Section 3(d) of Indian Patents Act 1970

Between rejection and approval of the a grant of patent to sovaldi durg (sofosbuvir)

The U.S. Food and Drug Administration on Dec. 6, 2013 approved Sovaldi (sofosbuvir) to treat chronic hepatitis C virus (HCV) infection. Sovaldi is the first drug that has demonstrated safety and efficacy to treat certain types of HCV infection without the need for co-administration of interferon.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take several years. Some people with chronic HCV infection develop scarring and poor liver function (cirrhosis) over many years, which can lead to complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections or liver cancer. According to the Centers for Disease Control and Prevention, about 3.2 million Americans are infected with HCV.

Sovaldi is a nucleotide analog inhibitor that blocks a specific protein needed by the hepatitis C virus to replicate. Sovaldi is to be used as a component of a combination antiviral treatment regimen for chronic HCV infection. There are several different types of HCV infection. Depending on the type of HCV infection a patient has, the treatment regimen could include Sovaldi and ribavirin or Sovaldi, ribavirin and peginterferon -alfa. Ribavirin and peginterferon-alfa are two drugs also used to treat HCV infection which is sold at a price of 1,000 dollars per pill.

Sovaldi’s effectiveness was evaluated in six clinical trials consisting of 1,947 participants who had not previously received treatment for their disease (treatment-naive) or had not responded to previous treatment (treatment-experienced), including participants co-infected with HCV and HIV. The trials were designed to measure whether the hepatitis C virus was no longer detected in the blood at least 12 weeks after finishing treatment (sustained virologic response), suggesting a participant’s HCV infection has been cured.

And also the company Gilead Sciences company obtaining a patent from Pakistan, South Africa, Uganda, Nigeria and the European Commission have also approved the molecule, and it is yet unknown how much Gilead will charge for its treatment on the Indian sub-continent.

But at the same time you do not get access to the patent from Egypt and Ukraine license. As for India, I found it difficult to get a patent, although given licenses to some Indian companies. Where he faced, non-governmental human rights organizations against this property because of the high cost and it is innovative. In January 2013 it a filed to (IPO) in India to get ‘patent license’.
the Sovaldi application was initially rejected by the Indian Patent Office (IPO) in 13 January 2015, the Delhi HC resurrected it and remanded it back to the IPO for fresh consideration in the same month. The Delhi HC upheld Gilead’s contention that the IPO's order was most likely influenced by Natco’s arguments in pre-grant oppositions and that it moreover contained verbatim portions of the latter.

Most recently, Gilead’s Sovaldi application has also overcome each of these oppositions through the Deputy Controller’s order on 9th May 2016.

Gilead’s voluntary licensing agreements (VLAs) with Indian generic firms are another cause for worry which needs to be thoroughly investigated. In particular, he fears that the traditional innovator-generic dynamic of fighting infringement suits is degenerating into an alliance; with generics jumping on the innovation bandwagon. This will disrupt competition and result in fewer patent challenges and oppositions, just as Natco withdrew its pre-grant opposition against Sovaldi after entering into a VLA with Gilead.

The Caravan piece also reveals that the VLAs contain draconian anti-diversion measures to ensure full control over Sovaldi distribution in India. For example, it requires that the drug (which is packed in bottles) be sold only to patients who could provide “proof of identification, citizenship and residence.” This leaves an already distressed consumer at the complete mercy of the company’s edicts. Such a practice should amount to a blatant abuse of dominant position in violation of Indian competition law.

According to my opinion, we find that the coalition held through “voluntary licensing” to jump on the Indian Act under Section 19(1) to investigate deeper into Gilead’s potential anti-competitive practices.

But Earlier in May 9 2016, the Indian Patent Office (IPO) in New Delhi gave its approval to Gilead Sciences Inc, allowing the company to market its treatment against hepatitis C in the country. The drug Sovaldi (sofosubvir) was rejected in January of 2015, based on the opinion that modifications from a previous formulation were only of a minor nature. Following an appeal by Gilead, the IPO has reverted its decision finding the compound to be “novel” and “inventive” and did not fall within the preclusion of Section 3(d) of the Indian Patents Act.

The approval of Sovaldi has been a sensitive case as Gilead’s compound is already licensed to 11 Indian drug producers including major corporations such as Cipla, Hetero Labs Ltd and Aurobindo Pharma Ltd to produce generic versions of the molecule (sofosubvir) to be sold in 101 low and middle income countries.

Various health activists as well the international medical humanitarian group Medecins Sans Frontières (MSF) have explicitly voiced their opposition to such a decision. They claim that retail prices would be unaffordable for a major section of the population, and that the raw materials exported to other countries would become unavailable with regards to production of the drug. Indeed, organisations such as MFS are highly dependent on generic treatment for their operations and activities around the world, calming that the approval of Gilead’s treatment could potentially stop affordable copies of the drug being made.
But on May 13, 2016, I-MAK and DNP filed an appeal with the Delhi High Court on the grounds that the decision of the Indian Patent Office is contrary to the public interest, fails to assess the full scientific and legal evidence presented and ignores key Indian patent law and judicial precedent. Please watch the BRIC Wall Blog for further updates on this appeal.

**My Opinion**

Patent system is a contract between the inventor and authority whereby the inventor gets exclusive rights for a period of 20 years in return for disclosing full details of the invention. The main purpose of patent system is to encourage innovation and eventually results in technological development.

The present Patents Act, 1970 came into force in the year 1972, amending and incorporating the existing laws relating to Patents and Designs act 1911 in India. The Patent (amendment) Act 2005 came into force from 1st January 2005, which brought changes in the previous patent system of India wherein product patent was extended to all subjects of technology consisting of food, drugs, chemicals and micro organisms. Moreover, Section 3(d) introduced in to the said amendment act 2005 and introduces pharmaceutical product patents in India for the first time. The Patent (amendment) Act 2005 defines what invention is and makes it clear that any existing knowledge or thing cannot be patented. The provision defines that a ‘novelty’ standard - which, along with ‘non-obviousness’ or ‘inventive step’ and industrial applicability, are the three prerequisites for ‘patentability’. “Discovery” essentially refers to finding out something which already existed in nature but was unknown or unrecognised. Therefore, discoveries are excluded from patent protection under section 3 of the Indian Patent Act 1970.

**SECTION 3(D) STIPULATES THAT-**

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant, is not patentable.

**MERE DISCOVERY OF A NEW FORM OF KNOWN SUBSTANCE**

A mere discovery of a new property of known substance is not considered patentable. For instance, the paracetamol has antipyretic property. Further discovery of new property of paracetamol as analgesic can not be patented. Similarly, ethyl alcohol is used as solvent but further discovery of its new property as anti knocking, thereby making it usable as fuel, can not be considered patentable.

**MERE DISCOVERY OF ANY NEW USE OF KNOWN SUBSTANCE**

For instance, new use of Aspirin for treatment of the cardio-vascular disease, which was earlier used for analgesic purpose, is not patentable. However, a new and alternative process for preparing Aspirin is patentable. Similarly, the new use of methyl alcohol as antifreeze in automobiles is not patentable. The use of methanol as a solvent is known
in the prior art. A new use has been claimed in this claim as antifreeze which is not allowable.4

The main objective of this section is to prevent several pharmaceutical companies from obtaining patents on old medicines which are just a mere increment or trivial improvement of the known substances and also a refusal to the patent on discovery of new form or new use of old drugs.

The most recent case, Novartis AG v Union of India5 decided by Supreme Court of India in 2013 where the case began in the year 1997 with patent application filed by the petitioner before Chennai patent office related to drug name GLIVEC which was slightly a different version of their 1993 patent for ANTI LEUKAEMIA drug. In this case the Assistant Controller of Patent and design, Chennai Patent Office rejected the application under section 3(d) of the Indian patent act 1970. Consequently the petitioner challenged the constitutionality of section 3(d) before High Court at Madras.

The applicant in the present appeal contented on two issues:

• Section 3(d) is unconstitutional as it violates the provision of the TRIPS agreement.

• The Indian patent act doesn't define the term 'efficacy' and provides unguiede power on the Controller. Hence it is arbitrary, illogical and vague

In response to the above contention the court held that:

• The WTO's Dispute Settlement provides the exclusive remedy adn a comprehensive dispute mechanism for violation of TRIPS Agreement. The High Court looked into the conflict between the international law and municipal law and decided that municipal law prevails in such conflict. Moreover, in India, international treaties are not directly enforceable.

• The court also rejected the second contention that the provision is providing unguieded power to the patent controller being arbitrary on the basis of the term 'efficacy' was undefined and therefore the court observed that "Efficacy means the ability to produce a desired or intended result. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'.

Therefore it is found that the Novartis’ patent application for the beta-crystalline form of Imatinib Mesylate (polymorph B) did not pass the test of section 3(d) as it did not have any enhanced therapeutic efficacy. The Supreme Court thereby upheld the observation of the High Court and Indian Patent office and rejected the patent application filed by the petitioner.

The provision under section 3(d) has been approved by WHO Public Health, Innovation and Intellectual Property Rights Report, 2006, that countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent ever-greening patents from being granted. The ruling of the Novartis’s case in Indian patent law represents a major victory for community’s access to inexpensive medicines in developing countries and influences the access of medicines to the poor. If Novartis had succeeded the case,
patenting on drugs would have likely been approved more widely in India, restricting generic competition and thus also hindering access to reasonable medicines in the developing world. Moreover the practice is anti competitive in its effect as the practice will enable pharmaceutical MNCs to eliminate competition from the generic manufacturers and charge exorbitant prices for their patented drugs. This in turn will cause adverse effect to public interest in developing countries since many essential drugs become inaccessible to the general public on account of unaffordable pricing.

according to my the opinion I find that to granted a patent to Gilead Pharmacy, LLC infringement of section (3)d according to Indian patent aw act 1970 in addition to the starter monopoly and price exaggerated.