Freeing the Free Tree. A Briefing Paper on the Neem Biopiracy Case

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- Winning against genetic engineering [1]

Freeing the Free Tree

A BRIEFING PAPER on the FIRST LEGAL DEFEAT OF A BIOPIRACY PATENT: The Neem Case

Research Foundation for Science, Technology and Ecology, New Delhi, India
The Greens/European Free Alliance in the European Parliament
International Federation of Organic Agriculture Movements

by Linda Bullard, March, 2005

Legal history was made on March 8th, 2005 in Munich, Germany when the Technical Board of Appeals of the European Patent Office (EPO) revoked in its entirety a patent on a fungicide made from seeds of the Neem tree, concluding a ten-year battle in the world’s first legal challenge to a Biopiracy patent.

THE NEEM TREE

The botanic name of the Neem Tree is Azadirachta indica, which is taken from the Persian name for the tree, Azad-Darakth, meaning "the free tree". The tree is a member of the mahogany family and is indigenous to the Indian subcontinent. Over the past century it has been introduced and now flourishes in many countries of Africa, Central and South America, the Caribbean and Asia. Neem trees are attractive tropical evergreens that can grow up to 30 meters tall and 2.5 meters in girth. Their spreading branches form rounded crowns as much as 10 meters across, and they may live for more than two centuries.

It is in India that the tree is most widely used. It is mentioned in Indian texts written over 2000 years ago and has been applied for centuries in agriculture as an insect and pest repellent, in human and veterinary medicine, toiletries and cosmetics. It is also venerated in the culture, religions, and literature of the region. India has freely shared its "free tree", and knowledge of its myriad uses with the world community; but now, through the patent system, this important resource is becoming the private property of a few corporations.

THE NEEM PATENTS

Sixty-five patents for products derived from the Neem tree have been filed with the EPO to date, of which 22 have been granted, 28 are "dead", for various reasons, and 9 are currently being examined. These include claims for insecticides, fungicidal effects, methods of extraction, storage stable formulations of one of the active ingredients, azadirachtin, contraceptives, and medical uses. Although some Indian companies have claimed patents on the Neem, they are outnumbered 2 to 1 by multinational corporations, such as the U.S. pharmaceutical company Rohm and Haas and the infamous agrochemical giant W.R. Grace.1

It is important to note that none of the Neem patents do not involve a genetically engineered product; neither has the tree itself been patented, nor any of its parts.

THE NEEM TREE AND BIOPIRACY
The Neem patents are resulting in major financial gains for their so-called owners, while the communities which first understood the Neem's uses and shared this knowledge with the rest of the world will not be compensated at all. The Neem patents are just one in a large catalogue of genetic resources originating in the South over which intellectual property rights are being asserted by a few multinational corporations originating, for the most part, in the North. The Northern patent system was not equipped to recognise or reward as inventive the products of community innovation processes such as those which created the various uses of the Neem today. It is only when these uses are described in the terms of Western science and technology that an "invention" is deemed to have taken place and an individual "inventor" or a set of individual "inventors" is allowed to be rewarded with the monopoly property rights that a patent confers. This is the mechanism through which a massive transfer of biological and intellectual wealth is taking place--from the "Third World" to the North.

One direct impact of the corporate monopoly on the Neem made possible by the patent system is a staggering increase in the companies' demand for seed. The fungicide claimed in the USA/Grace patent cannot be produced without naturally-occurring Neem seeds. A processing plant set up by Grace in India can handle 20 tons of seed per day. Almost all the seed collected which was previously freely available to the farmer and healer is now purchased by the company, causing the price of Neem seed to skyrocket beyond the reach of the ordinary people. Neem oil itself, used for lighting lamps, is now practically unavailable, as the local oil millers are not able to access the seed. Poor people are losing a resource vital for their survival a resource that was once widely and cheaply available to them.

In an effort to combat the injustice of Biopiracy there were attempts to introduce a mechanism for "prior informed consent" into the EU Directive on "Legal Protection of Biotechnological Inventions". But this highly controversial legislation was finally enacted in July 1998 without any of the proposed protective measures built in. Transposition of this Directive into national law has proved complicated, however, and the European Commission is late in producing a mandated report on its functioning. Another focus of attention has been the Convention on Biological Diversity (CBD), the aim being that this international legal instrument require its Parties to ensure that patent applications involving biological resources identify the source of the material and provide measures for prior informed consent of the communities so identified. Vast NGO energy was also directed at TRIPs (Trade-Related Intellectual Property Rights), the multilateral agreement on patent regimes which formed part of the original General Agreement on Tariffs and Trade (GATT). But the most direct approach to fight these Biopiracy patents in Europe was to actually oppose one within the legal system which granted it and thereby attempt to create case law.

CHRONOLOGY OF THE CASE

On December 12, 1990 the multinational agribusiness corporation W.R. Grace of New York and the United States Department of America as represented by its Secretary of Agriculture, filed a European Patent Application with the European Patent Office (EPO) on the basis of a U.S. priority application of December 26, 1989, covering a method for controlling fungi on plants by the aid of a hydrophobic extracted Neem oil. This was the third application for a Neem-derived product which had been filed by W.R. Grace.

After a very difficult and controversial examination procedure, the grant of a European patent for this application was published on September 14, 1994, with the number 436257, the main claim having been restricted by the EPO to:

"A method for controlling fungi on plants comprising contacting the fungi with a neem oil formulation containing 0.1 to 10% of a hydrophobic extracted neem oil which is substantially free of azadirachtin, 0.005 to 5.0% of emulsifying surfactant, and 0 to 99% water".

Nine months later a Legal Opposition to this patent was filed jointly by three "plaintiffs".: Magda Aelvoet, MEP, then President of the Green Group in the European Parliament, Brussels, Dr. Vandana
Shiva, on behalf of the Research Foundation for Science, Technology, and Natural Resource Policy, New Delhi, India, and the International Federation of Organic Agriculture Movements (IFOAM), based in Germany and represented by its future President, Linda Bullard. The three partners consciously chose to oppose this particular patent in part because of who its "proprietors" were: They wished to illuminate how governments of wealthy countries "in this case the United States " and multinational corporations "in this case the infamous W.R. Grace (whose exploits are chronicled in the book and movie "A Civil Action".) "collude to steal biological resources from the south by means of the patent system. It is also not by accident that these particular three Opponents joined forces to launch the Opposition: an organization from the country where the resource was stolen, an international organization representing organic users and producers of Neem products throughout the world, and an environmental political party, well positioned to pursue changes in the legal system itself to outlaw Biopiracy. And from within these organizations it was women who initiated the action and sustained it "an Indian, a Belgian, and an American.

Although the Opponents filed the original Opposition without benefit of legal representation, they soon afterwards authorized Prof. Dr. Fritz Dolder (Professor of Intellectual Property, Faculty of Law, University of Basel, Switzerland) to represent them, and he functioned in that capacity for the ten years it took to bring the case to a close.

The Opponents claimed that the fungicidal effect of hydrophobic extracts of neem seeds was known and used for centuries on a broad scale in India, both in Ayurvedic medicine to cure dermatological diseases, and in traditional Indian agricultural practice to protect crops from being destroyed by fungal infections. Since this traditional Indian knowledge was in fact ubiquitous in Indian culture from ancient times, they asserted that the patent in question lacked two basic statutory requirements for the grant of a European patent, namely "novelty". (Article 54 of the European Patent Convention [EPC] and "inventive step". (EPC Article 56, in the U.S. called non-obviousness).

In addition, the Opponents charged that the patent was contrary to "morality" Article 53 (a) of the EPC, because the so-called inventors claimed monopoly property rights on a method which forms part of the traditional knowledge base of India "in essence stealing it "and theft is regarded as immoral in European culture. Finally, they cited the formal grounds of "insufficient disclosure". (EPC Article 83) and "lack of clarity". (EPC Article 84) in calling for the revocation of the patent.

Subsequently, the Opponents requested an additional ground for opposition, namely that the patent constituted de facto a monopoly on a single plant variety, which is barred by Article 53 (b) of the EPC.

It took five years for the case to come before the Opposition Division of the EPO. During this period the Opponents submitted evidence and affidavits gathered to support the claims they had made in the initial Opposition. Finally an Oral Proceeding was scheduled on May 9th and 10th, 2000, before the Opposition Division of the EPO in Munich.

At midday on the first day of the hearing demonstrators gathered in front of the EPO building holding banners reading "No Patents for Theft" and carrying signs representing all the European patents which had been granted or were pending on the Neem. A 2-metre tall Neem tree was symbolically "freed" from patents for public use by a delegation of scientists and farmers from India and Sri Lanka. They then presented to a representative of the EPO packages of signatures of 100,000 Indian citizens demanding that all patents on the Neem be revoked.

To support the substance of its case, the Opponents had brought two expert witnesses from India: Dr. Udai Pratap Singh of Varanasi (Professor and Head Department of Mycology and Plant Pathology, Institute of Agricultural Sciences, Banaras Hindu University) and Mr. Abhay Dattaray Phadke of Puna (Managing Director of Ajay Bio-Tech (India) Ltd.). Dr. Singh is widely regarded as India's greatest expert on Neem from the scientific community. Mr. Phadke is an agronomist and had commercialized a Neem product in India (without claiming patent protection), following a development phase and extensive field trials with farmers. Interestingly, Mr. Phadke had once worked for Rhone-Poulenc and had proposed that they commercialize the Neem product; however, that company declined, judging that it would never be
possible to obtain a patent on such a product, which would make it commercially uninteresting to produce. He also personally provided samples of his Neem fungicide, called "Neemark" to W.R. Grace.

The patentees first attempted numerous manoeuvres to have the Opposition declared inadmissible on procedural grounds "claiming, for example, that since there were three Opponents, they should have paid three Opposition fees (never mind that the two "proprietors" had paid only one Application fee), or that the fee had not been paid in time, or that the non-European Opponent was not duly represented at the time of filing the Opposition. However, one after the next, the Opposition Division found in favor of the Opponents on all the procedural questions, leaving the room each time to confer, and then returning to announce their decision and resume the proceedings.

Then the first witness was called, Mr. Phadke. His testimony was lengthy, extraordinarily detailed, supported by a great deal of documentation, and absolutely crushing. Dr. Singh was not allowed to be present during the hearing so as not to influence his testimony. For a day and a half he waited patiently in the hall outside for his turn to testify, but was never called, as sufficient evidence to overturn the patent was supplied by the first witness.

At the end of Mr. Phadke's testimony, the Opposition panel ruled that the patentee's claim of novelty had been destroyed on the basis of clearly demonstrated prior public use. According to Dr. Dolder, it is difficult and quite rare to defeat a patent on the basis of novelty, but here it happened. At that point it could have been all over, but the lawyers for USA/Grace submitted an "auxiliary request", which amended their Neem formulation slightly, so that it fell just outside the parameters described by Mr. Phadke: The concentration of Neem oil contained in the preparation was now specified as 0.25% ONLY, no more, no less. In practical terms, this altered claim would have been useless to the patentee, because the percentage was so narrowly defined that it actually no longer constituted a monopoly (in other words, it would have been very easy for a competitor to avoid infringing the patent). Nonetheless, this amended claim was immediately examined, and this time the Opposition Division ruled that even in amended form, the "invention" was lacking an inventive step. Thus, the patent was revoked in its entirety.

The panel had not found in favor of the Opponents on their charge that the patent constituted a de facto monopoly on a single plant variety or that it was a violation of "public order and morality." On the other hand, they accepted the Opponents argument that patents should not be granted for common traditional knowledge, but pointed out that this argument should be used for establishing "prior art" and is not a question of morality in the sense of the European Patent Convention.

The USA and W.R. Grace appealed to the next level within the EPO, the Technical Appeals Board, demanding that the decision of the Opposition Division be overturned and submitting yet another modified formulation of their original claim.

Five more years of deadlines and submissions ensued before the case once again reached the level of an Oral Proceeding at the EPO. In the meantime, W.R.Grace transferred its patent rights to a daughter company, Thermo Trilogy, which had begun as a research group within W.R. Grace and then became Grace Biopesticides Division before being sold. Thermo Trilogy specialized in so-called "biorational". pesticides. In 2001 Thermo Trilogy's assets, including its patents, were acquired by Certis, a wholly-owned subsidiary of the Japanese company Mitsui & Co., which is now one of the largest providers worldwide of "safe food" technologies. Throughout these business mutations, the United States of America has remained the constant "coproprietor" of the patent.

Although two days had been set aside to examine the Appeal, the case was so compelling that the Technical Board of Appeals needed only two hours to reach its decision. It had earlier declined to hear Mr. Phadke again, or Dr. Singh, although the work of both was referred to during the proceedings. The patentees had renewed their attempts to have the case declared inadmissible on procedural grounds, but the panel did not even discuss these questions. A second "auxiliary request". amending the formula of the product was refused on the grounds that it enlarged the scope (Article 123(2)). Then the main
body of the patent was examined with regard to novelty, disclosure, and inventive step. After hearing the Opponents’ arguments, the Board went into closed conference to come to a decision.

Shortly after 11 a.m. on March 8th, the Chairman announced, "The Appeal is dismissed. The patent is revoked". The Board did not explain the grounds for its decision, but it may be assumed that the reasoning of the Opposition Division was upheld, that the patent did not satisfy the requirements for novelty and/or inventive step. A written decision which does provide the grounds for the decision of the Board will be sent to both parties. In any event, the United States and Thermo Trilogy have no further recourse on this particular patent: It is irrevocably revoked.

JURISPRUDENCE

The Neem patent challenge now becomes part of case law within the European patent regime and will hopefully have an impact not only on the Neem patent applications which are still pending, but also on ALL Biopiracy patents which have been filed in the EPO. It is important to note that the case was won on the basis of affidavits and testimony, and that the intellectual achievements of traditional societies were recognized officially as a means to establish "prior use":

"Moreover, the opposition division agrees with the Opponents that no patents should be granted for anything which was known previously, for example as part of common traditional knowledge [emphasis added]. However, under the EPC this is not a matter of Article 53(a) EPC, but is a question of novelty or prior public use".

Revocation of the Neem patent shows that it is possible to defeat Biopiracy, but doing so will require that this historic precedent be further developed and transposed into overarching international legal frameworks. The revocation has no direct effect, for example, on Neem patents in other legal regimes. However, following the final ruling of the EPO, the "Ad-hoc Open-ended Working Group on Access and Benefit-sharing" of the Convention on Biological Diversity (CBD) invited the Opponents in the Neem case to submit their experience regarding "the occurrence, nature, extent and cost of misappropriation of genetic resources [, deriva-tives] and associated traditional knowledge". The immediate interest shown by the Working Group is an encouraging sign that the precedent set by the defeat of this Neem patent can be fed into other binding international treaties and legal instruments.

THE NEEM CAMPAIGN

The Neem Patent challenge was initiated in solidarity with the Neem Campaign of India, which was launched in 1993 by farmers in India who feared that their genetic resources and traditional knowledge were coming increasingly under foreign control through the legal mechanism of patents. They likened what they were experiencing to a modern form of "enclosure of the commons". "but in this case it was not public land being privatized but rather public knowledge. The idea for the case was born at a meeting of social/environmental activists in Malaysia in 1994. The next year Magda Aelvoet and Linda Bullard travelled to India at the invitation of Vandana Shiva to speak to NGOs, government authorities and the press about the issue of Patents on Life, European and international patent law, and the Neem patent challenge, which they filed two months later.

In addition to the three "plaintiffs", who filed the Legal Opposition to the patent, the following organizations were listed as associating themselves with and supporting the action: Karnataka Rajya Raitha Sangha (India); Third World Network (Malaysia); the Green Group in the European Parliament (EU); the European Coordination No Patents on Life! (Switzerland); Rural Advancement Fund, International (Canada); Cultural Survival Canada (Canada); the Cultural Conservancy (USA); the Edmonds Institute (USA); Institute for Agriculture and Trade Policy (USA); Washington Biotechnology Action Project (USA); Rio Grande Bioregions Project (USA). A broad coalition of other European NGOs also supported the Opponents materially, physically, and morally.

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All legal documents connected with this case are available for inspection by the public on the Web Site of the European Patent Office in the "epoline". section: Enter the Publication Number 0436257.

For further information, contact the offices of the Opponents:

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The lawyer for the Opponents, Dr. Fritz Dolder, is also available for questions at fritz.dolder@unibas.ch [5]

1 A list of all the Neem patent applications at the European Patent Office and their current status has been compiled by Dr. Ruth Tippe and is available from Kein Patent auf Leben! (rtippe@keinpatent.de [6])


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