the early 1800s. Today the island is a self-governed, British protectorate. Tristanians earn their living from lobster fishing and subsistence farming, and selling the island's much sought-after postage stamps. In 1961, worldwide attention was focused on tiny Tristan da Cunha when a volcano erupted there and the inhabitants were temporarily evacuated to England. Virtually all of them returned to Tristan after the danger had passed.

In 1991, researchers from the University of Toronto's Genetics of Asthma Research Group first proposed to take blood samples from all the residents of Tristan da Cunha. But the islanders were not eager to participate. According to University of Toronto researcher, Patricia McLean, it took two years for the researchers to convince the island's inhabitants to participate in the programme.<sup>9</sup> After being subjects of scientific inquiry in England nearly 30 years ago, "they wanted no part of being guinea pigs again," McLean told *Biotech Business*.<sup>10</sup> It was the island's resident physician, provided by the British government, who finally convinced the people of Tristan to participate in the study. Permission was granted by the Tristan's Island Council.

In 1993, Patricia McLean and Noe Zamel, Canadian scientists from the Samuel Lunenfeld Research Institute in Toronto, made the long journey to Tristan da Cunha and spent three and one-half weeks on the island. On the very last day of their visit, the researchers spent 8 continuous hours taking blood samples from 272 of the 295 Tristanians.<sup>11</sup> The scientists returned to Canada with some 1,200 blood samples stored in ice-packed coolers.

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It was not until the following year that Sequana Therapeutics announced a collaboration with the Samuel Lunenfeld Research Institute of Canada, and DNA samples from the people of Tristan da Cunha were turned over to the company. According to scientists at Lunenfeld, Sequana has in-house technology (automatic DNA sequencer) that will speed-up identification of the asthma gene. Founded in January, 1993, Sequana is a private company whose mission is to "to discover the genes involved in widespread human diseases and to apply these discoveries to the development of novel diagnostic and therapeutic products."

Sequana has already completed the initial genome-wide scan of the Tristan families' DNA, which consists of markers placed along all of each Tristanian's chromosomes. The high-resolution genetic map has already been analyzed by Sequana to detect the common genetic regions inherited by Tristan's asthma sufferers. By concentrating on these regions, the company hopes to pinpoint the genetic mutation that predisposes the people of Tristan da Cunha to the disease. Scott Salka, Sequana's Director of Operations, says that the company has "made tremendous progress" in locating the precise location of the so-called asthma gene.<sup>12</sup>

#### Patent Pending?

If Sequana is successful in identifying the mutant gene or genes, it will file for patent claims immediately. According to Salka, any patent application filed by the company would be made in Sequana's name, with sharing of economic benefits with the Lunenfeld Institute in Canada. When RAFI asked Salka if it is too early for his company to have made patent claims on the asthma gene, he responded quickly, saying, "I wouldn't say that."<sup>13</sup>

Salka would not elaborate further. Since patent applications filed at the U.S. Patent and Trademark Office are not made public until they are issued, there is no way to confirm whether or not patent applications have been made.

Will inhabitants of Tristan da Cunha benefit from the discovery of the asthma gene? University of Toronto scientist, Patricia McClean, explains that the Canadian researchers made an agreement to leave their lung-functioning equipment on the island following their departure. This gives the islanders the technology they need to assess their asthmatic condition before treatment.

### Wanted: Human DNA

The people of Tristan da Cunha represent only one of many populations that have been targeted or who have already provided raw material for human DNA research. The following are just a few examples:

Sequana, for instance, has established relationships with health maintenance organizations (institutional health care providers) and academic investigators to gain access to "large, accurately diagnosed patient populations" for genetic linkage analysis and positional cloning. In addition to the collaboration with the Lunenfeld Institute as suppliers of DNA from Tristan da Cunha, the company has established collaborations with Kaiser Permanente of Northern California (for access to patients who have Type II diabetes), Shanghai First People's Hospital, the Foundation for Osteoporosis Research and Education (osteoporosis), and the Pacific Bariatric Surgical Medical Group (obesity).

Last year, the asthma researchers from Lunenfeld Research Institute traveled to a small island off the coast of China, Nantian, located in the East China sea to take blood samples from a 150-member, 4 generation family that suffers from asthma. It is not clear whether these DNA samples will go to a private company, or be used by Lunenfeld researchers.

Rockefeller University researchers in New York City announced on December 1, 1994 the discovery of the mouse obese gene and its human homologue. Discovery of the so-called "obesity gene" will generate fat profits for the patent holders. Although the patent has not yet been granted, Amgen (a biopharmaceutical company based in California) has already agreed to pay Rockefeller

University \$20 million up-front for the licensing rights to the gene, plus milestone payments that could total \$90 million. Rockefeller University scientist Jeffrey Friedman told *BioWorld Today* that it is still necessary to show that the protein expressed by the *ob* gene functions as a hormone that regulates the amount of fat stored in the body.<sup>14</sup> To further their research, the Rockefeller group has begun to study the genetics of inhabitants of Kosrae, an island in the Federated States of Micronesia in the South Pacific. The incidence of obesity in the population of Kosrae is reportedly very high.

In 1993, the CEO of Sequana Therapeutics told *Biotechnology Newswatch* that his company is also looking for a human population, such as the Pima Indians of Arizona who have a high incidence of obesity and diabetes, to screen for human obesity genes.<sup>15</sup> RAFI has not confirmed whether or not blood samples were taken from the Pima Indians.

In the mid-1980s, Japanese researchers took DNA samples from the Huilliche people of Chiloe, an island off the coast of Chile.

### Call for Action

There is an urgent need for an international protocol to protect the rights of human subjects from patent claims and unjust commercial exploitation. The widespread concept of "prior informed consent" currently contains no provision for informing individuals that their DNA or a product derived from it may become a marketable commodity, or that someone stands to profit if a commercial product is someday developed from their DNA. And there is no provision for "no intention of consenting"—the unconditional right of all individuals and/or communities to deny access to their genetic material.

Issues of national sovereignty are also at stake. When the U.S. government applied for patents on the human cell lines of indigenous peoples from Panama, the Solomon Islands and Papua New Guinea, U.S. Secretary of Commerce Ron Brown dismissed the protests of national governments, indigenous peoples and NGOs by asserting that "Under our laws, as well as those of many other countries, subject matter relating to human cells is patentable and there is no provision for considerations relating to the source of the cells that may be the subject of a patent application."<sup>16</sup>

The issues of genetic expropriation, patenting, and commercialization of human DNA can no longer be ignored in regulations governing biomedical and human genetic research. The concept of "informed consent" must include information about the researcher's intent to patent or commercialize human DNA, and (in the case of human cell lines) disclosure and permission to "immortalize" an individual's DNA. Permission to export genetic material out of the country must also be obtained

The Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization, most recently revised its "International Ethical Guidelines for Biomedical Research Involving Human Subjects" in February, 1992. However, the area of human genetic research does not receive special mention in the guidelines. The CIOMS steering committee "considered that since there is not universal agreement on the ethical issues raised by these research areas it would be premature to try to cover them in the present guidelines."<sup>12</sup>

RAFI calls on the Council for International Organizations of Medical Sciences and inter-governmental bodies that oversee regulations governing human genetic research to re-convene and address urgently the issues of patenting and commercialization of human genetic material. It is interesting to note that the ethical guidelines governing research on human subjects prohibit large payments of money or in-kind contributions to research subjects because it could "undermine a person's capacity to exercise free choice and invalidate consent."<sup>13</sup> This is sound reasoning. But in the midst of widespread commercialization and patenting of human genetic material, this position becomes supremely ironic and hypocritical. Isn't the orientation and integrity of researchers similarly distorted and invalidated when they seek to patent and commercialize the human DNA that they are collecting from research subjects around the world? The contradictions are undeniable. Ultimately, human genetic material must be held outside of the patent system.

Life patenting is a conflict that requires global resolution. To that end, RAFI is preparing to launch a campaign to take the issue of life patenting to the International Court of Justice in The Hague, Netherlands. Global civil society can intervene through a competent UN agency or persuade

sovereign states to request an advisory opinion from the Court. An opinion by the International Court of Justice could have ramifications for GATT-TRIPs, the Biodiversity Convention and the World Intellectual Property Organization, ultimately requiring a societal review of the entire intellectual property system and its UN conventions. At the very least, a campaign to take the issue of life patenting to the International Court of Justice is a means of mobilizing public opinion and engendering a political debate at the highest and most visible judicial level. RAFI welcomes the partnership of interested NGOs, indigenous peoples organizations, and national governments in developing and promoting this campaign.

## Indigenous Peoples Assert their Intellectual Integrity

In June 1993, the First International Conference on the Intellectual and Cultural Property Rights of Indigenous Peoples was organized by the Maori Congress, in Aotearoa (New Zealand). It was certainly not the first time that indigenous peoples had discussed intellectual property, but it gave momentum to discussions that were occurring in many places, and brought the weight of many discussions together. Its concluding statement, the Mataatua Declaration, has since received widespread support from the international indigenous community, with signatories from indigenous peoples from over 60 countries.

Later in 1993 RAFI completed a study for the United Nations Development Programme (UNDP), on how indigenous peoples might be affected by new global debates surrounding biodiversity and intellectual property rights. In August 1994, *Conserving Indigenous Knowledge: Integrating Two Systems of Innovation* was published by the UNDP in English and Spanish. The report documents two related trends: one toward patenting of living organisms; and the other toward "piracy" from the South of biological resources and indigenous knowledge about them—for commercial uses in the North. RAFI asserts that intellectual property rights—then being negotiated by GATT, and newly enshrined in the Biodiversity Convention—are a new mechanism for the North to control biological resources and related indigenous knowledge from the South. RAFI's report suggested some alternatives and strategies for the consideration of

indigenous peoples, and proposed that the UNDP fund several gatherings where indigenous peoples from different continents could consider these issues, and develop strategies to confront them.

Parallel to these events, RAFI and Swiss Aid were unearthing information about patent claims on the cell lines of indigenous peoples (see RAFI Communiqués "Patents, Indigenous Peoples and Human Genetic Diversity," May, 1993 and "Patenting of Human Genetic Material," Jan./Feb., 1994). Concern and protest was mounting around the world about life patenting in general, and the patenting of human genetic material in particular. Indigenous people were among the most vocal critics of human patenting, seeing themselves the "targets" of research and the unwitting subjects of corporate patent claims.

The UNDP immediately took up RAFI's recommendation for regional workshops. It proposed the idea to indigenous peoples' organizations in Latin America, Asia and the Pacific, and ultimately agreed to fund three events—to be planned and run by host organizations in each region. RAFI was invited as "international consultant" to each of these meetings, where our work was complemented by that of regional consultants who reviewed the regional context, relevant experiences, and legislation. With our Southern counterparts, we tried to provide enough information for delegates to discuss the issues, and facilitate the development of responses.

The first workshop was held in Santa Cruz de la Sierra in Bolivia in late September 1994. Organized by COICA, the Coordinating Body for Indigenous Peoples' Organizations of the Amazon Basin, it brought together 35 indigenous leaders from 12 countries in Central and South America.

The second workshop was held in Tambunan, Sabah, East Malaysia in February 1995—organized by Philippines-based SEARICE, and PACOS (Partners of Community Organizations of Sabah). It too had about 35 participants—indigenous representatives from 12 Asian countries.

The final meeting in the Pacific was coordinated by the Pacific Concerns Resource Centre in Suva, Fiji. It was held in April 1995, with 25 indigenous participants from 14 Pacific countries.

The participants came from dramatically varied contexts, and though there were marked differences

between the three gatherings, all were remarkable in their success, and consistent in their conclusions. At all three meetings, participants stressed the connection between biodiversity, indigenous knowledge and intellectual property, on the one hand, with cultural survival, land, and self determination on the other.

*"I am really shocked by this information we are hearing [about patenting of living things]. It is almost unbelievable. But I have a comment. We must not focus only on 'biodiversity' and knowledge, because we are talking about much more than that. We are really talking about our whole worldview, our cultures, our lands, our spirituality as indigenous peoples. These are all linked. We must look at the whole picture" — Stella Tamang, Federation of Nationalities, Nepal, at Asian Consultation/Workshop*

Each concluded that the intellectual property systems of the industrialized world were alien to indigenous peoples. While all three groups made short-term proposals to defend themselves from exploitation, all recognized the need for longer term strategies which would take as their starting point indigenous cultures, legal concepts and notions of knowledge and innovation.

*"A system of protection and recognition of our resources and knowledge must be designed which conforms with our worldview and contains formulas that, in the short and medium term, will prevent the appropriation of our resources by the countries of the North and others." (Excerpt from the Final Statement, Indigenous Peoples, Biodiversity and Intellectual Property, Santa Cruz de la Sierra, Bolivia, 30 September 1994.)*

All three conferences expressed the need for policy measures to protect indigenous peoples from "biopiracy", and all committed themselves and their organizations to a programme of education, research and action—including actions to make indigenous people heard at international discussions in the year ahead.

*"Indigenous peoples are willing to share our knowledge with humanity, provided we determine when, where and how it is used. At present the international system does not recognize or respect our past, present and potential contributions." (Excerpt from the Final Statement, South Pacific Consultation on Indigenous Peoples Knowledge and Intellectual Property Rights, Suva, Fiji, April 1995)*

Participants at all three conferences declared their opposition to patenting of living organisms. Fortuitously, the Sabah meeting concluded on the eve of the European Parliament's (EP) vote on life patenting. Outraged by information that cell lines of people from Panama, Papua New Guinea and The Solomon Islands had been claimed by the US government in patent applications, the Asian conference sent a strong statement to members of the European Parliament, just hours before the vote in Brussels. In their statement, participants opposed patents on all living things, and made particular reference to patenting of human cell lines. At a critical moment, Asian indigenous people thus added their voice to many others from around the world. On March 1, the European Parliament voted against the bill. (See update below.)

### **Indigenous Peoples Call for Life-forms Patent-Free Zone in the Pacific**

In Fiji, participants went a step further. They resolved to take matters into their own hands, and to "initiate the establishment of a Treaty declaring the Pacific region to be a life forms patent-free zone." More specifically they agreed to:

- Include in the Treaty protocols governing bioprospecting, human genetic research, 'in-situ' conservation by indigenous peoples, 'ex-situ' collections and relevant international instruments.
- Issue a statement announcing the Treaty and seeking endorsement by the South Pacific Forum and other appropriate regional and international fora.
- Urge Pacific governments to sign and implement the Treaty.
- Implement an educational awareness strategy about the Treaty's objectives.

The Pacific Concerns Resource Centre is now in the process of drafting the Treaty, which they intend to complete by August of this year.

Similarly, the Fiji conference called for a moratorium on bioprospecting in the Pacific and urged indigenous peoples "not to co-operate in bioprospecting activities until appropriate protection mechanisms are in place."

#### ***For further information:***

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RAFI's report, "Conserving Indigenous Knowledge: Integrating Two Systems of Innovation," is available in Spanish and English, published by the United Nation's Development Programme. To receive a free copy, write: UNDP, Bureau for Policy and Programme Support, One United Nations Plaza, New York, NY 10017.

## **Life Forms Patent Update**

### **European Parliament Kills Biotech Patenting Directive**

On March 1st the European Parliament rejected legislation aimed at removing all barriers to the patenting of life forms in the European Union. The proposed legislation, defeated by a vote of 240 to 188, with 23 abstentions, would have introduced common standards for the patenting of plants, animals and human genes. European NGOs,

supported by a broad coalition of development and environmental NGOs worldwide, battled for seven years to defeat the directive.

The European Parliament's rejection of the patent directive does not however abolish life patenting in Europe. The European Patent Office (EPO), which has granted numerous patents on genetically engineered plants, animals and human genetic material, is not affected. Nevertheless, the Parliament's vote sends a clear and forceful message that life patenting is unacceptable and that civil society demands consideration of the social, ethical and moral implications of life patenting. The campaign against life patenting will now focus on challenging and amending patent laws at the national level, at the EPO, and ultimately, at the World Trade Organization (WTO).

### **Indian Parliament Rejects Patent Amendment Bill**

As a signatory to GATT, the Indian government is obliged to bring the Indian Patent Act of 1970 into line with the requirements of GATT's Trade Related Intellectual Property Rights (TRIPs) agreement of the WTO. On 7 March, India's Upper House of Parliament deferred indefinitely a patent amendment bill that would have forced the Indian government to grant patents on all life forms, their parts, characteristics and products. The patent amendment bill stands in stark contrast to the Indian Patent Act of 1970, which excluded product patents in pharmaceuticals and agriculture in the interests of Indian society.

### **Landmark EPO Ruling Restricts Plant Patents**

In March, the Appeals Board of the European Patent Office ruled that a patent granted to Plant Genetic Systems (PGS) in 1990 for a genetically engineered herbicide-tolerant rapeseed is too broad, and does not cover the plants and seeds resulting from the process. The ruling is critically important because it means that patent claims on genetically engineered plants do not extend to plant varieties, seeds and future generations of plants.

The EPO ruling stems from Greenpeace's challenge that the PGS claim constitutes a patent on a variety, and was therefore inadmissible under Article 53b. Although plant varieties are excluded from patentability under the terms of the European Patent Convention, this is the first time the EPO has restricted a patent from covering a specified

plant. The EPO's decision is expected to have a major impact on future patent claims for both plants and animals. While biotech companies may continue to claim patents on the process for manipulating plant cells and the inserted genes, they cannot now assume that their claim extends to seeds or further generations of plants.

### **Religious Leaders in the United States Condemn Patenting of Life**

On 13 May the *New York Times* announced that more than 80 religious leaders were preparing to issue a declaration against the patenting of human and animal genes as a violation of the sanctity of life. The coalition of church leaders, including mainstream Protestant denominations, evangelical Christian, Catholic, Jewish, Muslim, Hindu and Buddhist faiths is petitioning the U.S. Patent and Trademark Office to overturn its 15-year policy of granting patents for human and animal genes. The churches' vocal opposition to life patenting is key to a successful campaign against life patenting. Unfortunately, the coalition's initial declaration opposing the patenting of life failed to include plants. The religious leaders' declaration arises from organizing work undertaken by the Foundation for Economic Trends, a Washington, D.C.-based policy NGO.

### **No Patents on Life Coalition Meets in United States**

In early June, RAFI joined a coalition of NGOs from North America and around the world at a meeting in the Adirondack Mountains of New York to plan strategies for opposing life patenting. Among other activities, the coalition gathered to plan educational programmes, as well as legal and legislative challenges to life patenting. The NGOs concluded that the patenting of life is morally unacceptable, fundamentally inequitable, and technically unworkable.

### **Human Genome Organization Confirms Support for Patents--Releases Statement on Patenting of DNA Sequences**

The Human Genome Organization (HUGO) is an international membership organization whose goal is to coordinate and enhance efforts in genome research. It is also the parent organization of the Human Genome Diversity Project, the controversial project that proposes to "immortalize" human DNA collected from more than 700 indigenous communities around the world. If there were ever



any doubt about HUGO's position on patenting, it is now crystal clear.

The February 2nd issue of *Nature* reports on a meeting of leading genome scientists in Paris that concluded "the patent system is 'the mechanism of excellence' for commercializing the results of the human genome project."<sup>19</sup> The genome scientists concluded that commercialization of the human genome "does not require reinventing the internationally proven, 200-year-old patent system, but simply adapting it."<sup>20</sup>

HUGO recently released a 15-page statement expressing concern about the patenting of partial and uncharacterized cDNA sequences. The statement was issued in response to growing controversy surrounding attempts by government and industry to file patent claims on thousands of human gene sequences without determining their biological function or application. (For background, see RAFI Communique, "The Patenting of Human Genetic Material, January-February, 1994.)

HUGO is not against the patenting of human DNA, but against the patenting of partial DNA sequences based on sequencing efforts that are "increasingly mechanical and straightforward." The HUGO statement concludes:

"It would be ironic and unfortunate if the patent system were to reward the routine while discouraging the innovative. Yet that could be the result of offering broad patent rights to those who undertake massive but routine sequencing efforts—whether for ESTs or for full genes—while granting more limited rights or no rights to those who make the far more difficult and significant discoveries of underlying biological functions."

Copies of the HUGO statement are available from: HUGO Americas, 7986 Old Georgetown Rd., Bethesda, MD 20814 USA, fax: 301 652-3368, e-mail: hugo@gdb.org

### **Biotechnology Company Receives Broad U.S. Patent Covering Modified B.t. Genes in Plants**

On January 10, 1995 the U.S. Patent and Trademark Office issued a broad patent (Patent No. 5,380,831) to Mycogen, a California-based biotech company, covering any method of modifying *Bacillus thuringiensis* (Bt) genes to make them resemble plant genes. B.t. is a naturally-occurring

microbe that expresses a toxic protein when ingested by insects. It is the most widely used source of natural insect resistance in crop genetic engineering.

The patent is extremely broad in scope because it covers the method all agricultural biotechnology companies now use to modify Bt genes to genetically engineer crop plants with built-in protection from insect damage. According to Mycogen, "All insect-resistant transgenic plants now under commercial development have used the synthetic Bt gene technology that this patent now covers." (Mycogen press release, 11 January 1995).

According to *Biotech Reporter*, February, 1995, Mycogen intends to keep exclusive patent rights for proprietary B.t. on maize and cotton. In "non-strategic" crops such as soybeans, rice, wheat, vegetables, etc., Mycogen intends to license rights to the synthetic B.t. gene method. According to Mycogen, the first generation of B.t., insect-resistant transgenic plants developed with the gene synthesizing method before the patent issued on January 10, 1995 will be able to proceed with commercialization. Plants containing synthetic B.t.'s developed after that date, could infringe the patent.

Mycogen claims that it holds the industry's "strongest and broadest portfolio of intellectual property assets for Bt-based crop protection and pest control."<sup>21</sup> In addition to the United States, the same broad patent has been issued to Mycogen in Australia, New Zealand, South Africa, Taiwan, and the European Patent Office. Mycogen's patent is pending in the following jurisdictions: Argentina, Canada, China, Japan, Korea, Russian Federation and Ukraine.

### **Genetic Privacy Act Introduced in the United States**

In the United States there is growing concern about "genetic discrimination"—the use of genetic information to deny people their basic civil rights. Insurers, for example, are demanding access to the genetic profiles of people seeking health, life and disability insurance. Employers are using genetic information to determine terms of employment or advancement. Existing genetic databanks maintained by hospitals and health insurers have no regulations to ensure confidentiality of the genetic information they contain. As a result, individuals from whom DNA samples are taken

lose control over their own genetic material once it is removed from their body.

In response to these abuses, the U.S. Human Genome Project's Ethical, Legal and Social Issue Working Group has drafted a proposed federal statute governing collection, analysis, storage, and use of DNA samples and the genetic information obtained from them. Under the act, anyone who collects a DNA sample (e.g. blood, saliva, hair, or other tissue) for genetic analysis would be required to:

- provide specific information verbally prior to collection of the DNA sample;
- provide a notice of rights and assurances prior to the collection of the DNA sample;
- obtain written authorization
- restrict access to DNA samples to persons authorized by the sample source;
- abide by the source's instructions regarding maintenance and destruction of DNA samples.

The overarching premise of the act is that no stranger should have or control identifiable DNA samples or genetic information about an individual unless the person from whom the sample is taken, specifically: 1) authorizes the collection of DNA samples for analysis and the creation of genetic information; and, 2) retains access to and control over its dissemination.

The Genetic Privacy Act moves far beyond current guidelines in the United States, requiring that researchers disclose to the individual who provides a DNA sample of his/her intention to patent or commercialize material that could be derived from the genetic material. According to one of the authors of the proposed legislation, the Act does not cover U.S. researchers working outside of the United States, but would include tissue samples that end up in the United States and stored in the American Type Culture Collection, for example.<sup>22</sup>

The Act has been introduced into six state legislatures in the United States, but has not yet been introduced in the U.S. Congress.

<sup>1</sup> DNA is the chemical structure that forms chromosomes. Chromosomes are self-replicating and contain all the inherited genetic information in the of genes that are the blueprint for every protein.

<sup>2</sup> Incyte Pharmaceuticals, 1994 Annual Report, p. 12.

<sup>3</sup> Incyte Pharmaceuticals, 1994 Annual Report, p. 5.

<sup>4</sup> Human Genome Sciences, Inc., 1993 Annual Report, p. 12.

<sup>5</sup> Incyte Pharmaceutical, 1994 Annual Report, p. 7.

<sup>6</sup> Nature Genetics [9(4), 347-50 (April, 1995).

<sup>7</sup> Rose, Craig D., "Race is on to stake claims to our DNA," San Diego Union Tribune, September 11, 1994.

<sup>8</sup> Sequana Therapeutics, Press Release, September 21, 1994, "DNA from Residents of the 'Loneliest Island' May Provide Key to the Genetics of Asthma."

<sup>9</sup> Personal communication with Patricia McClean, May, 1995.

<sup>10</sup> McClean is quoted in *Biotech Business*, December, 1994, V. 7, No. 12.

<sup>11</sup> Personal communication with Patricia McClean, May, 1995.

<sup>12</sup> Personal communication with Scott Salka, Sequana Therapeutics, May, 1995.

<sup>13</sup> Personal communication with Scott Salka, Sequana Therapeutics, May, 1995.

<sup>14</sup> Leff, David, 1994. "Just-Discovered Obesity Gene Points to (Distant) Future Slimming Therapy," *BioWorld Today*, Vol. 5, No. 232, December 1.

<sup>15</sup> *Biotechnology Newswatch*, July 19, 1993.

<sup>16</sup> Letter from U.S. Secretary of Commerce, Ronald H. Brown to the Ambassador to the Solomon Islands, March 3, 1994.

<sup>17</sup> "International Ethical Guidelines for Biomedical Research Involving Human Subjects," Prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization, Geneva, 1993, p. 7.

<sup>18</sup> "International Ethical Guidelines for Biomedical Research Involving Human Subjects," Prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization, Geneva, 1993, p. 19.

<sup>19</sup> "Patent System Gets Vote of Support from Gene Workers," *Nature*, Vol. 373, 2 February, 1995, p. 376.

<sup>20</sup> *Nature*, Vol. 373, 2 February, 1995, p. 376.

<sup>21</sup> Mycogen Corporation, 1994 Annual Report, p. iii.

<sup>22</sup> Personal communication with Dr. George Annas, Boston University School of Public Health, one of the authors of the Genetic Privacy Act.

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