

PAY-FOR-DELAY AGREEMENTS AND COMPETITION

LAW,2002

Varendyam Jahnawi Tiwari*

Vidushi Puri**

“What I fear most is power with impunity. I fear abuse of power, and the power to abuse.”

-Isabel Allende

Introduction:

Intellectual property promotes dynamic efficiency and encourages innovation in the market with variety of goods and services thereby contributing to consumer welfare. Competition can itself serve as a driving force for new inventions and creativity to sustain one’s position/dominant position in the market. Both regimes can thus be concluded to have one common goal that is the consumer welfare and wealth maximization while they may seem to be different in certain other aspects. Intellectual property law creates and protects monopoly power and the competition law seeks to exclude it. IP exclusion provisions are included in the Indian Competition Act, 2002 in Section 3(5). IP rights *per se* do not violate competition law provisions.

The interface or coherency of IP rights and competition law reveals a lot of complex issues one of which is ‘**Pay For Delay Agreements**’ in regard to patents, which is an issue of cardinal importance as it shows that how monopoly power granted and protected by IPR laws can become a threat to competition and the consumer welfare and in fact may lead to abuse of dominant position if the patent holder comes to misusing it.

Pay For Delay Agreements – Meaning:

Patent holder drug makers (Originators) use a number of strategies to extend the exclusivity period of their patented drug in order to prevent the market entry of generic drug suppliers (Generics) on or before the expiry of their patents.

Generally, a patent is granted for a term of twenty years. After the expiry of this period, the patentee's exclusive rights of producing, manufacturing or selling this patented product or process also expires. Thereafter, it falls in the general or public domain for being used by the generic producers/manufacturers.

Thus, the Originators enter into deals with the generic producers to keep their drugs out of the market for a specified time. Under such agreements, the generic company receives a consideration from the Originators to refrain from marketing its generic product for a specific period of time and thus, delay the entry of the lower priced generic drug for a considerable amount of time.

It is pertinent to note that this comes at the expense of consumers whose access to lower priced generic drugs is delayed, sometimes for many years.¹ The consumers miss out on low cost generic drugs, which may be as much as 90% less than Originator's prices. Thus, both the Originators and the generic drug manufacturers are mutually benefitted as a consequence of such deals.

Nature Of Pay-For-Delay Agreements:

*Ll.M.- National Law University, Jodhpur .

**Ll.M.- National Law University, Jodhpur .

¹ Competition Law and Indian Pharmaceutical Industry- By Centre for Trade and Development (CENTAD), New Delhi, 2010, Pg-39.

- This arrangement between the Originators and the Generics can be viewed as anti-competitive in nature.
- It eliminates competition and leads to market allocation.
- It may lead to delay and decline in new medicines reaching the market.
- It leads to arbitrary price determination by the Originator.
- It limits or controls the production and supply of generic drugs.
- It leads to market foreclosure as it creates a barrier for the entry of the generic drug.
- It also leads to abuse of dominant position which has been defined under Section 4 of the Competition Act, 2002- It is not itself illegal for an undertaking to be in a dominant position, but it is against the competition Laws for an undertaking to abuse or take advantage of its dominant position in the market. Thus, such an unfair or unreasonable conditions imposed by the dominant players (which are the Originators) may amount to abuse of dominance in the market.
- It also leads to Appreciable Adverse Effect (AAE) on Competition (Section 3 of the Competition Act, 2002) the factors of which have been listed out in Section 19(3) of the same Act.
- When the originators enter into ‘pay-for-delay’ agreements with these generic firms, there could be a scope for the Indian market to be adversely affected as this would delay the availability of lower cost version of the generic drugs.
- Also, such agreements would prove to be a major blow to the consumers in India as they would have to pay more for those drugs which could have been easily availed at lower costs in case of absence of such agreements.

Major Pronouncements:

A. International Scenario

United States:

The U.S Supreme Court, in *Federal Trade Commission v. Actavis*² held a settlement between pharmaceutical companies anti-competitive, as it was a pay-for-delay agreement- wherein the originator *Solvay Pharmaceuticals* (which obtained a patent for a testosterone gel called Androgel in the year 2000) made payment to the generic manufacturers, including Actavis for delaying the entry of their generic version of the drug into the market until 2015.

European Countries:

In June 2013, the EC imposed huge fines on *Lundbeck* and four generic pharmaceutical companies, including *Ranbaxy*, for delaying the entry of generic medicine Citralopram (antidepressant drug) in the market pursuant to the agreements and linked such delay to the payments made to the generic companies.³

More recently, Laboratories *Servier* and five generic drug makers, including India's *Lupin*, were fined more than USD 570m for allegedly delaying the availability of a generic blood pressure drug.⁴

B. Indian Scenario:

² FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013).

³ Pay for Delay: The end of Sweetheart Deals- Article by Vibhav Choukse, Senior Associate with Law Firm, Vish Associates, 2013, Available at <http://us.practicallaw.com/6-532-9447?q=&qp=&qo=&qe=> (Last Accessed: 25/02/2016 at 1.25 A.M)

⁴ “India-Pay-For-Delay-Agreements-On-The-Cci-Radar”, 12 September, 2014 , Available at <http://www.conventuslaw.com/archive/india-pay-for-delay-agreements-on-the-cci-radar/>(Last Accessed: 25/02/2016 at 9.00 P.M)

An important aspect which requires attention is the reaction and involvement of the Indian companies in such settlements. Though the instances of pay-for-delay agreements among Indian firms have not been reported very frequently in the Indian market, it cannot be presumed that such settlements are completely absent or non-existent. Some recent cases where the conflict between the brand owners and the Generics has been highlighted are discussed below:

Novartis AG v. Union of India⁵: Pay-for-Delay:

A Swiss pharmaceutical giant *Novartis AG* had given payment for delay to an Indian Generic drug producer *Natco Pharmaceutical*. *Natco* was paid to keep its generic version of the drug Gleevec (which was used for the treatment of leukemia) off the shelves from the Indian market. In 2004, *Natco Pharmaceuticals* was restrained by Novartis from manufacturing the generic version of the drug and was therefore, given certain monetary compensation for staying out of market competition.

Other cases:

Case of **Natco Pharma Ltd. v. Bayer Corporation⁶** wherein *Bayer Corporation* tried to prevent an Indian Generic company *Natco Pharma Ltd.* from manufacturing the generic version of its patented drug Nexavar and **Hoffmann La Roche Ltd. and Anr. v. Cipla Ltd⁷** a case on delay in launching generic drugs through abuse of Patent Litigation mechanism where *Cipla* won the right to manufacture and market the generic version of the patented drug Tarceva (treatment of cancer) and was originally patented by the Swiss pharmaceutical company Hoffman La Roche.

Extra-Territorial Jurisdiction -The Competition Act, 2002:

⁵ (2013) 6 SCC 1

⁶ Order No. 45/2013

⁷ 148 (2008) DLT 598, MIPR 2008 (2) 35

If an anti-competitive agreement like *pay for delay* has been made out of India which has AAE on competition in India, then as per the provisions of Section 32 of The Competition Act, 2002, “the Competition Commission of India has the extra-territorial Jurisdiction to undertake an inquiry into the agreement or an abuse of dominance that has taken place outside India so long there is an Appreciable Adverse Effect on Competition in India.”⁸

These practices are monitored and penalties for such agreements are imposed accordingly which have been enshrined under section 27 of the Competition Act, 2002.

Conclusion & Recommendations:

It is quite evident that *Pay For Delay Agreements* are not only anti-competitive but they have Appreciable Adverse Effect on competition and signify blatant misuse of IP rights by the Originator thereby harming consumer welfare and hence neither it is fulfilling the objective sought by IPR Laws nor Competition Law. Hence an effort must be made to curb such a practice. A few suggestions are as follows:

- **Monitoring** - The Competition Commission of India may install a mechanism to keep a constant eye on the expiry of Patent rights of any patented drug and see whether the Generic manufacturers are causing any delay to introduce the generic versions of those drugs into the market.
- The Competition Commission of India may take *suo motu* action against such agreements where there is any information or apprehension that such an agreement has been made.

⁸ Supra 3.

- **Setting up of Patent Pools-** A patent pool is a group initiative whereby patent holders ‘pools’ multiple patents related to one particular drug in one place, which are then licensed out by the same one entity to the generic producers here patent holders are compensated for sharing their patents, generic manufacturers gain access and consumers benefit more easily from medicines at affordable prices. Thus, this can be used as a tool to fight back with the anti-competitive “Pay-for-Delay” agreements. However, this shall also be done under the supervision and control of the government authorities.

