

Introduction

It has long been the case, and not just in the pharmaceutical sector, that a highly visible fault line exists between monopoly rights granted by patents, and the inherently anti-monopoly mind-set of European and national competition authorities. Along that line there are regular tremors, occasional earthquakes, and always friction.

Both sides claim to be on the side of right. The patent lobby points to the need to stimulate innovation and, more importantly, investment in the implementation of innovation, by the grant of limited monopolies to allow the recovery of the massive investment costs, in exchange for the disclosure of the invention to the public.

The competition lobby avers that monopolies are intrinsically bad and by their nature dangerous, in that they lead to high pricing policies and put the monopoly holder in a position to dictate the operation and direction of the market. This can lead, so it is argued, to all manner of abuse, including withholding important drugs in order to create demand for newer, more expensive drugs from the same source.

The dichotomy of views has been played out in courts and other tribunals at all levels.

The European Commission has been careful to remain impartial as far as it can in its public utterances – it does after all administer a treaty which recognises the legitimacy of properly obtained intellectual property rights.¹

However, its Directorate General for Competition (DG Comp) is somewhat less even-handed and has conducted a series of inquiries specifically targeted at what it sees as unfair and monopolistic practices in relation to the use of intellectual property, and particularly patents, in the pharmaceutical sector.

Where does the balance really lie? Is the approach of DG Comp justified, or should more heed be given to the importance of the role of patents in encouraging innovation and a thriving market for new drugs and remedies?

The Competition Perspective

The ‘Citizen’s Summary’ of the European Commission’s inquiry into the pharmaceutical sector² makes the DG Comp position quite clear. Referring to ‘a variety of techniques’ and ‘certain drug company practices’, it alleges a concerted effort to abuse the patent system, and in doing so to delay the availability in the market of lower-cost generic medicines. It further alleges that these practices and techniques actually reduce the number of innovative medicines reaching the market, and champions the cause of a pan-European patent and enforcement system to enable Europe-wide challenges to the validity of patents and the reduction in artificial national divergences of outcome and emphasis.

EDITORIAL

THE GREAT DIVIDE? THE INTERACTION OF PATENT LAW AND ANTITRUST IN THE PHARMACEUTICAL MARKETS

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1) TFEU Articles 36 and 118, for example.

2) Competition Inquiry into the Pharmaceutical Sector (2009).

DG Comp promised to apply much closer scrutiny of the sector and to prosecute companies for alleged violation of competition law. Underlying this is the assumption that the patent system is open to material abuse, and that such abuse is both commonplace, and damaging to the over-arching goal of putting innovative medicines into the market as quickly as possible.

What exactly are the so-called ‘techniques’ and ‘practices’ deployed to abuse the patent system and cause delay in the availability of generic drugs and bio-similars? According to DG Comp they include: the creation of patent clusters and the filing or acquisition of large patent families, with a view to limiting freedom to operate in specific markets; large-scale and expensive litigation strategies to create prohibitive cost and delay in achieving clarity as to market entrance; highly restrictive settlement agreements, sometimes featuring ‘pay for delay’ provisions, encouraging manufacturers of generic drugs to hold back in return for favourable financial terms; and the prolongation of patent protection through prosecution strategies, including filing multiple divisional patents.

The question arising from all of the allegations and assertions is this: what is, or should be, the role of DG Comp in addressing issues relating to patents and the patenting system? DG Comp’s view is that, notwithstanding its acceptance that Europe is blessed with an excellent patent office and systems, it still has a key role in policing misuses of that system and the behaviours which bring that about. Its approach is somewhat transparent from a passage in the full report into the progress of the Commission’s work following the 2009 inquiry.³

Innovation is crucial in the pharmaceutical sector, with pharmaceutical companies among the leaders in investing in R&D. However, market participants may sometimes engage in conduct that affects the incentives to innovate (patenting, interventions before authorities, acquisitions of competing technologies etc.). In doing so they may breach competition law. (emphasis added)

The import of this is clear. DG Comp sees the business of patenting in itself as conduct that ‘affects the incentive to innovate’ and which ‘may breach competition law’.

When it came to report on the outcome and effectiveness of its work between 2009 and 2017, it claimed success but without actually identifying particular abuse relating to the filing and prosecution of patents. It pointed to significant use of ‘pay for delay’ settlement deals, but these, it could be argued, fall outside the scope of what could properly be called abusive patent filing and enforcement strategies. The ‘exclusionary conduct’ DG Comp identified related to the intervention by pharmaceutical companies in the approvals process for generic drugs.

³) Competition Enforcement in the Pharmaceutical Sector (2009–2017) page 4.

However, there are now potential actions pending concerning actual patent filing and prosecution practice, including one announced as recently as March 2021.⁴ It is quite clear that DG Comp does indeed see the oversight of the patenting system as a key part of its role, notwithstanding its acceptance that the EPO is equipped to manage and conduct the patent system in Europe, supported by national offices and courts.

The Patent Law Perspective

There was a period when, in the United Kingdom, the deployment of the so-called 'Euro-defence' was a regular feature of patent litigation. The nature of the defence was an assertion that by its very nature a monopoly, however granted, gave rise to a dominant market position, so that the aggressive enforcement of a patent underpinning such a monopoly could give rise to abuse. These arguments were rarely made out and, until recently, became much less popular. They were expensive to run and a few well-placed punitive costs orders sent a strong message that the courts did not much like having their time wasted in this way.

The UK courts have, on the whole, adopted the line that the patent system is a force for good and is to be encouraged, though also scrutinised very carefully by the courts themselves and policed by the granting offices.

In the *Chiron* cases⁵ in 1995, Aldous J said of the opportunity to acquire monopoly rights:

First it encourages research and innovation; secondly, it induces an inventor to disclose his discoveries instead of keeping them secret; thirdly, it offers a reward for the expense of developing inventions to the state at which they are commercially practical and, fourthly, it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. Those are particularly relevant to the development of medicinal products.

More recently, in 2020, in *Edwards v Evalve*,⁶ Birss J referred to the patent system as being 'criss-crossed' with provisions which strike balances between public interests.

What are these provisions which, in the context of the pharmaceutical sector, provide the balance between the monopoly incentive and the public interest in having access to plentiful, affordable and efficacious medicines?

Threshold control. It is not easy to obtain a patent. There are a complex range of factors which have to be satisfied if a patent is to be granted. The invention must be novel, non-obvious, and capable of industrial application. These factors are all rigorously examined in the patent offices affecting European business. Lengthy exchanges and office actions all illustrate the complex assessment applied to the grant of a valuable monopoly right.

4) The investigation into alleged abuse by Teva in relation to Copaxone by filing and withdrawing divisional patents to delay the arrival of generic manufacturers in the market by creating overlapping 'patent walls' to act as barriers to market entry.

5) *Chiron Corporation and others v Organon Teknika Ltd* No.10 [1995] FSR 325.

6) *Evalve Inc v Edwards LifeSciences Inc* [2020] EWHC 513 (Pat).

Pre-grant intervention. *In both the EPO and the UKIPO it is open to an interested party to intervene in the prosecution process to challenge the application for a patent – the procedure is not necessarily limited to participation from the granting office and the applicant.*

Post-grant challenges (1). *The opposition procedure in the EPO is powerful and thorough. Any party who wishes to challenge the validity of a granted patent may do so within a period of nine months from grant, and appeals are available from the first assessment of the opposition. The revocation or amendment of a granted patent by this process applies across all countries where the patent has been designated, so anyone objecting to the grant of a European patent is afforded the opportunity to ‘clear the path’ across the whole of the EPC territory.*

Post-grant challenges (2). *It is open to any party to challenge the validity of a patent in the courts of the countries in which it has been granted. The impact of a court finding will be limited to that country, but strong decisions in key jurisdictions can have an advisory effect across the wider territory of the EPC.*

Compulsory licences. *In relatively extreme circumstances, compulsory licences can be obtained by third parties to ensure that valuable technology is not being blocked by the unwillingness of a patent owner to exploit the patented invention.⁷*

The term of patents. *A 20-year monopoly does not provide excessive support for investment and, as is mentioned below, in some limited cases increased protection is necessary to provide fairness to the investing patent owners.*

The ‘criss-crossed’ provisions, of which the above is an incomplete list, are administered by patent offices and national courts, to ensure that the patent system is rigorously policed. Many applications do not result in granted patents, and statistics from the UK courts in recent years demonstrate that fewer than half of patents which actually end up being litigated in court are found to be valid and infringed, and the proportion is lower still for pharmaceutical patents.

Is that not enough? The thresholds to be met to obtain a patent, and the steps available to those who wish to oppose or challenge a patent, both administered by experienced and rigorous offices and tribunals, would seem to provide sufficient balance to ensure that the system operates fairly and in the public interest.

The assumption which appears to underlie the attitude of DG Comp is that the public interest is served best by permitting rapid market access to generic manufacturers, to drive down prices and to increase the availability of medicines. This does not appear to take into account the competing public interest in ensuring that the incentive is there for companies to spend huge sums of money and huge amounts of time researching, developing and obtaining approval for innovative medicines and therapies.

7) Patents Act 1977 sections 48 to 50, TRIPs Article 31.

These issues have been played out at length in the long-running Paroxetine saga, which ended in the Court of Justice of the European Union.⁸ At the heart of this was the so called ‘pay for delay’ issue, which arose from the settlement of patent litigation. When the case was heard before the Competition Appeals Tribunal in 2018, the unanimous judgment of the tribunal, comprising antitrust specialists, included the following passage:

In our view, an outcome of the litigation whereby the patent was upheld and the generic company found to infringe is not to be regarded as less competitive than an outcome the other way, since the purpose of the patent system is to stimulate innovation, which promotes dynamic competition. A court determination that a patent is valid and infringed therefore cannot properly be regarded as a ‘negative’ result for consumers even if it means that they will continue to pay higher prices for the patented goods. Such determinations are a necessary means of ensuring that patent-holders receive the proper rewards for their innovations.⁹

It is interesting to find a competition law tribunal acknowledging with such clarity the need for a working patent system to encourage innovation and development of working medicines.

The same point was made in rather more basic terms in the famous blog post of AIDS survivor Andrew Sullivan on 1 July 2005 when he said:

The ‘evil’ pharmaceutical companies are, in fact, among the most beneficent organisations in the history of mankind and their research in the last couple of decades will one day be recognized as the revolution it truly is. Yes, they’re motivated by profits. Duh. That’s the genius of capitalism – to harness human improvement to the always reliable yoke of human greed. Long may those companies prosper. I owe them literally my life.¹⁰

Mr Sullivan may not be seen as the most objective observer of the market, and claims no expertise in economics, but he speaks for a large part of the population who have benefitted directly from heavy investment in the research and development of innovative medicines. The same issue has, of course, raised its head in 2020/21 and when the world needed it most, it has been AstraZeneca (with Oxford University), Pfizer/BioNTech, Moderna, Johnson & Johnson and others which have stepped up to develop and provide functioning vaccines, in some cases on a reduced or non-profit basis.

There is further evidence to support the general contention that patent protection is necessary to encourage innovation in the complex rules regarding Supplementary Protection Certificates¹¹ and the designation of orphan drug status.¹² Both are designed to ensure adequate duration of patent protection, in the first case to ensure a useful term of protection if the marketing authorisation process is prolonged, and in the latter case to encourage investment in drugs necessary for rare conditions and diseases which might otherwise not attract the necessary financial support to develop innovative and useful medicines and treatments.

8) Case C-307/18 *Generics UK and others (Paroxetine)* ECLI:EU:C:2020:52, January 2020.

9) *Generics UK Ltd and others v Competition and Markets Authority* (2018) CAT 4 at paragraph 321.

10) The text is no longer directly available but it has been widely reported in various internet discussion groups and this version was taken ironically, from the book *Against Intellectual Property* by Boldrine and Levine (Cambridge University Press, 2008).

11) Regulation (EC) No 469/2009.

12) Regulation (EC) No 141/2000.

Summary

At the end of it all, the fault line is still there and it will continue to generate heat and tremors. There is no perfect solution, and there will always be issues which cause great concern on either side of the divide. However, the balance is delicate and, for the most part, it is managed by the 'criss-crossed' provisions in the patent statutes and conventions which govern this complex area of economic activity. There is no serious economic argument that there should not be an element of patent protection to encourage investment in innovation and development, and as Aldous J said (quoted above), this is 'particularly relevant to the development of medicinal products'.

The patent offices and the courts police the application, grant and enforcement of patents. It seems inappropriate for the Competition Authorities to maintain any other than the very lightest of touches in a largely self-governing area, where a shift in the balance could have seriously adverse effects on the progress of medicines and therapies.