

## Indian patent wars

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In the past couple of years there have been some interesting and at times very contentious decisions regarding patent practice in India. We have previously reported on a couple of court decisions<sup>1,2</sup> and there are no signs of the battles abating.

### Cipla asks Indian Government to revoke five Novartis patents

Generic drug maker Cipla has recently asked the Indian government's Department of Industry Policy and Promotion to consider revocation of five Novartis patents related to their product Onbrez. Onbrez has the active ingredient indacaterol and is used to treat chronic obstructive pulmonary disease. Cipla estimates more than 15 million Indians are affected by the disease, but believe only a fraction of this need is being met by the current imports of Onbrez.

Cipla is launching a generic product with the active indacaterol under the name Unibrez. Cipla has indicated Unibrez will be sold at about a fifth of the price of Onbrez. Once Unibrez is on the market, it seems very likely Novartis will take court action against Cipla for infringement of their patents. The request to have the Indian government revoke the patents is likely a pre-emptive strike against this.

There have been similar situations in the past in India, but this case is notable for a new tactic being employed by Cipla.

In previous cases patents have been revoked or refused because they have not met the requirements to be granted a patent.<sup>1</sup> While the requirements to be granted a patent can vary slightly between countries (which can cause tensions itself), this is the standard way of overturning a patent. An alternative tactic used in a case in India in 2012 was to use the "compulsory licence" provisions of the patent system. This was alarming to big pharma as it allowed the court to force Bayer Corporation to grant a licence to their patent so that a generic manufacturer could sell the patented product if they paid a relatively modest licence fee.<sup>2</sup>

In this latest case it seems likely these previous tactics will also be employed, but Cipla also goes one step further and has asked that the government revoke the patent on the ground it is *mischievous to the state or generally prejudicial to the public*.<sup>3</sup> This could be seen as cutting to the heart of the patent system. Are patents *mischievous to the state or generally prejudicial to the public*?

The basic intention of the patent system is to reward and encourage innovation. In return for developing a new product or process and publically releasing the details of how to perform the invention, a monopoly is granted for up to 20 years.<sup>4</sup> At the end of the term of the patent,

anyone should be free to use what was described in the patent. However, in some cases where there are multiple patents around a product (an approach sometimes called *evergreening*), even when one patent expires it can still be difficult to put a generic product on the market.

Clearly there is a fine balance between granting a monopoly so that others cannot immediately copy a product that has taken years and great expense to develop, while still ensuring a product that is desired by the public is available on reasonable terms.

Innovator drug companies would likely argue without their research and development programs new drugs would not even exist, and without the patent system it would not be economically viable to carry out the level of research and development required for these new drugs. However, if a patent is granted does it give the owner the right to wholly dictate on what terms they will supply the product? Is this just a problem with the patent system or does regulatory and competition law have a part to play? Is there, perhaps, a difference between first, second and third world countries when considering these issues?

This is clearly a very difficult and complex problem. All eyes are presently on the Indian government to see how they will deal with this request and whether it will open another pathway for others to challenge Indian patents.

If you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact us.

### References

1. Chemistry in New Zealand Volume 77, No. 3, July 2013, Patent Proze, "Indian patent decision highlights the bond between politics and patent law".
2. Chemistry in New Zealand Volume 77, No. 3, July 2012, Patent Proze, "First compulsory licence in India serves as a wakeup call to global pharmaceuticals firms".
3. Section 66 of Indian Patents Act 1970.
4. The standard term of a patent is 20 years but renewal fees must be paid to keep it in force. In addition in some specific circumstances the term can be extended in some countries.



Katherine Hebditch of Baldwins Intellectual Property in Auckland specialises in chemistry and biotechnology patents. Katherine obtained her PhD in organic chemistry from the University of Manchester in the UK in 2004. She is currently working towards registration as a patent attorney.