

Neem (*Azadirachta indica*) in Context of Intellectual Property Rights (IPR)

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Article Info	Abstract
Article History <i>Received</i> : 11-01-2011 <i>Revised</i> : 26-01-2011 <i>Accepted</i> : 01-02-2011	India has come alive to the need for recognition and protection of intellectual property. In post GATT regime, India has transformed from purely agricultural to agricultural-cum-industrially developed nation. The Industrial progress of a country generally depends upon inventive talents of the entrepreneurs and the number of invention made by them. There is a no doubt that India became member to the Uruguay Round of Multilateral Trade Negotiations and also agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS) is a part of the agreements establishing WTO from GATT and India ratified such agreements. This research article express importance of Intellectual Property Rights with special reference to neem products have been patented and some controversial patents on neem.
*Corresponding Author <i>Tel</i> : +91-9675164910 <i>Email:</i> Ompalsingh1977@rediffmail.com ©ScholarJournals, SSR	Key Words: Neem, <i>Azadirachta indica</i> , Intellectual Property Rights, Neem patents

Introduction

The neem tree (*Azadirachta indica*) originates from the Indian sub-continent and now grows in the dry regions of more than 50 tropical countries around the world. Generally, its properties are used to cure common colds and flu. The oil extracted from its seeds can be used to cure various diseases. Mixed in soap, it offers cheap and easy relief from malaria, skin diseases and even meningitis. It is mentioned in Indian texts written over 2000 years ago and has been used for centuries by local communities 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.

Even though first report on pesticide property of neem was reported in India in 1928, only after 30 years later systematic research work on neem was initiated. The past five decades witnessed intensive investigation and upward trend to scientific interest on neem and its diverse properties, resulting in large number of research publications, books and conferences at national and international levels. It led to isolation and identification of more than 140 compounds, from various parts of the plant [1-5]. It showed anti-inflammatory [6], anti-ulcer [7-10], antimalarial [11,12], antifungal [13-17], antibacterial [18], antiviral [19-23], antioxidant, antimutagenic and anticarcinogenic activity [24-26]. It also exhibited impeccable insecticidal property which found its applications in pesticide [27]. Neem extracts can be used against over 250 pests including whiteflies, aphids, mealybugs, mites, and termites. It is also effective against fungal diseases such as rusts and powdery mildew that attack the leaves of ornamental plants and food crops, medical, healthcare and cosmetic industry all over the world [28].

In the post GATT era, when India is a signatory to the TRIPs agreement and is a member of WTO, intellectual

property rights (IPRs) are being considered as a tool to create wealth through knowledge. The TRIPs agreements on one hand, and restrictions on dual use technology, marketing, territorial restrictions and non-tariff barriers on another hand have thrown many challenges and opportunities for scientist and industrialists. The major challenge is in the area of IPR which has lead to its recognition of importance by the R&D and to industrial organizations. After signing of TRIPs agreements, awareness about the importance of IPR has grown tremendously since 1994. It is essential to understand the importance of IPR, why to protect IPR and its importance in technology development. Such issues are discussed in this paper with special reference to neem patents.

IPR is concerned with the intangible property, it may be called as Intangible Property Rights; as industrialists are concerned with IPRs mainly in the context of exclusive protection and rights for their investment, so one may call it a Investment Protection Rights too, however its correct connotation is Intellectual Property Rights.

The TRIPs agreement deals with seven areas of IPR:

- Patents
- Industrial designs
- Copyright and related rights
- Trademarks
- Geographical indications
- Layout designs of integrated circuits.
- Protection of undisclosed information.

Protection of IPR

Today we are living in an extremely competitive world where the technology is ever changing. New and improved technology are being developed at a very fast rate than ever before. Here one may raise the question that when the

technology is said to be ever changing/improving, then why do we need to go for safeguarding the IPRs. This is mainly due to the desire of the inventor to have exclusive rights/monopoly over the advancements made in technology and at the same time to exclude others from exploiting the same for commercial benefits. The awareness of exclusive rights to the original inventor(s) and penalty/punishment to infringer of such rights are the basis for the creation of IPR related laws.

Further, safeguarding the IPR ensures better returns on inputs of the R&D efforts. It is observed that the development of a new technology is often followed by the challenge to utilize it or to transfer it for commercial exploitation. The utilization or transfer of technology is faced by another challenge i.e. how to avoid unauthorized copying and use so that the hard inputs e.g. intellectual and financial, are not wasted without appropriate returns. The only means to meet the challenge of avoiding the unauthorized copying or use of the technology is to safeguard the technology by IPR instruments. In today's world it is understood the protection of one's IPR is mainly to safeguard exclusive rights/monopoly, but actually it gives exclusive rights to use, manufacture, sell etc. only for a limited period of time. Such exclusive rights/monopolies for a limited period of time are the main reasons for one to go for protection of one's IPR.

The appropriate returns come only if the invention is kept secret by means of trade secret or is safeguarded by securing IPR. If the invention is kept secret by means of trade secret, there is every chance of disclosure of information to the third party. Once the information is disclosed, then one cannot expect returns of his/her inputs. But if the invention is safeguarded by securing the IPR then the risk due to disclosure is totally eliminated, because the information is published by the government itself in the form of patent document and, in return, the government grants the exclusive rights/monopoly.

The exclusive rights/monopoly was granted by the government only if the invention meets the criteria of award of such rights. Therefore, one should take care that the invention is not made known to public by way of demonstration, exhibition, publication or use within the country or elsewhere before the date of filing the patent application.

Importance of IPR in Technology Development

The protection of technology from piracy and counterfeiting is increasingly becoming important for industrial investment specially in technology sensitive sectors or where the technology is R & D intensive, such as, information technology, defence sectors etc. This becomes more important because the investment required in bringing research activities to the industrial applications and/or market stage has already arisen very high. In the presence of IPR system the protection of intellectual properties, which particularly means the protection of knowledge, research and development for industrial investments, becomes possible due to the reasons stated above. The new technological information disclosed in the patent document plays a vital role in the technological development. Therefore, such disclosure of inventions, in return of grant of exclusive rights/ monopolies by one may help others in the development of new technology by way of providing solution to the ongoing technical problems.

Measures of Intellectual Property

Trade Measures

The trade measures that are most relevant to the neem tree case are intellectual property and patents. United States patents on neem tree products are seen as forms of "biopiracy" by country of India, the Green Party and the European Patent Office. There are three main issues surrounding the patenting of local products used for medicinal or agricultural purposes by the United States. First, the farmers will no longer be able to use these products without paying royalties to the company that has a patent on it. Secondly, consumers will be deprived of cheap medicines and agriculture products. Last, local communities should receive a share of the profits because the companies learned the value of the species from local knowledge.

Since 1985, over a dozen of the U.S. patents by the United States and Japanese firms are for the neem-based solutions and emulsions. There are a total of four patents are owned by W.R. Grace. Three patents are owned by another U.S. Company, the Native Plant Institute. Two others own by the Japanese company, Terumo corporation. Remember that these patents are used for the process of making the emulsion from the neem tree, not on the neem tree itself. The US Company had in fact created a new invention from the neem extraction process. The local population, however, has been extracting the substance from the seeds for years, too, using a more traditional method of "smashing the seeds" and "scooping the emulsion."

The neem is not only living organism that has become a subject of "patent" debate. There are scientists and farmers around the world that are trying to gain rights to protect their organisms. For example the Africa Soapberry has properties for insecticidal soap, fish intoxicant and a spermicidal contraceptive that African have used for a very long time. In 1964, though, things changed due to Dr. Akillu Lemma's report to the Tropical Products Institute in Britain that it killed water snails (which are used to fight the disease, bilharzias). At the time of his report, he was stunned to find out that the Institute placed a patent on the extraction process without consulting or crediting him [29].

Legal Groups of Patentization

The World Trade Organization (WTO) is encouraging developing countries to expand their legal protection of intellectual property rights in order to be on a similar "playing field" with the developed countries. In an effort to standardize trade rule, the WTO is also asking developing countries to open up top foreign direct investment from abroad and to liberalize their trade policies. The WTO believes that the restructuring will lead to a development of more modern economies.

There has been a restructuring of the General Agreement on Tariffs and Trade (GATT) into the WTO. This resulted in agreements on Trade-Related Aspects of Intellectual Property forum for dispute, created a trend towards a legal framework of patent rights [29]. According to Shiva, "the northern countries argued that when southern farmer's attempted to retain free use of their own seeds, developed by them over thousands of years, it was a form of piracy, but the pirate's hat clearly belongs on the other head" [29].

One of the major parties involved is obviously the Indian government who has signed onto the TRIPs agreement. India's laws still do not allow patents on agricultural and pharmaceutical products. Another party involved is the business community (like W.R. Grace) that needs intellectual property rights to encourage development in foreign countries because it gives more incentive to the business owners that their property or "inventions" will be protected. They believe that the result of researching and development in foreign countries can lead to a greater public good because of the new discoveries of medicines and other innovations that will result.

Another forum for dispute surrounding the neem tree is the Convention on Biological Diversity (CBD) that took place in 1992 at the United Nations Conference on Environment and Development. Article 15 of the convention states bio-assets are the property of the sovereign states in which they are from. In other words, they are not the property of the world at large. India's claim is that what the Western world is calling discoveries is actually an indigenous method that they have been using for years. They say that it is a bioassets that is protected under Article 15 of the convention. While CBD emphasizes the rights of sovereign nations over biological resources, such as the neem tree, it still calls for the acceptance of intellectual property rights. What this means is the CBD calls for governments, such as India, to provide the proper patents or other forms of protection on the life forms and include pharmaceutical products.

On the other hand, WTO dispute that relates to the TRIPs agreement is a case that involves India, as well. This case is regarding Basmati rice. India feels that because the United States has granted a patent for Basmati rice, that it is violating the TRIPs agreement. They say that Basmati rice is exclusively associated with India and Pakistan. They want the United States to take away their patent on the rice because they felt it is an indigenous product of their country. India's problem with the neem tree is similar to the Basmati case because they have realize the importance for creating laws that conserve bio-assets and control piracy. They feel that protecting their assets through patents may protect them from other companies like Rice Tec that took advantage of the nonexistent Indian laws. Indian farmers want to protect their cultural heritage. It seems the best way to do it is to change their philosophical attitude that natural resources should not be patented in order to protect and preserve India's biodiversity and also to conform to international laws and agreements like the TRIPs agreement. According to Shiva, there has been a new alliance of farmers and scientists to formulate an alternative form of intellectual property rights—what they term collective intellectual property rights (CIPR's) [29]. It allows people to have the right to benefit commercially from traditional knowledge. In other words, the farmers want to solve their disputes at the local level or village organizations rather than through GATT panels.

Neem Patents

Since the 1980s, many neem related process and products have been patented in Japan, USA and European countries. The first US patent was obtained by Terumo Corporation in 1983 for its therapeutic preparation from neem bark. In 1985 Robert Larson from (USDA) obtained a patent for his preparation of neem seed extract and the Environmental

Protection Agency approved this product for use in US market. In 1988 Robert Larson sold the patent on an extraction process to the US Company W.R. Grace (presently Certis).

In 1990 patent is for a method of producing neem extract that can be stored well. The abstract says: "Storage stable pesticide compositions comprising neem and extracts which contain azadirachtin as the active pesticidal ingredient wherein the compositions are character sized by their non-degrading solvent systems. In a first embodiment, the pesticide compositions contain solvent systems character sized as having greater than 50% by volume aprotic solvents and less than 15% by volume water. In a second embodiment, the pesticide compositions contain solvent systems characterized as having greater than 50% by volume alcohol and less than 5% by volume water. The pesticide compositions contain surfactant concentrations of at least about 1.0%, up to 10%."

In 1994 patent is for a specific method of extracting and treating active substances from neem seeds so that the resulting solution is stable enough to store. The abstract says the patent is for a "process for the production of stable azadirachtin solutions comprising extracting ground neem seeds with a solvent having azadirachtin extract solution and then adding an effective amount of 34 Angstrom molecular sieves to selectively remove water from the extract to yield a storage-stable azadirachtin solution having less than 5% water by volume".

It is only these specific newly invented processes that are covered by the patents. Farmers always have and will continue to be free to use neem in any traditional way they desire. The use of neem extract, or its seeds or leaves, cannot be patented, since they have been used for centuries. Its properties can only be patented if they are considerably modified. For instance, any synthetic variation of a naturally occurring product is patentable, as it does not occur in nature in that form.

Having gathered their patents and clearance from the EPA, four years later, Grace commercialized its product by setting up manufacturing plant in collaboration with P.J. Margo Pvt. Ltd. In India and continued to file patents from their own research in USA and other parts of world. Aside from Grace, neem based pesticide were also marketed by another company, AgriDyne Technologies Inc., USA, the market competition between the two companies was intense. In 1994, Grace accused AgriDyne a non-exclusive royalty-bearing license. During this period in Indian large number of companies also developed stabilized neem products and made them available commercially. The number of patents filed in this period were limited and geographically confined to few countries.

According to Rekhi [30], one hundred seventy one (171) product of neem have been patented till now which are given below as:

Total Patents on Neem

United States	54
Japan	59
Germany	05
EPO	05
Great Britain	02
India	36
PCT	10

(Austria, Belgium, Denmark, Ireland, France, Greece, etc.)

Total 171

Dispute Matter on Neem Patentization

There is an increasing awareness in India of the modification of neem will lead to the expropriation by multinational corporations, like W.R. Grace [31]. On Indian Independence Day in 1995, farmers in from Karnataka rallied outside the district office to challenge the demands for made by multinational corporations for intellectual property rights. As part of their protest, the farmers carried twigs and branches from the neem tree as a symbol of their collective indigenous knowledge of the properties of the neem [31].

The United States, on the other hand, states that what they are doing will help the Indian economy. India is not against sharing its information about the Neem tree's virtues, but it is against countries and corporations that intend to stop India's present use of it.

Another issue is whether the neem tree is patentable, since it is a product of nature, which shows that it is not a result of innovation and discovery. The problem is that W.R. Grace does not have a patent on the tree itself, but rather on the process of making the emulsion. They believe that this process is a discovery because it entails manipulation yielding greater and better results. In other words, discovery seems to have both old and new definitions. The problem is over the use of novel scientific advances on traditional Indian techniques. According and Natural Resource Policy in India, "Corporate processes are supposedly novel advances on Indian techniques" [31]. She goes on to state that the reluctance of scientists in India to patent agricultural and pharmaceutical inventions may be a result of their recognition that the bulk of work had already been accomplished by generations of anonymous, Indian experimenters, for example, Dr. R.P. Singh of the Indian Agricultural Research Institute asserts: "Margosan-O is a simple ethanolic extract of neem seed kernel. In the late sixties we discovered the potency of not only ethanolic extract, but also other extracts of neem [32, 33]. Work on the neem as pesticide originated from this divisions as early as 1962. Extraction techniques were also developed in a couple of years. The azadirachtin – rich dust was developed by me" [34]. Shiva also states that the discovery of the neem's properties and the means of processing the extract was not "obvious" but rather evolved through extended systematic development in non-western cultures.

The World Trade Organization (WTO) is asking developing countries to open up to foreign direct investment from abroad to liberalize their trade policies. There has been a restructuring of general agreement on Tariffs and Trade (GATT) into the WTO. This resulted in agreements on trade-related aspects of intellectual property rights (TRIPs) made during the Uruguay Round. These agreements created a trend towards a legal frame work for intellectual property rights including a consensus to follow and establish patent laws in conjunction with those of the developed world.

While this can be seen as a good sign for India, it still causes a problem because of the Indian government's reluctance to issue patents on agricultural and pharmaceutical product. Also, there is a lack of knowledge of the legal process that surrounds intellectual property rights. Indian business owners argue that the lack of patents leads their technology to

move to the developed world India feels that by letting foreign companies control resources, they become more vulnerable to them. As a result, there has been a backlash on foreign investment and less joint ventures between India and United States.

Controversial Patents on Neem

US patent No. 4946681 – granted in 1990 for improving the storage stability of neem seed extracts containing azadirachtin (a naturally occurring substances that belongs to an organic molecule class called triterpenoids. Azadirachtin occurs in all parts of the neem tree but the majority of it is concentrated in the neem Kernal. It is one of more than 70 limonoids produced by neem). The inventor is named as James F Walter of Ashton, Maryland.

US patent No. 5124349 – granted in 1992 for storage of stable insecticidal composition comprising neem seed extract. The major contribution was increasing the shelf-life stability of azadirachtin solution (Four people are named as the inventors).

Recent Indian Patents on Neem

70/BOM/91-13.3.91 (171888)– A process for treating (Upgrading) Neem Oil – Hindustan Lever Ltd., Bombay, India.

668/Mas/93 – 23.3.903– A combination of hydroponic and a spray to improve the survival of tissue cultured plants with specific references to Neem – Dalmia Centre of Biotechnology.

757/Del/93 – 20.7.93- Preparation of edible Neem oil – Rohm and Hass Co.

758 Del/93 – 20.7.93- Stable extract from neem oil – Rohm and Hass Co.

759/Del/93 – 20.7.93- Preparation of neem seed extract – Rohm and Hass Co.

1270, 1271, 1272 & 1273/ Del/93– 12.11.93- A process for preparation of a spermicidal agent from neem oil or extractives – National Research Development Corporation.

7/Mas/94– 7.1.94– A Method for preparing ayurvedic antivirus compound comprising three oils mainly neem seed oil – Girivas Vishwanath Seth.

9/Mas/94– 10.1.94– Nimbecidine – Vegetable oil including neem oil, enriched with azadirachtin and the same extracted from neem seed and other parts of neem-T. Stanes and Company Ltd.

1397/Del/93- 9.12.93– A method for producing azadirachtin – Rohm and Hass Co.

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