Novartis Must Not Win This Case

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Capital is as terrified of the absence of profit or a very small profit as nature is of a vacuum. With suitable profits, capital is awakened; with 10 percent, it can be used anywhere; with 20 percent, it becomes lively; with 50 percent, positively daring; with 100 percent, it will crush all human laws under its feet; and with 300 percent, there is no crime it is not willing to dare, even at the risk of the gallows."

When Marx wrote about the crimes Capital can commit, given the right circumstances, the present intellectual property system was just being born. A hundred and fifty years later, perhaps nothing exemplifies better, Capital's thirst for profit, as the current regime of intellectual property protection. It is a system that seeks to generate super profits through monopoly control over knowledge. When applied in the medicines sector, it translates into millions of deaths and destitution for an even larger number. Today, products to treat a range of diseases are denied to those who need them most because they cannot pay for them. It is denied to them not because these medicines cannot be produced at affordable costs, but because a few multinational corporations treat the knowledge as their property and sell these medicines at exorbitant prices. They also, use the monopoly created by patents, to prevent other companies from producing and selling these drugs at much lower prices.

Current Patent System: A Crime Against Humanity

The current patent system, as part of the global intellectual property regime, has assumed proportions that are unthinkable. It is the perpetrator of one of the longest standing, persistent and nefarious crimes against humanity. It denies a majority of humankind the benefits that can accrue through advances in science. Nothing illustrates this better than the impact of the HIV/AIDS epidemic in Africa. Half the continent of Africa has virtually lost two decades – developmental and health indicators at the turn of this millennium in 2000, were worse than in the 1980s. A major reason for this has been the decimation of the most productive section of the population – in many countries over 1/3rd of people in the 15-45 age group are infected by HIV/AIDS. A whole generation suffered and died, not because HIV/AIDS could not be treated, but because those who had the knowledge to make the necessary medicines used their patent monopoly to sell the medicines at costs that almost nobody in the African continent could afford. In 2001, the annual cost of treating one patient of HIV/AIDS was $10,000. Some African countries would have had to spend more than half their GDP to procure these medicines for those who needed them. The tragedy is, that these medicines need not have been so expensive. In 2003 the Indian company Cipla, finally started selling the same medicines at $250 per annum – at 1/40th the earlier cost! Even this was high, and the same drugs can be accessed today at less than $100, for a year's supply.

India was mercifully spared the effect of medicine patents till 2005 because it had one of the most progressive patent laws in the world, enacted in 1972. That ahs however now changed and the signing of the WTO agreement in 1994 also marked India's accession to a patent system that puts profits before people. India's earlier patent Act worked on a very simple principle. It said that patents (a monopoly over use of a product) would be allowed in all sectors except the two that were most vital for human existence – food and health. So patents on medicinal products were not allowed in India and new medicines could be manufactured by a range of Indian companies without hindrance. This is why Cipla, was able to manufacture and supply HIV/AIDS medicines at a fraction of the earlier costs. Much of this enabling environment for Indian companies changed when India amended its Patent Act in 2005 – after completing the ten year transition period allowed when India signed the WTO agreement in 1994.

The History of Novartis' Battle in India

A clear example of profiteering at the cost of peoples' lives, in India, has been the case related to a vital anti-leukemia (blood cancer) drug called imatinib mesylate. The drug was introduced in 2001 and has quickly become the key drug that is used to treat a form of leukemia, called chronic myeloid leukemia (CML). For patients suffering from CML the drug is the difference between a healthy life and a death sentence.

Imatinib mesylate has been patented in many countries by the Swiss MNC, Novartis, which sells the drug under the Brand name of Glivec. In India, the initial patent application for the medicine was rejected by the patent office in 2006. Novartis persisted in its efforts to get a patent and appealed to the Patent Appellate Board. When the Board rejected Novartis' application again, the company challenged the decision in the Chennai High Court. Not only that, it also challenged a key provision of the Indian Patent Act, that had been cited by the Patent office while rejecting the Glivec patent application. The Chennai high court rejected both the appeals by the Swiss company. Novartis has, however, continued to persist in its efforts to secure a patent for its drug. The final step is its, now pending appeal, before the Supreme Court of India.

In the Supreme Court Novartis is now challenging the interpretation of a crucial section of India's Patent Act – Section 3(d). When India amended its patent laws in 2005, Parliament tried to ensure that the amended law would contain some safeguards against rampant profiteering by foreign MNCs. One of these safeguards introduced was this section. Section 3(d) essentially stipulates that trivial changes in existing molecules cannot be candidates for fresh patenting. Such trivial patenting (known as 'evergreening') is an old ploy used by drug companies to extend their monopoly. Companies first apply for a patent for the basic molecule and then attempt to extend the life of their monopoly by subsequently applying for fresh patents after a few years on as lightly different version of the original molecule.

In the case of Glivec, the original patent was filed by Novartis in 1993 for the 'amorphous' molecule of the chemical, Imatinib Mesylate. An amorphous salt is what exists in nature and is usually a mixture of different variants. In the late 1990s Novartis filed a fresh patent for the Beta variant of the molecule, which is already present in the amorphous salt that they had earlier patented. They also claimed that the Beta variety is better absorbed by the body. The 1993 patent was not recognized in India as at that time Indian law did not allow patenting of medicines. When the law was changed in 2005, Novartis applied for a patent for the Beta variety of the salt. The patent office rejected the patent and opined that under Indian law a slightly modified version of a known molecule cannot be patented. The patent office also said that the patent application does not fulfill two necessary criteria for patenting – novelty, and inventive step. The beta salt of imatinib was not an entirely new product, and neither was there any major inventive step involved in preparing a purified beta salt from the existing amorphous salt.

As we mentioned earlier, Novartis' subsequent appeals in the Patent appellate board and Chennai high court were rejected. Interestingly Novartis also challenged Section 3(d) of the Indian Act in the high court, claiming that it was in violation of India's obligations at the WTO. The Chennai high court pointed out that domestic courts cannot be asked to give an opinion regarding international treaties and obligations, and Novartis should take its complaint to the dispute settlement mechanism in the WTO. Novartis, has never done so and clearly Section 3(d) does not violate international obligations.

This time around, in the Supreme Court, Novartis has decided to use a novel plea. Instead of challenging Section 3(d) itself, they now argue that the section has not being properly interpreted. The section says that minor variations in an existing molecule cannot be patented unless there is a 'significant' enhancement in efficacy of the medicine. Now Novartis claims that since the Beta variant is better absorbed (by about 30%) it constitutes a significant enhancement. Clearly Novartis and its panel of expensive lawyers are clutching at straws! The patent office, while rejecting the company's earlier patent application, had stated that anybody trained in chemistry would know that an amorphous salt is made up of different variants, and it is common knowledge that the variant are likely to have slightly different properties. However, it is this trivial piece of research, that is the basis for the entire case that Novartis is now fighting.

Novartis: Philanthropist *par excellence*!

How much would Novartis gain if its patent were to be upheld? The mathematics speaks for itself. A month's supply of Glivec costs Rs.120,000 – way beyond the means of more than 99% of Indians. Remember that the drug has to be taken lifelong. Yet the same drug is sold by several Indian companies at a price of Rs.8,000 for a month's supply – 1/15th of what Novartis charges! Marx talked about capital willing to dare any crime for a 300% profit, here Novartis is fighting for a 1500% profit! At the heart of Novartis' battle is a $ 4 Billion plus global market for Glivec – about Rs.20,000 crores, which is equal to the entire Union health budget of India for 2010-2011.

Novartis tries to give a different spin to the whole issue of access to the medicine. It claims that price is not an issue in India because 'eligible' patients are covered by a programme called GIPAP – Glivec International Patient Assistance Programme. The only problem with Novartis' spin on the issue is wrong mathematics. Novartis claims that it supplies the drug, free of cost, to about 11,000 leukemia patients in India. The Cancer patients Association in India estimates that there are over 100,000 patients in India who suffer from chronic myeloid leukemia and that 20,000 odd new patients are added every year (the disease has an annual incidence of 1-2/100,000 population per year). Studies also show that the disease strikes earlier in India – among a younger age group – than in Europe and North America. Yet, Novartis' publicists glibly continue to claim that all 'eligible' patients in India are cared for by GIPAP.

The GIPAP programme itself is an interesting case study. Novartis has regularly flogged it to claim credit for an act of charity. How altruistic is the GIPAP programme? The programme was launched in 2002 and Novartis claims that it reaches 35,000 patients in 80 countries. In 2003 the New York Times carried an investigative report that blew the lid off the claims of altruism. The NYT report (as well as another report from Argentine) documents how GIPAP has been used by Novartis to first create a demand for Glivec and then to pressure governments and heath management organisations to reimburse the cost of the medicine. The NYT reported: "*In wealthier countries like South Korea, Hong Kong and New Zealand, Novartis, meanwhile, has encouraged patients who have received free drugs to become advocates, pressing public health systems to pay high prices for the drug. One company document declared that drug donations along with media campaigns and legal tactics were part of a concerted plan to win reimbursement for Glivec*".

The story gets even murkier. The website, www.healthyskepticism.org documents GIPAP's record in Argentine and reports of a case filed in the country's court: "*The Program kept a 3-month reserve supply of Glivec for the patients. When the doses for the first phase of the treatment were delivered to the patients, including a 30 day supply to cover their immediate initial needs, the patients or their relatives were instructed to retain an attorney to start legal proceedings against the health care institutions which did not include Glivec in their formularies. After that, the provision of Glivec by the Foundation through their GIPAP Program was stopped. The investment by Novartis consisted of a single treatment [i.e. for one month] and then the company recovered its so-called donation by forcing the health care institutions to buy the product*"…."*the claim also details other illicit practices, such as the making of secret payments of bribes to doctors in order to position Glivec in Argentina, or the giving of gifts to oncologists*".

Novartis: The Victim!

Novartis has consistently played the victim in the Gilivec case. It says that it is not fighting the case to make money but to uphold the principle that it deserves credit for the investment it has made in research to develop the drug. What Novartis does not tell us is that Glivec was granted 'orphan drug' status in the United States and was therefore eligible for tax rebates equal to half the cost of clinical testing (the major cost for drug development). We turn to what Brian Druker, one of the scientists involved in developing Imatinib while working in Oregon Health and Science University Cancer Institute, has to say. In a signed article in livemint in 2007, Druker wrote: "*In the recent debates on patents, pharmaceutical prices and access to essential medicines, the critical role of scientists and resources of the public sector and academic institutions involved in medical research have often been overlooked. As one of the scientists behind the development of the medicine 'imatinib' (marketed as Glivec by Novartis), which has allowed the effective control of a devastating form of cancer, I have witnessed the vital role that academic researchers and public institutions play in bringing new medicines to the market.*

"*Many scientists, if not most of those I have collaborated with in these settings, are engaged in research primarily motivated by the pursuit of knowledge as a means to help patients. For many of these scientists it is, therefore, of great concern that the results of their efforts can't reach patients and save lives because of pricing strategies and patent policies such as "patent evergreening" (minor changes to existing molecules designed to extend patent monopolies) used by partners further down the drug development process".*

Druker, goes on to relate how a large portion of the research was made possible because of public funding and how the company was actually not very interested, initially, in pursuing the research on a cure for CML. He writes: "*My work in Oregon on a therapy for CML was primarily funded by public sources, particularly the National Cancer Institute. My persistence with scientists at Ciba-Geigy (now Novartis) helped to keep the development of imatinib on their agenda despite uncertainty from product managers. As imatinib progressed through early and late clinical trials and demonstrated outstanding results, scientific and media interest in our discovery increased. The approval of imatinib by the FDA in May 2001 for use in CML was the culmination of a 10-year project for me, something I had dreamed of since medical school*". And yet, Novartis laments that it is not being given due credit for its 'original' research!

Corporate greed versus the lives of millions

Let us complete the Novartis story in India. What Novartis is challenging in the Supreme Court of India is not just the order denying the company a patent for Glivec. Novartis is challenging the very heart of the Indian Patent Act and its attempt to balance the rights of patent holders with the needs of the Indian people for access to treatment that is affordable. Section 3(d) of the Act has been used several times by the Indian patent office to deny patents for other similar trivial inventions, especially in the case of HIV/AIDS medicines. If the section is diluted or overturned, all these cases will be reopened. Not just that – it will open the door for a flood of applications, many of which were not filed by companies because of the existence of Section 3(d). So the case can have implications for access to medicines not just for CML patients but for a whole range of patients who are today able to access cheaper drugs made by Indian companies. These patients are located not just in India but in over a hundred countries in Asia, Latin America and Africa. For example, over 80% of all patients in developing countries who consume HIV/AIDS medicines are able to do so because Indian companies supply them at an affordable rate. This is a case that Novartis must not win because it is not about corporate pride. It is a case that sets corporate greed against the lives of millions across the world.