

# Expropriation in Relation to Drug Patenting Concerning Pharmaceutical Companies

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## Abstract

With the development of trade companies started transacting business across its borders attaining the character of Transnational Corporation's/Multinational Corporation's which in some cases taken over by the sovereign country what has been called as expropriation. The expropriation at initial stage proceeded towards immovable and movable properties attracting the attention of international community to ponder over the issue with the result permitting the expropriation but after satisfying limitations like public purpose, good faith, non-discriminatory followed by compensation. With the developments in law and technology, the intellectual property as a patent has also come within the ambit of expropriation. In developing phase of jurisprudence, the expropriation was said to be either direct or in direct and/or creeping. The Australian case of concessional rights in favour of US company regarding coral reef and its cancellation had been subject of debate inter alia as an expropriation. In the world of technology and drug pharmacy, the manufacturing units of drugs in most of the cases registered their patents with local law protection under the coverage of WIPO. An emerging concern has been Eli Lilly case of Canada where the patent of the two drugs namely olanzapine and atomoxetine was invalidated in Canada resulting in the litigation. The Company lost both at original stage as well as before the appellate court in Canada. But before the NAFTA Tribunal the orders of national courts were reversed in the favour of ELI Lilly. The case has thrown new dimensions towards expropriation, besides, the status of NAFTA tribunal overruling national courts. In the context the research article is of essence and is based on doctrinal methodology.

**Keywords:** Expropriation, Drug Patent, Intellectual property, Transnational Corporation, NAFTA Tribunal.

## Introduction

The topic under deliberations has assumed relevance especially since the period patents have been considered as intangible property. In modern era, individual health has assumed attention from state in adopting welfare activities. The Governments have shown concern towards drug/medicine and their manufacture with availability to common masses. The corporate entities in the field

of Drug manufacturing have shown their presence not only nationally but also globally. The companies assumed transnational character by establishing industries in countries other than the country of their origin. This gave rise to Transnational corporations and/or Multinational Corporations. This on one side has satisfied the concept of Foreign Direct Investment in a host country with an object of business and profitability as far as the corporation is concerned while development as an intent for Host country. Like Industrial companies other than Pharmaceuticals, one witnesses Expropriation by the Host country but there also have been issues where Expropriation has entered into Pharmaceutical arena especially in Eli Lilly and company<sup>1</sup>, a multinational pharmaceutical corporation whose two patents were invalidated by the Canadian government thereby claiming that such an invalidation of the patents amounts to an unlawful expropriation of corporation's property

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thereby claiming damages in excess of half a million dollars. The award/adjudication raised questions as to whether patent in the form of Intellectual property can be expropriated, secondly if so, whether invalidating a patent in particular geography amounts to expropriation. Besides, under the circumstances, what are the limitation in International scenario for expropriation of drug patents. Before entering into analysis and finding out the answers it is prudent to understand the expropriation in the international scenario.

### Material and Method

The research is doctrinal in nature whereby both Primary and secondary sources data has been evaluated and analysed for this research in arriving at definite conclusions. The data comprises of different patterns including commentaries/digests, articles/writings in journals, case laws from different tribunals so on and so forth.

**Expropriation/Property Meaning & Ambit:** As per the Chambers Dictionary<sup>2</sup> Expropriate means: “. . . to dispossess (of property), esp. for use by the state . . .” Expropriation as per literal dictionary meaning is stated as:

*“A taking, as of privately owned property, by government under eminent domain”.*<sup>3</sup>

The use of ‘eminent as mentioned in the referred dictionary opens the debate as to what it means. Basically, the eminent domain being the right of a government to expropriate private property for public use, with payment of compensation. Accordingly, the expropriation means taking over property by the government for public use subject to payment of compensation.

On the other, the property has different dimensions. In its traditional way it is categorised into immovable and movable. In its evolutionary phase emerged third category of property in the form of right like in case of intellectual property. The intellectual property are in fact intellectual rights in isolation or in unison. This intellectual property rights also called intangible rights have legal recognition and by now have assumed appreciable area in law including in the field of science and technology with much presence in relation to drugs and pharmaceuticals. So intellectual property right with respect to drug patent has protection. This protection to the patent regimen got its strength since globalisation and as a regulatory mechanism WIPO as an arm of WTO

is bestowed with responsibility to take care of the global regimen. On the other, in relation to Expropriation the intangible rights are also considered to be property. This kind of property in the nature of patents fall within the definition of property including in its ambit and scope. The learned author of Malcolm N. Shaw of International Law<sup>4</sup> while referring to this sort of property has quoted Higgins<sup>5</sup> by saying:

*“...property would clearly include physical objects and certain abstract entities, for example, shares in companies, debts and intellectual property.”*

The Harvard draft convention<sup>6</sup> has also included the intangible rights within the ambit of property for the purpose of expropriation. From the factual point of view patents does not seem to be capable of expropriated but declaring them invalid caused a loss to the corporation ‘Eli Lilly’ in its Canadian market.

While the property includes both immovable and movable. In addition, the intangible property and/or intellectual property is also a property which can be the subject matter of expropriation and/or for computation of compensation. When taken into consideration in its broader perspective the concessional right under contractual obligations have been considered to be property rights in a case decided by the Australian high Court with respect to contractual right and termination of contract by the government on the ground of Environmental Protection pertaining to coral reef<sup>7</sup>.

The fact remains that the property under expropriation involves different dimension of the property vis-à-vis to its right, enjoyment etc. The determination as to property is crucial and involves complicated questions of law and fact under some circumstances. Same is the situation with respect to manufacturing of drugs and their patenting. Under normal circumstances most of the countries have Intellectual Property Laws including those concerning Patents especially pertaining to Drugs, cosmetics etc. In India in addition to Patent Laws<sup>8</sup> there are also laws regarding Drug and Cosmetics<sup>9</sup>. The industry with respect to referred commodity assumes importance in Health perspective with a regulator thereto. The Drug Patenting in India squarely falls within the ambit of Patent Laws read with International Conventions and WIPO guidelines. In case of Transnational Corporations/Multinational Corporations dealing with Pharmaceuticals, in short, Drug manufacturing for Medical and health purposes they assume importance in

multidimensional ways by generating employment in the Host country coupled with payment of Taxes, helping in balance of payments, besides other beneficial aspects of meeting the health hazard challenges by providing the Drugs/Medicine with recommended specifications in compliance to national Health regulations and WHO guidelines<sup>10</sup>. It is a fact that expropriation is permissible but there do arise difficult questions when merely a drug having Patent is banned in a particular territory of the Globe like Canada as happened in the referred case. To understand the genesis and intricacies it is prudent to enter into permissible limits of Expropriation.

**Permissible Limits of Expropriation:** Once arriving at a conclusion as to what is meant by Expropriation and also what constitutes property, the permissible limits of Expropriation are based on Hull Formula<sup>11</sup> read with World Bank Guidelines<sup>12</sup>. The international Law guidelines and also what is said in Hull Formula five parameters are to be followed namely (i) Expropriation ought to be in accordance with Law (ii) It ought to be for public purpose (iii) To be made in good faith and (iv) Shall be non-discriminatory and (v) To be followed by compensation<sup>13</sup>.

**Intangible Property and its Expropriation:** With respect to Transnational Corporations/Multinational Corporations dealing in Pharmaceuticals, the Expropriation is not on any different footing than expropriation generally expressed. It is only the issue of the Patent which is debatable. Thus, in a case where pharmaceutical company has not been Expropriated or there was no possibility for expropriating such pharmaceutical company because of its manufacturing unit being in any different country and in the process only banning its patent. There have been cases where Expropriation has been extended to concessional agreements as referred and also in some cases Expropriation has been used for preventing Environmental violations<sup>14</sup> but the case of Eli Lilly claims against the Canada with respect to two drugs namely compound olanzapine (Zyprexa Patent) and atomoxetine (Strattera Patent) is unique in nature. The case has thrown neo-dimensions in relation to expropriation of property and competence of national forums to adjudicate and overriding power of NAFTA tribunal. This being the case having importance and essence.

**Case Study and Evaluation:** Eli Lilly is a company incorporated in US in 1943 carrying its activities of pharma

by manufacturing drugs of different diversifications including that olanzapine and atomoxetine. The company has its market in number of countries including that of Canada. The Canadian government within whose territory the referred drugs were marketed invalidated therein patent. The invalidation of patent tends to cause losses to the company in case of shrinking market and imitation of the drug in other name to facilitate the companies of the Canadian origin for carrying on similar manufacturing process. After finding indifferent attitude of the state, the company approached the court in Canada having jurisdiction against the invalidation against the patent. But the company could not succeed at the original court and in process approached the appellate court where also they could not succeed and order of invalidation of the patent affecting the Canadian market for the company remain in force. Being aggrieved by the orders from national courts, the company Eli Lilly agitated the matter before NAFTA tribunal under NAFTA Agreement. The tribunal in its order annulled the decisions/order of the national courts of Canada. The case has thrown the issues of superiority of the tribunal over the decisions of the national court on one side and on the other extension of expropriation to the areas of manufacturing/marketing of the drugs duly patented. This case is a pointer towards jurisprudential expansion by entering into areas of marketing rights and the rights of patentee.

**Expanding Horizon of Expropriation:** The realistic school of Jurisprudence bases the foundation of Law on the assumption 'certainty of Law is a judicial myth'<sup>15</sup>. When applied to the developments in arena of Expropriation, there seems to be some truth in the assumption. After the advent of concept of sovereignty and emergence of Transnational Corporations/Multinational Corporations the Law towards expropriation came into being in 'Conflict jurisprudence' for search towards proper law which may be applicable to the situation. As the concept of sovereignty concretised, the comity of Nations did not like to disturb the sovereign authority in the result the expropriation of Transnational Corporations/Multinational Corporations have been recognised but with limitations. The limitations on the expropriation was immediate jurisprudential development in relation to expropriation. As already said that the expropriation initially was limited to immovable property, thereafter to movable property, subsequently the intangible property was also brought within the ambit of expropriation as dealt earlier. In its emerging trends in SD Myers<sup>16</sup> and

Saipem<sup>17</sup> the cases related to Canada and Bangladesh have thrown new dimensions with respect to the sanctity of the national courts. In the case of Eli Lilly the further expansion of the scope of expropriation becomes apparent when in fact the Judgment of the National courts including that of Supreme Court of Canada invalidated the patent of Eli Lilly with respect to the two drugs but still the corporation aggrieved by the adjudication of Canadian National courts agitated the matters before NAFTA tribunal and succeeded in getting the award to the tune of US\$5,198,323.29. Besides annulling the order of the National courts, all these adjudications at global/regional tribunals are bent upon to affect the orders of the national courts maybe in dilution to the sovereign principals or by adhering to global regulatory mechanism. The emerging jurisprudence with respect to drug patenting is presenting new dimensions specially towards marketing, sale and patenting.

#### **Comparative Study and Adjudicatory Approach:**

For the purpose of comparative study which is limited to expropriation with respect to tangible property on one side and intangible property merely by invalidating the patent is taken into consideration. As already said in its expanded horizons patents have been considered as property but one sees that though they can't be physically taken away, but their invalidation allows other manufacturers to produce such medicines and market them in a definite territory. In the case, once patent is invalidated in a host country the manufacturers of that country have a free hand to copy and market the patent though considered under laws unethical. The different cases are there with respect to taking over the tangible property and/or the management of said property but in case of patents nothing is taken away but only the right of the patent holder is invalidated posing a complicated question of law and fact in the realm of International investment laws especially within the scope of Drug patenting.

#### **Conclusion and Suggestions**

In view of the deliberations based on doctrinal methodology and evaluation of data on the factual matrix by adopting an analysis congenial to the subject, it is revealed that expropriation in the context of International Law has assumed certainty as far as its form is concerned. It is with respect to the content and/or the subject matter of the expropriation which has assumed elasticity and stretched from time to time for different dimensions. The expropriation is a concept started from

right of a sovereign state to which International obligation are being imposed giving rise to legal framework that though the expropriation is permissible in International Law but it has its own limitations in the nature of the fact that it ought to be in accordance with law, for public purpose, in good faith, non-discriminatory and followed by compensation. The deliberations in the Article are also dealt with indirect expropriation besides others where International Law has given coverage, but the case of Eli Lilly have thrown complicated question of law and fact for jurist to ponder over. The issue of the substance remains whether the case falls under expropriation where the companies immovables and movables have not been taken over but only their patent with respect to two drugs has been invalidated making the market indifferent to the product of the Eli Lilly in absence of Patent protection. On the other the referred case has raised an issue that where the judgements of the national tribunals have become absolute but still have given chance to NAFTA tribunal to overrule the decisions of the National courts of Canada only because of the treaty agreement. The patent invalidation has arisen with much consequences on sovereign laws by expanding the International Jurisprudence on the subject of expropriation. The ratio of the case is much open for the future to unfold on the subject.

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2. The Chambers Dictionary, Allied Chambers (India) New Delhi, Edition 2000, Reprint 2006, 571
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4. Malcolm N. Shaw, International Law published by Cambridge University Press, 6<sup>th</sup> edition 2008
5. Rosalyn C. Higgins, Baroness Higgins, was the President of the International Court of Justice since 2006. She was the first female judge elected to the ICJ.

6. Harvard Draft convention, 1961 on International Responsibility of States for injuries to aliens
7. Dillingham- Moore v. Murphyores (1979) 136 CLR 1 (Great Barrier Reef case)
8. The Patent Act, 1970 read with The Patent (amendment) Act, 2005
9. The Drugs and Cosmetics Act, 1940
10. WHO Drug Information, 2000 and later guidelines
11. Hull Formula laid the standard of compensation based on triple criteria of 'Prompt', 'adequate' and 'effective' given by Cordell Hull who was longest-serving U.S. Secretary of State
12. World Bank Guidelines section IV (1) regarding treatment of Foreign Direct Investment referred in 31 ILM, 1992
13. The referred fundamentals for expropriation have find place in various international awards especially from ICSID
14. Metalclad Corporation v. The United Mexican States, ICSID Case No. ARB(AF)/97/1
15. Jerome Frank, an American legal philosopher and legal realism movement author. He was Chairman of the Securities and Exchange Commission, and a United States Circuit Judge of the United States Court of Appeals for the Second Circuit.
16. SD Myers Inc v The Government of Canada, Partial Award (13 November 2000, NAFTA/UNCITRAL) at para 263
17. Saipem SPA v. The people's Republic of Bangladesh, Award (30 June 2009) ARB -05-07 (ICSID)