EU dispute with India and Brazil ups stakes in generics saga

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In January 2008, a generic version of Cozaar™ (an antihypertensive drug) en route from India to Brazil was seized under EU customs regulations while in transit in the Netherlands. The seizure, carried out at the behest of the patent owners Merck and DuPont, has reignited the debate over the extent of intellectual property (IP) rights and the availability of patented medicines to developing countries.

Despite the absence of a patent in Brazil or India, Dutch officials deemed the "storage" of the patented drug on Dutch soil to be infringement of the Dutch patent. Although the seizure was later released and flown back to India by the generics producer (in this case Dr Reddy's Laboratories), the fallout from this and more recent EU seizures has led India and Brazil to beat a path to the door of World Trade Organisation (WTO) to file a complaint. If high-level diplomatic talks between the EU and India/Brazil fail to reach a settlement, it seems likely that the WTO will be left to decide on the extent of protection afforded by IP laws to goods in transit. The international interest (and in some quarters, outrage) in this case highlights the deeper rifts in respective attitudes towards IP between the so-called developed and developing countries.

Protecting your investment

Multinational pharmaceutical companies (collectively “Pharma”) argue that a robust IP enforcement strategy is essential to protect their investment in research and the extraordinary costs and time (on average USD802 million and 7.5 years) to take a drug to market . They might ask why it is that generics companies are able to steal the fruits of their labour and sell them on as cut-price and, in some cases, sub-standard pharmaceuticals. It is argued that the practice exposes patients to potentially harmful counterfeit pharmaceuticals, and that cut-price generics deprive Pharma of revenue to develop new and improved medicines to treat future generations. Enforcing IP laws is therefore said to be an essential part of Pharma’s strategy to ensure survival in a competitive global marketplace.

Protecting the poor

In the other corner of the ring are the generics manufacturers who argue that seizures such as those seen in the EU constitute anti-competitive practice on the part of “Big Pharma”; solely designed to sustain the market status quo and deny opportunities to companies from growing economies. Such practices are also argued to be to the detriment of millions of people in developing countries by denying them access to affordable medicines. The recent EU dispute drew protests from those in the Indian pharmaceutical industry who felt that the seizure was taking the scope of IP laws in Europe too far. Amar Lulla, the joint managing director of Cipla (one of India's largest pharmaceutical manufacturers), expressed his opposition to the seizure saying “The EU has to be resisted at every forum as this is an outrageous step to scuttle Indian exports. This is part of Big Pharma's multi-pronged strategy arising out of their desperate

situation of scanty product pipelines".

The Patent System

Patent protection is designed to stimulate and incentivise innovation by guaranteeing the inventor a limited period of monopoly in exchange for publicly disclosing how to produce or work the invention. However, the scope of the monopoly only extends to the countries in which a patent has been granted. A "global" patent does not exist. Potential patent owners must therefore determine where to invest in a patent; a choice dictated by both economics and whether patent rights can be obtained and effectively enforced. These decisions can restrict access to the product from both a supply and affordability perspective; a situation more likely to occur in less developed countries where healthcare funding is limited or non-existent.

In the countries where the patent has not been granted or has expired (usually after the twenty year term), generics manufacturers may legitimately take up the slack by manufacturing the drug and supplying it domestically and to other countries where a patent is not registered.

At the time the original Cozaar™ patent application was filed (1989), India did not allow patents on pharmaceutical compounds; only the manufacturing process could be protected. Reform came about as a result of a WTO deadline to adhere to the TRIPS agreement. From 2005, patent owners could obtain patents on the active compounds and could gain protection for novel compounds invented after 1995. Despite the reforms and significant improvements to the level of IP protection in India in recent years, India still lies second to bottom of the Global IP Index (China sits at the bottom).

This index assesses and compares how 24 major IP jurisdictions fare on obtaining, exploiting, enforcing and attacking particular types of IP.

Brazil (which lies one place ahead of India in the Global IP Index) has also had issues with providing robust IP protection to patent holders. While not overtly refusing to grant patents on active compounds, Brazilian patent law (in common with Indian and New Zealand patent law) contains compulsory licensing provisions that can be invoked if favourable terms are not offered by the patent holder. Potential enforcement of these provisions has been used as a bargaining tool by the Brazilian government to force patent owners to reduce prices and indications are that this trend will continue. Despite this, only one compulsory licence has been issued to date (for the antiretroviral drug efavirenz).

The decision by governments on how to legislate and apply their own IP law to benefit their economy has to be finely balanced with honouring commitments to international trade treaties (such as the TRIPS agreement). Other countries and organisations try to influence these decisions by employing incentives and penalties such as trade agreements and import tariffs. The recent reform in India reflects the shifting of this balance as the Indian economy moves from manufacturer towards an R&D led knowledge economy supported by strong IP protection.

The Ideas Pipeline

The practice regarding enforcement of IP rights is in a constant state of flux and depends on interpretation as well as statute. This fact is illustrated by a recent decision in the UK which allowed the transit of counterfeit goods; the court found that trademark

infringement does not occur unless the counterfeit goods were likely to be placed on the market in the transit country. The UK decision appears to be at odds with the Dutch practice although EU deliberations may lead to a more unified outlook.

The EU dispute is a minor piece in an immensely complex jigsaw to which this short article cannot do justice. The overwhelming reality is that many millions of people in developing countries lack access to even the most basic medicines and this is a situation that should not be overlooked by the more fortunate in developed countries. Generics manufacturers play an important role in providing competition in the global pharmaceutical economy. However, diluting the power that IP has to incentivise innovation in developed nations is not a sustainable solution. The developing world will only benefit from new medicines if the product pipeline from knowledge-based economies keeps flowing; patents and a return on investment are an essential part of that pipeline. The solution lies in government, Pharma and NGO backed initiatives and partnerships. These initiatives could include promotion of multi-tier pricing strategies by Pharma and the use of development funding to subsidise medicines and develop distribution infrastructure. The goal of providing affordable, high quality healthcare to the masses may then be a step closer.

A reminder: if you have any queries regarding intellectual property related matters (including patents, trademarks, copyright or licensing), please contact: tim.stirrup@baldwins.com or katherine.hebditch@baldwins.com