

Why the Novartis patent refusal puts evergreening back in the spotlight

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The decision of the Indian Supreme Court to deny Novartis' application for patent protection for an improved version of its Glivec drug - the culmination of a seven-year battle - has certainly made world headlines and put the spotlight on generic drugs and the practice of evergreening, which could have a significant impact on the local pharmaceutical industry.

The generics industry is huge - worth some R6 billion in South Africa alone - and major players in the local market include Aspen, Cipla Medpro and Adcock Ingram. What generics companies do, essentially, is to replicate drugs that are no longer protected by patents. In order to register a generic with the Medicines Control Council (MCC) you simply need to show that you have mimicked the original in terms of dissolution and absorption. You don't need to prove efficacy because that's already been established.

Because generics pose a threat to pharmaceutical companies, the issue of evergreening has become very important. Indian patent law is known to be hostile to evergreening, but it's been reported that there are patents for the new Glivec in a number of countries, including the US, China, Russia and South Africa.

So just what is the position in South Africa on this?

The South African Patents Act does not say anything about evergreening and there have not been any decisions as far as we are aware. Generics companies do, however, complain that the system works against them. For starters, in South Africa there is no examination of patent applications (except for formalities), which means that the only time that a patent is considered on its merits is if it's challenged in court, something that only really happens as a response to a claim of infringement. But, say the generics companies, even if they do want to contest the validity of a patent on the basis of evergreening/ lack of novelty - perhaps because the new patent comprises no more than a different manufacturing process or dissolution profile - the reality is that the pharmaceutical company will get an interim interdict because the "balance of convenience" favours it, and the issue of the validity of the patent will be put off for another day (another year really!). Which means that, irrespective of the merits of the new patent, the pharmaceutical company can buy a few years extra protection.

It is for reasons like this that certain parties, including the Treatment Action Campaign (TAC), are calling for a reform of the patent system in South Africa. Such reform could mean amendment of the Patents Act to include clauses similar to those found in section 3 of the Indian Patents Act, which are perhaps a little more "politicised" and "generic friendly", and the application of which made the Glivec decision in India less surprising. Intellectual property laws do, however, not receive a great deal of attention from the government and court cases are few and far between, which means that it may be some time before we have clarity on the issue of evergreening.

Why did the Indian court deny the Novartis application?

There are a number of reasons for this. Firstly, Glivec is a well-known drug - described by some as a "wonder drug" - that's used to combat cancer, including leukaemia and gastro-intestinal cancer. Secondly, pharmaceutical patents are inherently controversial because they're emotive - pharmaceutical companies argue that they deserve as much protection as they can get because so much research and development goes into drugs, whereas civil society often argues that patents allow the drugs companies to charge a premium, thereby placing life-saving drugs beyond the reach of much of the world's population. And, thirdly, the Glivec case dealt with the issue of evergreening, which is the practice of patenting modifications or improvements to a patented drug and thereby extending the 20-year protection granted by the original patent.

It's no coincidence that this high-profile drama played itself out in India - with its population of 1.2 billion people; India is one of the most important and fastest-growing pharmaceutical markets in the world. India is also the centre of the world's generic drug industry and it's a country where few people can afford Glivec, but where generic versions of that drug sell for some 1/10th of the price of the original product.

The facts of the case were straightforward. Novartis applied to patent the updated version of Glivec, claiming that the new compound was a significant improvement in that the original compound was never really suitable for making a pill, and that the development of a chemically stable form took a great deal of extra work. The court, however, ruled that the new patent did not satisfy the requirement of novelty, being no more than an amended version of a known compound, namely that of the original Glivec - novelty does, of course, lie at the very heart of the patent system, which rewards new inventions through monopoly protection.

The comments released after the announcement of the Novartis decision show just how wide the divide is - a Novartis spokesman said that the decision "discourages innovative drug discovery essential to advancing medical science for patients", whereas a spokesman for one of the groups opposed to the patent said that the decision would "go a long way in providing affordable medicine for the poor". The commercial importance of the case was illustrated by the fact that the Novartis share price dropped on the announcement of the decision, whereas the share price of a major generics company rose sharply. The decision was also not good news for the pharmaceutical companies Pfizer and Roche, which are both facing similar legal issues in India.

The Novartis decision certainly raises questions about the patent system in general. As a result of the extraordinary amount of patent litigation that's been going on in the field of mobile devices - for example Apple vs Samsung - a certain amount of soul searching has been taking place. A highly respected US patent judge and academic, Richard Posner, has, for example, queried whether patent protection should be the same for all inventions, suggesting that short-lifespan products like mobile devices should also have a short term of patent protection.

Even more controversially, he has suggested that "most industries could get along fine without patent protection". But it's significant that he describes pharmaceuticals as "the poster child for the patent system", arguing that 20 years for pharmaceuticals is more than warranted given the R&D that takes place.

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