

A dangerous practice?

Settling patent litigation is not such a bad idea

by Ian S Forrester QC *

In a mooted competition, teams may learn at short notice which side they will be advocating in the next round. At a recent conference in London on IP law and competition organised by Bristows, it was my unusual experience to be asked to stand in for the representative of the European Commission who was blocked from attending. So it turned out that I described at the start of the afternoon the prosecutorial position of DG Competition and ended the afternoon by giving the position of the accused pharmaceutical patentee, regretting the encroachment on rights which are crucial for the business model of the pharmaceutical industry. This article will review the arguments in the hope of leading readers to a better understanding of the present tensions.

Predictability

First, there is a certain predictability in any debate on IP and competition. Those who favour the encroachment of competition law on the scope of the right usually invoke supposed consumer benefit, lower prices, the danger of monopoly exploitation and the dubious nature of the right itself. The defending company will state that the Commission has no competence to decide whether a right is valid or desirable; that inevitably any exercise of a patent, copyright or trademark right will restrict competition and that it is pointless to speak of the absence of competition when a legal monopoly is present; that the limiting principles of the encroachment are not clear; uncertainty for the future will therefore ensue; and good-faith rightholders will not be able to invoke their intellectual property rights without risk of accusations of infringing the competition rules. Such has been the case in celebrated past controversies: Volvo/Veng, Magill, IMS, Microsoft and TetraPak. Such is the case in the pending disputes about the settlement of patent litigation.

Why the row?

Wearing the hat of the prosecutor, I observed that the Commission would contend that the pharmaceutical industry was given a comfortable ride during the first 40 years after the adoption of Regulation 17/62, and that with the exception of parallel trade (where the industry won in *Bayer/Adalat*), core pharmaceutical industry policies had not been challenged; and indeed the settlement of pharmaceutical patent disputes had been notified to the Commission, and no action taken. So the Commission would deny that it could be reproached for victimising the industry. At most, it could be criticised for devoting effort to pursuing common pricing, since the member states that were paying for medicines plainly did not need or desire parallel trade. If governments want lower prices, they could impose them directly rather than relying on intermediaries who themselves pocketed most of the difference.

Moreover, it has been accepted for years that settlements are not immune from the competition rules, as the ECJ confirmed in *Bayer Sullhofer*. On one occasion (Toltecs Dorset) the Commission condemned a trademark settlement over an expired trademark. Why, then, the current excitement over the settlement of pharmaceutical patent disputes?

Interestingly, there are no complainants urging the Commission to be severe. Both generics and innovators want to retain the possibility to settle patent litigation, which is a necessary feature of the industry, with mutual concessions. So the commercial pressure against settlements is non-existent or minimal. By contrast, the paying social security organisations might have an interest in seeing prices fall quickly after a medicine goes off-patent; but they also have an interest in seeing new medicines emerge via research. It is maybe more relevant that in the friendly transatlantic rivalry between antitrust enforcers, the European Commission has not only adopted as a target a favourite theme of the Federal Trade Commission but has overtaken the FTC and now is comfortably ahead, in the sense that the decisions it is taking are far more interventionist than the line endorsed by the US Supreme Court.

Reasons to get tough

There is another plausible, institutional reason for the Commission's attacks on patent settlements. Anyone connected with the pharmaceutical industry will well remember the immense disruptions six years ago associated with the pharmaceutical sector inquiry. Heavy administrative investment requires administrative output. Lord Justice Jacob, not a particular friend of the industry, voiced fierce dissent when invited to address the meeting to report on the inquiry in 2008. Far from commending the Commission's hostility to industry practices, he mocked it as misplaced. He went further in the newly-published *Festschrift für Joachim Bornkamm*:

“The danger exemplified by the Commission's pointless and damaging pharma sector inquiry ... is forgetting that we are looking at the unpredictable and hugely dynamic business of innovation. Classical competition law is ill-equipped to do this. It is constructed around cartels and abuse of de facto monopoly power. So when it comes to monopolies actually recognised by the law, it struggles. (The inquiry cost the industry a huge amount ... and nothing or virtually nothing came out of it.)”

The public policy rationale for the Commission is bold indeed. A patent is a publicly-granted monopoly that confers upon the patentee a very valuable privilege, which allows the sale of a medicine at a higher price to the public purse than would apply in the presence of generic competition. Such privileges require strict construction. It is therefore in the public interest for weak patents (especially process patents) to

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be challenged and judicially annulled. So when a patentee and a generic potential rival are disputing validity or infringement (and commonly both), a settlement cheats the public of its chance of seeing the technology released to everyone after a judicial decapitation of the patent. On this theory, a settlement term by which the generic acknowledges the patent's validity and drops its challenge is therefore anticompetitive.

Why settlements are a good idea

The pharmaceutical industry, and the IP industry, would disagree. The patent is not a lottery ticket that might bring a prize or might not. It is not a claim but a right. It does not become better by being challenged repeatedly. The process of issuance is slow, careful, costly and sceptical. It is a publicly-granted right, granted after careful examination of technology and the literature by the world's leading patent agency. There is no merit in a rule that punishes contractual recognition of a patent's validity; nor in a rule that proscribes settlements by the making of mutual concessions. Litigation is a contest conducted under formal rules of procedure, ostensibly polite but intellectually brutal. It yields winners and losers. Unexpected things happen. Witnesses appear unreliable. Experts disagree. Surprises are routine. It is costly, very costly in England. Doubt about the outcome is universal, and there may be multiple outcomes in Europe.

While the Commission claims to favour settlements, the reality of its policy is that true settlements, those in which both sides believe they have a chance but each side harbours doubts, are likely to be forbidden by its new policy. Yet settlements are vital, and should be routine. It is not materially possible or economically desirable to pursue every litigation to the bitter end. There is no public interest in requiring that litigation, once commenced, be pursued uselessly or in duplicate proceedings. There is public benefit in removing cases from the court rolls – and deciding to settle a dispute rather than to fight it to the death is perfectly honourable.

Limitations of litigation

Litigation is not a service performed for others, like clearing the footpath after a snowfall. Litigation as to whether a patent is valid or invalid, infringed or not infringed, is conducted for private profit, not for the public interest. It is a means of vindicating or defending a property right. There are many areas of dispute where a public interest might exist in the underlying dispute and might not welcome settlements. Professional negligence, defective products, damages for breach of European competition rules (not involving pharmaceutical patents), sexual harassment and libel are a few. Many parties may have an interest in avoiding a public examination of the merits. I submit that there is no good reason to regard as presumptively unlawful settlements of patent litigation by mutual concessions.

The patentee may feel that its expert witness is not as clear and easy to understand as had been hoped. Perhaps the tests on the technology do not show as clearly as expected that the generic rival must be using the patented technique. Alternatively, perhaps the generic would-be competitor discovers that even if it wins the litigation, it lacks an approved product to sell.

Each side will be aware of the specific weaknesses of its case. A settlement ends the litigation risks by an outcome which is less attractive than hoped but less bad than might be feared. When faced with the reality of disappointment in the litigation, it is natural to seek something better than total defeat. When faced with a huge risk and an unpredictable process, it is natural (and prudent) to try to palliate the risks of the litigious process. Some negotiations will be uphill because the adversary conveys confidence, even if the adversary actually conceals a weak hand. A litigation fought to the bitter end is not competitively superior to a settlement before the courtroom door.

Taking a sensible business decision

In one case of which I have personal knowledge, the generic was faced with a bleak future. The legal costs were ruinous; there was a significant risk that the judge would find the patent had been infringed; and the product which it was planning to launch if it won the litigation had impurities which justified the regulatory authorities in banning it. So it decided to look for a settlement. Was that a wickedly anticompetitive choice?

In another case, the generic rival was sure it could show the process patent had been wrongly granted, and confidently launched its own product on several national markets. To its chagrin, it lost: the patent was upheld. The company emitted a few expletives, lamented the uncertainties of patent litigation, and decided to develop a non-infringing product over the next two years. Good, commercially intelligent choices. But what to do on the several national markets during the two years? It wisely chose to seek a licence from the winner of the patent dispute, since otherwise the sales would be illegal and the damages huge, and that way it stayed in the market.

However, according to zealots, the generic committed a gross fineable violation by settling. It should have done its public duty (litigate, litigate, litigate) regardless of other considerations (like commonsense). Surely this cannot be right? Do we need a new regime which makes an economic crime out of settling a patent dispute to avoid financial ruin?

Guided by reality

If there are abuses supposedly associated with settlements (sham litigation serving as a cloak for market-sharing agreements, settlements regulating matters beyond the scope of the patent) or other uncertainties, the matter deserves to be examined in the light of the facts: no immunity but no presumption. It cannot be a bad thing to be guided by reality.

We have no need of fresh automatic condemnations as by-object infringements. European competition law spent an eccentric period of some 40 years wrestling with the absurdities of a regime under which almost anything notionally restrictive was caught by the basic prohibition of article 101 (née 85) and was therefore prohibited, void and fineable, even if evidently commercial reasonable. Cures for these dire maladies were available only in the form of a rarely-granted specific blessing from the European Commission, or by accepting the prescriptions of a Commission regulation. The problem was that rational thought was unnecessary for the purposes of competition law analysis. It would be a great pity if competition law were to revert to the old days of treating words as more important than facts.