CASE COMMENT: NOVARTIS AG VS UNION OF INDIA

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Abstract

The domains of human rights have always been at odds with the domains of intellectual property rights. Intellectual property rights are the sole dominion that is granted over the creation of a person's mind, where the person may either be a real person or a juristic person. This creates a competition with the realm of human rights in regards to profit mongering and the exorbitant amounts patients pay for lifesaving patented inventions. This incompatible regime and the primacy of human rights over IPR fosters the idea of an eternal conflict between the two regimes.

The intellectual property rights are in a way helping to realise the potential of human rights, for example the right to healthcare of various individuals in least developed countries is being supported by the regime of IPR that promotes the marketing of a generic drug of at a lower price range that is affordable for all.

The crux of the matter is simple, A strong patent regime directly impacts the attainment of the broader spectrum of human rights. The clamour is especially visible in the medical sector , where the in accessibility of drugs and life saving machines can cost the life of hundreds and particularly in the realm of pharmaceutical patent protection.

In a country like India, the ability of firms to legally reverse engineer the formulas of drugs promulgated by foreign companies and sell it in India for a fraction of the cost was something that could be considered an equaliser, but this all changed when the TRIPS agreement came into force. A recent case in the Indian Supreme court has reignited the debate between patents and patients , and triggered the age-old apprehension of protecting ideals which may be detrimental to the society at large.

The case of Novartis vs The Union of India , regarding the patent of Novartis's leukaemia drug Gilvec, has produced two sets of competing opinions, One set of opinions celebrated the judgement as a great equalizer to the inequality of the richer percentage of population being able to easily afford life saving drugs more easily than the common folk. Another set of opinions decry it as the herald of an age of diminishing innovation as the IP safeguards falter and diminish and their protection is eroded, creators are more apprehensive about innovation , let alone benefitting from it.[178]

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[178]https://www.blog.ipleaders.in/human-rights-intellectual-property-allies-enemies-strangers/#Is_the_patent_regime_the_culprit

A snapshot of the Case

Court: Supreme Court of India

Citation: Novartis Ag .vs, Union of India and Ors., AIR 2013, SCW 2047

Petitioner: Novartis Ag

Respondent: Union of India

Date of Judgement: 1st April, 2013

Facts-in-Brief

In 1998, the International_Pharmaceutical company, Novartis International AG, filed an application before the Indian patent office in Chennai , for its anticancer drug Gilves, which can also be used to treat Chronic Myeloid Leukaemia and Gastrointestinal Stromal Tumours. Gilvec, however was the beta crystalline form of the popular cancer drug Imatinib Mesylated, that is patented in almost 35 countries.

When Novartis filed for patent, the Patent act, particularly section 5 , only provided for a product by process claim and for substances that intended to be used as food or drugs could not be patented.

After the section was repealed by the Patent[Amendment] act, 2005, the application of Novartis was taken into consideration and summarily rejected by the patent office as it did not satisfy the conditions of novelty and the drug was anticipated by previous publication and was thus unpatentable under Section 3[d] of the patent act , which states that no patent protection is to be granted to a creation that is a new form of a previous publication and does not possess any increased therapeutic efficiency.

Then in 2006, Novartis filed two writ petitions in the Madras High Court basing their plea on the violation of TRIPS and a violation of Article 14 of the Indian constitution.

The Madras High Court , then transferred the matter to the Intellectual Property Appellant tribunal[179] which rejected the case on the un maintainability of the patent due to section 3[b] of the patent act.

[179] Novartis AGvs Union of India , 2013: indiankanoon
2. https:// www.mondaq.com/india/patent/826478/a-study-on-novartis-ag-vs-union-of-india#

Issues

The main issues in this case were:

1. The patentability of the creation , specifically regarding the section 3[d] of the Patent Act of 1970?
2. What is the interpretation of " Efficacy " in Section 3[d] of the Patent act?
3. Is the invention a novel idea of an engineered form of a previously known substance?
4. Does the new beta crystalline structure of Imatinib Mesylate discovered by Novartis have any improved attributes or is it the same as generic Imatinib Mesylate?

Arguments raised by both parties

Arguments by Appellants

The main gist of the appellant 's arguments was to prove the novelty of their invention and to undermine the basis in law for their patent application's rejection and to further prove that such a rejection was arbitrary and ambiguous and violates their rights. Some of these arguments are:

1. The provision of Section 3[b] of the Patent Act, 1970 is ambiguous and arbitrary as the interpretation of the phrases" significant enhancement of efficacy" and enhancement of efficacy is still unclear.
2. The creation meets the qualifications as an invention under Section 2[1][i] of the Patent act and thus the provision pertaining to discoveries does not apply to it.
3. The basis for rejection of patent by the Intellectual Property Appellate Board is shaky as they had regarded an "invention " as a "discovery" and rejected the claim based on section 3[b] of Patent act.
4. The enhanced efficacy of imatinib mesylate beta structure was a feature unique to the beta crystalline form of the substance and could not be found in the original Imatinib.[180]

Arguments by Respondents

The main gist of the respondent's arguments was to prove the derivative nature of the invention and promote the interest of the public and prevent the ever greening of an already patented substance. Some of these arguments are :

1. The beta crystalline form of Imatinib Mesylate is not novel or non-obvious , as the discovery of the drug was published in the magazine " Cancer research and nature"
2. The interpretation of efficacy as in under Section 3[d] of Patent act should only be confined to " therapeutic efficacy" rather than physical efficacy.

[180] https:// blog.ipeaders.in/analysis-Novartis-g-vs-union-India/

The Supreme Court's Judgment

The Hon'ble Supreme Court of India, set aside the appeal filed by Novartis and upheld that the beta crystalline form of Imatinib Mesylate is indistinguishable from its base form. The court further stated that the interpretation of Efficacy as in under Section 3[d] of the Patent Act only means " Therapeutic efficacy" and no other properties are relevant. And the beta crystalline structure of imatinib mesylate , upon further scrutiny does not hold any features that contribute to an increase in therapeutic efficacy of the drug and Novartis had not submitted any document or evidence regarding their claim of their new beat structure being 30% more efficient than its base molecule. The Supreme court ruled it lacked originality and further held that a patent holder cannot use a restricted interpretation of an already existing invention when assessing novelty in relation to a derivative.

Author's Take

The court in this decision , struck balance between innovation and public interest . It prevented the potential evergreening of an already patented drug by the making of small structural changes . The court then clarified the interpretation of potential ambiguous provisions of the Patent act. The courts also upheld the integrity of Indian IPR regime by guaranteeing that only legitimate novel ideas are given patent protection in India.

This ruling was a big win for public health and access to medications and put the spotlight on the predatory practices of the Big Pharma by misuse of IPR regimes. It also upheld Indian policy space for the balancing of patents and public interest.

The ruling gave relief to many impoverished patients who could not afford to have access to the high-priced medications. This ruling paved way for companies like Cipla to go on to produce much cheaper versions of these medicines and market them to the public at a fraction of the cost.

The decision oof the Supreme Court to take a limited stance on patenting and allowing only the novel, genuine ideas to be patented was warranted , especially by the essentiality of access to medicines to a growing population of a billion and preventing the corporations that have a stranglehold on medicines from preying on the impoverished .

This ruling also asserted the need to strike a balance between human rights and intellectual property rights . The rights have to be incorporated in such a way that one can be assimilated within the scope of another in a way their core legislations do not compromise their objectives and a unique redressal mechanism has to be drafted in order for conflict resolution.

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