
Editorial

The need to create a balanced system: How to discourage abuse by IP holders and patent infringement

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No doubt the granting of patents has been key to ensure high returns for the innovative industry. After all, these barriers to entry to competitors have allowed the innovative industry to price its medicines at values that the market could bear ensuring high returns for its shareholders. Its investment in the research and development of medicines cannot be underestimated (although it is not possible to know what the exact numbers are as there is no transparency as to how companies arrive to such figures), it is clear that high returns are needed in order to ensure the sustainability of the industry. At the same time, the generic industry has played a key role in providing more affordable live saving medicines for consumers and governments after the expiration of the patents.

Therefore, markets and societies need both types of companies and medicines, but has the system been balanced? This is questionable and in fact, many would argue that it has not. A recent report from the European Union (EU) shows that the system has been tipped in favour of the innovative industry, in part through actions intended to delay generic competition, such as the filing of frivolous patent infringement lawsuits.

Indeed the Preliminary Report on the 'Pharmaceutical Sector Inquiry' published by the European Commission on 28 November 2008 states that 'the number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007'. In addition, the report states that '[t]he majority of court cases were initiated by originator companies. However, generic companies won the majority of cases in which a final judgement was given (62 per cent)'.¹ The EU report goes even further when it states that '[e]nforcing patent rights in court is generally legitimate: it is a means of ensuring that patents are respected. The inquiry's preliminary finding is however that litigation can be an efficient means of creating obstacles in particular for smaller generic companies. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants'.²

Therefore, one could argue that the legal system may have been used to tilt the current patent system in favour of Intellectual Property Right (IPR) holders since even if they lose a case, they may succeed in delaying generic competition. Even if the courts rule against the innovative company, it may be a winning strategy as they may extend monopoly rights over a medicine, in most cases blockbuster medicines (those medicines whose annual revenues exceeds US\$ 1 billion). Nevertheless, if a generic company is found to have infringed a patent it needs

to compensate the innovator. In the United States such compensation may entail the payment of treble damages. Is this a balanced system?

Unfortunately, the system is also being gamed in other ways. The Preliminary Report of the European Commission cited above also found that 'originator companies have designed and implemented strategies (a 'tool-box' of instruments) aimed at ensuring continued revenue streams for their medicines. Although there may be other reasons for delays to generic entry, the successful implementation of these strategies may have the effect of delaying or blocking such entry'.³ In fact, the report concludes that '[t]he sector inquiry confirms that generic entry in many instances occurs later than could be expected'.⁴ Such delay may represent an unnecessary expenditure of drugs at monopolistic prices. In the case of sample of medicines reviewed in the report this alone amounted to about 3 billion of euros. The final report scheduled for early summer 2009 is expected to make recommendations to EU national governments, the EU and even the European Patent Office to make changes to improve the balance. The European Patent Office (EPO) has already started to look at raising the bar by looking at issues such as patent quality, inventive step and examination assessments. Many of these IP issues had been raised before the inquiry by the EGA in its report 'Patent related Barriers to Market Entry for Generic Medicines in the European Union'.⁵

It is important to keep in mind that the real purpose of the patent system is to promote innovation. A report of the US Federal Trade Commission entitled 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy' released in October 2003 specifically states that 'Competition and patents stand out among the federal policies that influence innovation. Both competition and patent policy can foster innovation, but each requires a proper balance with the other to do so. Errors or systematic biases in how one policy's rules are interpreted and applied can harm the other policy's effectiveness'.⁶

For a long time the talk has been about the rights of patent holders and the need to enforce patent regimes. Throughout the world laws impose strong penalties for patent infringement and there is currently a debate over the need to strengthen the enforcement of intellectual property rights. Although we fully support the protection of intellectual property rights and their enforcement, it is also important to respect and protect the rights of consumers and the generic industry. Thus, it is necessary to have a balanced system where competition is also respected. If a company infringes a patent it must face the consequences. By the same token, if a patent holder abuses its rights, it should also be subject to penalties. This way society will ensure the responsible behaviour on the part of all the parties involved.

Australia has set an important first precedent in that sense. During the implementation process of the Australia–US Free Trade Agreement, the Australian Parliament incorporated a set of provisions to penalise patent holders who abuse their rights. This is fully consistent with the TRIPS Agreement, which states in Article 8 that 'Members may, in formulating or amending their laws and regulations, ... adopt appropriate measures, ... to prevent the abuse of intellectual property rights by right holders ... '.

In addition, a number of countries have implemented pre-and or post-grant opposition systems to ensure the quality of those patents that are being issued. Nevertheless, the innovative industry is pressuring countries that have adopted some of these opposition systems to give them up. As the FTC report of 2003 states, questionable patents are a significant competitive concern and can harm innovation.⁷ Adopting effective and fair opposition systems and penalties for those who abuse their rights are important elements to strike a proper balance between patent and competition policies, which are the key to truly foster innovation and provide new and effective medicines.

NOTES

1. Executive Summary – Page 8.
2. Executive Summary – Page 8.
3. Executive Summary – Page 3.
4. Executive Summary – Page 3.
5. May 2008.
6. Executive Summary – Page 1.
7. Executive Summary – Page 5.

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