

INDIAN-US NEEM PATENT DISPUTE

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INTRODUCTION

This is a landmark case of biopiracy and a major win for India, protecting the centuries-old uses of the legendary Neem tree and establishing the importance of documentation of indigenous knowledge. Following an 11-year-long dispute, the European Patent Office upheld the revocation of a patent on the fungicidal properties of Neem oil granted to the US Department of Agriculture and a multinational.

The legal opposition to this patent, which resulted in its eventual revocation, was filed by the Research Foundation for Science, Technology and Ecology (RESTE), based in New Delhi, in collaboration with the International Federation of Organic Agriculture Movements (IFOAM) and a former Green Member of the European Parliament (MEP), Magda Aelvoet. Every part of the Neem tree, including its leaves, flowers, bark and seeds, has been used to treat a myriad of ailments ranging from diabetes, skin issues and ulcers to leprosy since time immemorial. In addition, it contains a potent chemical named azadirachtin, extracted from the seeds, which is used as an astringent in numerous fields. Ancient Indian ayurvedic texts were presented as evidence by the respondents which described and established how the hydrophobic extracts of Neem seeds were known and used for centuries in India, both in curing dermatological diseases in humans and in protecting agricultural plants from fungal infections. The patent was revoked in its entirety by the EPO on the grounds of lack of novelty, inventive step and established state of the art.

BRIEF FACTS OF THE CASE

1. In 1985, inventor Robert O. Larsson received the first US patent for the storage of a stable compound for Neem seed extract. W.R. Grace, a company based in the United States, improved on the patent by developing a storage-stable azadirachtin formulation that enhanced the pesticide shelf life to up to two years.
2. The European Patent Office (EPO) issued W.R. Grace and the US Department of Agriculture a patent (EPO patent No. 436257) in 1994, after a lengthy examination

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procedure, for a method of controlling fungus on plants using hydrophobic extracted Neem oil. However, the EPO had limited the patent's principal claims with respect to the patent awarded in the United States.

3. The Three litigants, Magda Aelvoet, Vandana Shiva, and Linda Bullard, filed a legal challenge to these patents. They stated that the fungicidal action of hydrophobic extracts of Neem seeds has been well known and utilized in India for centuries ago, both in Ayurvedic medicine and in traditional Indian agricultural techniques to protect crops from fungal infestations.
4. They claimed that the invention in question lacked two essential legislative conditions for the issuance of a European patent, namely, originality or novelty and inventive step because this traditional Indian knowledge has been prevalent in Indian society since ancient times. The patent was also deemed to be immoral since the patentees claimed monopolistic property rights over a process that is part of Indian traditional knowledge. Insufficient disclosure and lack of clarity were among the other grounds for the cancellation of the patent. Because the patent represented a de facto monopoly on a particular plant variety, it was also challenged under Article 53(b) of the EPC. They also presented EPO representatives with packets containing around a hundred thousand Indian citizen signatures requesting that all Neem patents be cancelled.
5. The opposition panel held after examination that the patentee's claim of originality had no ground due to clearly established prior public use. Since it involves an issue of novelty or prior public usage, the opposition division agreed with the respondents that no patents should be awarded for anything that was previously known, especially as part of common traditional knowledge. The patent was also evaluated by the Technical Board of Appeals for originality, disclosure, and inventive step consisting of Chair Members: U. Oswald, M.C. Ortega Plaza, P. Mühlens, J. Riolo and J.P.B. Seitz.
6. While allowing the opposition and revoking the patent, the EPO four-member panel concluded that the Neem patents amounted to bio-piracy and that the procedure for which the patent was awarded had been in use in India from time immemorial. Thus, on March 8, 2005, the ERO Technical Board of Appeals cancelled the patent on a fungicide derived from Neem tree seeds in their entirety, putting an end to a ten-year fight in the world's first legal challenge to a biopiracy patent.

ISSUES INVOLVED IN THE CASE

1. Whether the requirements of sufficiency of disclosure have been met.
2. Whether the state of the art as presented by the respondents is credible.
3. Whether the subject matter of the patent is novel.
4. Whether the subject matter of the claims lack an inventive step.
5. Whether the auxiliary request claimed by the appellants is admissible.

ARGUMENTS OF THE PARTIES TO THE CASE

Arguments of Appellant

European Patent No. 0 436 257 based on application No. 90 250 319.2 was granted on the basis of ten claims. Independent claim 1 as granted reads as follows:

A method of controlling fungi on plants comprises 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.

The appellants argued on technical lines that the respondents were not represented by a professional European representative and the opposition was not acceptable since the required opposition fee was not paid on time. The appellants further argued that the evidence of prior art as submitted by the respondents was not properly established. Because so much time had gone since the claimed conduct, the appellants wanted the supporting papers, as most people's recall of dates and digits was not credible.

The appellants, in a letter dated November 24, 2004, had withdrawn their request for oral proceedings and no further arguments were submitted by them in response to the board's communications.

Arguments of Respondent

The patents issued to W.R. Grace in Europe and the United States sparked outrage in India and it garnered a lot of attention from people who believed that W.R. Grace had claimed monopoly over knowledge that belonged to the Indian people. The storage stable formulation in question was thought to be obvious at best, and so devoid of any innovative step. Another major concern was that if they were to obtain a patent in India, the traditional usage and cultural practices with

respect to any use of the Neem tree would be considered patent infringement, along with the concern that W.R. Grace would drive up the price of the Neem seed.

A re-examination petition was organized and submitted by The Foundation on Economic Trends, based in the United States, on the grounds that the invention lacked non-obviousness in light of prior art, which was represented by the prior use in India. However, due to a geographical restriction in the US patent law involving state-of-the-art or prior use, the petition was denied.

Magda Aelvoet, a member of the European Parliament and a Green Party representative, filed an opposition to the patent with the EPO in 1995, in collaboration with two CSOs. The respondents took the grounds of lack of novelty under Article 54(1) and (2) EPC and lack of inventive step under Article 56 EPC while requesting that the patent be revoked in its entirety. They further argued that the patent was against morality [Article 53(a) EPC] and that there was insufficient disclosure [Article 100(b) EPC].

LEGAL PROVISIONS INVOLVED

The Boards of Appeal of the European Patent Office relied on the following provisions of the European Patent Convention, 1973:

Article 54(1)

An invention shall be considered to be new if it does not form part of the state of the art.

Article 54(2)

The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European Patent Application.

Article 56: Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

Article 83:Disclosure of the invention

The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Article 99:Opposition

Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid

Article 123(2):Amendments

The European patent application or European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed.

Rules relating to fees Article 8(1)(a)

The date to be considered is the date on which payment is made.

BRIEF JUDGMENT

The opposition division determined that the standards for sufficient disclosure had been met and that Article 53(a) EPC did not apply in this matter. They discovered, among other things, that the TK issue was one of originality rather than morality since the patent did not give its proprietor any right to prohibit acts in India.

However, when the issue of novelty was raised, the opposition division decided to favour the opponents. The opposition division determined that the 'when' and 'where' of claimed previous usage occurred in the Maharashtra districts of Pune and Sangli in Western India in 1985/1986. The opposition division based this on Mr. A.D. Phadke's declaration and testimony. Mr. Phadke, a witness for the opponents, is an Indian agronomic who produced a commercial Neem product in India without claiming patent protection and performed extensive field testing in partnership with Indian farmers throughout the course of his work.

The patentees filed an appeal, and the European Patent Office Board of Appeal issued its final verdict on March 8, 2005. The patent had been transferred from W. R. Grace to another US

corporation, Thermo Trilogy Corporation, during this time. However, the US government remained a co-owner of the patent throughout. The appeal was based on the claim that Mr. Phadke's affidavit and testimony were inadequate proof of past usage since their credibility may be questioned because they depended on specific accounts of events that occurred between 10 and 14 years ago.

Instead of determining this matter, and therefore the case, on the basis of past usage, which had been the foundation for the opposition division's ruling, the board elected to ignore this contentious issue and instead rely on a significantly less contentious piece of evidence:

The appellant's main argument was that the recollection of dates and numerals was uncertain for most people and hence some supporting documents, such as laboratory books or notebooks, were required. However, there is no dispute between the parties concerning the existence of the prior art document (8) as a part of the state of the art within the meaning of Article 54(2) EPC. In the board's view, document (8) is highly relevant for the ruling of the present case. Thus, it can be left open whether or not prior use is proven as the case can be decided on the basis of document (8) alone.

The board alludes to Document (8), a scientific publication published in Australian Plant Pathology in 1981 by H.B. Singh and U.P. Singh titled "Effect of Volatiles of Some Plant Extracts and their Oils on Conidia of ErysiphepolygonsC." The article highlights Neem oil as one of the plant extracts examined, as well as the antifungal impact of the Neem extract and the varied quantities of Neem oil utilized in the study.

Even though the board decided that the paper acknowledged the use of a Neem oil extract as a fungicidal on plants, it did not, in their opinion, disclose which solvent was used. Furthermore, the paper fails to reveal the existence of an emulsifying surfactant in the formulations used. As a result, the board determined that the patent claims were innovative in comparison to the substance of the article.

The board then went on to determine the inventive step. The board determined that the patent should be revoked for lack of inventive steps viewing the procedure stated in the article and the patent claim. The auxiliary request filed during the oral hearings was similarly denied by the board of appeal because it did not fulfil the standards of Article 123(2) EPC since the revisions went beyond the original application's substance. As a result, the patent was eventually revoked in its entirety.

CONCLUSION

The Neem dispute was a significant victory for India and for the protection of traditional knowledge. It highlighted the importance of safeguarding biodiversity and ensuring equitable access to natural resources. The case continues to be a reference point in discussions about biopiracy, intellectual property rights, and the need for a more balanced international framework.



REFERENCES

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