Competition and Patent Law in the Pharmaceutical Sector

An International Perspective

Edited by

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Published by:
Kluwer Law International B.V.
PO Box 316
2400 AH Alphen aan den Rijn
The Netherlands
Website: www.wklawbusiness.com

Sold and distributed in North, Central and South America by:
Wolters Kluwer Legal & Regulatory U.S.
7201 McKinney Circle
Frederick, MD 21704
United States of America
Email: customer.service@wolterskluwer.com

Sold and distributed in all other countries by:
Turpin Distribution Services Ltd
Stratton Business Park
Pegasus Drive, Biggleswade
Bedfordshire SG18 8TQ
United Kingdom
Email: kluwerlaw@turpin-distribution.com

Printed on acid-free paper.

ISBN 978-90-411-5927-4

Printed in the United Kingdom.

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Ian S. Forrester[*]

1 INTRODUCTION

The intrinsic tension between competition law and IP law has nourished many academic dissertations and has been at the core of several celebrated competition cases. I have written about this tension in such articles as Magill Revisited[1] and Compulsory Licensing in European Competition Law: The Power of the Adjective.[2] These cases often involve a conflict between 'free competition' on the one hand and on the other hand the classical exercise of an IP (closing down a copyright infringer, refusing to grant a licence). Sometimes, however, they involve an exercise of the right which is disputed as a matter of IP law (like invoking a trademark against the sale of non-spurious goods imported via parallel trade or tying to the licensing of a right acceptance of an obligation not conferred by that right). In the early cases, which came to the ECJ under the Treaty's provisions on free movement, the reason for condemning the invocation of the IP right was often conflict with the policy of market integration, as in the many Centrafarm cases from the 1970s:[3] there the holder of parallel patent or trademark rights in several Member States tried to block the sale of genuine goods to prevent parallel traders profiting from the differences in price in adjoining Member

* The opinions expressed are wholly personal. The law is stated as of December 2014, and may well evolve during the next five years.

1. See I. Govaere, R. Quick, M. Bronckers, *Trade and Competition Law in the EU and Beyond,* Festschrift for Jacques Bourgeois (Elgar Publishing, 2011).
2. See I. Forrester, K. Czapracka, *Compulsory Licensing in European Competition Law: The Power of the Adjective*, in S. Anderman, A. Ezrachi (eds) *Intellectual Property and Competition Law: New Frontiers* (Oxford University Press, 2011).
3. See Case 15/74, *Centrafarm, BV v. Sterling Drug, Inc.*, 1974 E.C.R. 1147, [1974] 2 C.M.L.R. 480 (1974); Case 16/74, *Centrafarm, BV v. Winthrop, BV*, 1974 E.C.R. 1183, [1974] 2 C.M.L.R. 480 (1974); Case 107/76 *Hoffmann-La Roche AG v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH*, [1977] ECR 957; Case C-102/77, *Hoffmann-La Roche & Co. v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse, GmbH*, 1978 E.C.R. 1139, [1978] 3 C.M.L.R. 217 (1978).

States. In the early cases, the European Court drew a distinction between core rights and ancillary rights (these are my glosses as existence and exercise were the words used), to justify a conclusion that the Treaty of Rome permitted the intervention of European law principles against obstacles to cross border trade. Those judicial theories were subsequently invoked in competition cases to argue that competition law could not constrain the assertion of a core or essential IP right, an assumption which subsequent cases such as Magill[4] and Microsoft[5] have shown to be ill-founded.

The topic described in this chapter is much more innovative, going to the core of the privileges conferred by IP law: it is a new kind of controversy, relating to the settlement of patent disputes. The topic originally became hot in the United States over the past ten years due to the quirks of US legislation about the status of generic competitors: they were encouraged by statute to enter the market, towards the end of the life of the patent, on favourable terms. As a result, litigation in the US offered a regulatory prize, and settling litigation became correspondingly more significant.

Officials have pursued the idea that there might be a comparable public interest in the EU, despite the different regulatory regime, in attacking agreements which settle litigation over whether a patent is valid or is infringed. How should competition law regard the settlement of a dispute over whether a patent on a pharmaceutical invention was validly granted and is infringed by a generic version of the original product? Is the settlement to be welcomed as a desirable resolution of an expensive and uncertain dispute, or should it be regarded as a scheme to perpetuate the existence of a patent of dubious validity, with the consequence that generic entry is postponed, to the detriment of tax payers in the sense that public health budgets have to purchase patented medicines during a longer period? Is there a competition law duty to prefer a judicial determination of a controversy over a contractual resolution of the controversy in which contract each side gets an outcome which is better than it feared but worse than it hoped?

2 SOME ECONOMIC AND REGULATORY CONTEXT

It may be helpful to begin by recording some of the context which may reveal a rationale for the recently adopted policy. Pharmaceutical medicines in European countries are sold in pharmacies to patients who have received prescriptions from doctors. In most EU Member States, the state pays a portion, sometimes a large portion, of the price paid by the patient;, and also the state usually prescribes the price. The more novel the medicine, the more elevated the price: governments set the price they are willing to pay in function of the therapeutic value of the medicine, and the price of other medicines in the same category. The price of patented medicines is usually higher than medicines no longer covered by patents (so-called generics). The shorter the period of patent protection, the sooner the price will fall; thus in Europe it can be

4. C-241/91 P and C-242/91P Judgment of the Court of 6 Apr. 1995, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Commission*, ECLI:EU:C:1994:210.
5. T-201/04 Judgment of the Court of First Instance (Grand Chamber) of 17 Sep. 2007, *Microsoft Corp. v. Commission*, ECLI:EU:T:2007:289.

argued that the challenging of the patent by a generic competitor is a merit, a public advantage, which may lead (if the court were to find that the patented invention had not been infringed or the patent itself had been wrongly granted) to a reduction of the country's health budget. Of course, it can also be noted that pharma companies make intense research to develop tomorrow's drugs using the revenues earned by selling patented medicines today. So if the patent is upheld the extra expense is not 'lost' to the public interest in that a percentage of the revenues thus earned will be spent on research by the patentee.

There is a related policy concern which has been articulated during the sector enquiry into the pharmaceutical industry, launched by Commissioner Kroes on 16 January 2008: that pharmaceutical inventors, instead of being content with the well-established years of patent protection deservedly accorded to the basic molecule, may additionally seek to get patent protection for complex steps in the production process which makes that molecule efficiently on an industrial scale. Thus a generic competitor would have to develop its own solutions to avoid the techniques covered by the process patents. As generics like quick low-price industrial operations, they prefer to make a product which is easy to copy or replicate. There may be a suspicion that these process patents are less worthy of respect than the original patents on the molecule itself. This policy approach (assuming it exists) confronts the problem that all patents are granted after extensive research by skilled patent examiners who have access to millions of publications about the prior art. They do not grant patents lightly. It is not easy to say that the European Patent Office (EPO) is systematically wrong, and it would be astonishing to argue that the competition law is a good remedy for any supposed over-generosity of the patent examiners at the EPO.

However, there is unquestionably suspicion about any agreement which appears to insulate a pharma patent from future challenge, and a readiness to assume that the agreement implementing a settlement of the dispute can be assessed by focusing on its prohibition of future challenges rather than by the saving of expense and effort which a settlement delivers.

One way of regarding a settlement is as a device to bring an end to an expensive and uncertain dispute. Another way of regarding a settlement is as a device to share a market between two natural competitors. The new, currently fashionable, theory is that while settlements are in theory desirable, their terms are to be reviewed so sceptically that genuine settlements of genuine disputes risk condemnation on the theory that they contain contractual restrictions typical of a settlement involving mutual concessions, by which each side binds itself to accept less than it might have hoped for at the moment the litigation was initiated. The settlement will exclude further litigious challenges.

As often happens when a major competition case is unfolding, the opposing theories are sharply opposed. The defending pharma companies say that a settlement makes commercial sense for both sides; every litigation presents a risk, the Courts are incapable of deciding all initiated litigations, and ending a dispute must be a public good. The competition enforcer says that of course settlements are to be welcomed, but

that there can be no immunity for anti-competitive agreements by labelling them settlements. Thus, when the settlement does no more than agree that a patent litigation has ended, it is acceptable. However, say the prosecutors, bad settlements which involve additional unacceptable features are to be condemned.

3 VALUE TRANSFERS

A 'value transfer' is the term attributed to a commercial advantage delivered by the inventor/patentee to the generic alleged infringer: this may be a new business opportunity or a payment or some other concession which is granted in order to make a conclusion of the litigation acceptable. Surely, says the critic, if the wrongdoer really was the wrongdoer and really was infringing the patent, the patentee would relish the chance of a crushing victory in court? Why should the confident patentee give a piece of business or a lump of money to the dishonourable generic who is violating a vital patent? Therefore, on this theory, any restrictive terms in the settlement agreement, even if they are typical of a settlement agreement, are manifestations of anti-competitive intent. Thus acknowledging that the patent is valid and promising not to infringe it are restrictions on the generic's freedom of action. This is true even if the generic had lost at first instance (since it could have appealed). This is true even if the generic had chosen to abandon the litigation, because it had no product to launch if the patent were annulled (since it might have been able to solve the biochemical purity problems which had thus far denied it a license to sell its products). This is true even if the generic producer would stand to lose millions if it lost the appeal or if it would have needed two years to develop a non-infringing technique to avoid the patent. Each of these commercial or regulatory difficulties might have been solved so the generic remained a potential competitor. And, last but not least, it is true even if the patentee settles a few parallel litigations and pursues the others to the bitter end. Generic litigants A through E fight; generic litigants F and G settle. The judicial examination is not thereby avoided. Yet, there is a gross infringement.

These elements, which do indeed seem surprising, confirm the extremely severe view taken of settlements as soon as they involve the conferring of anything that looks like a benefit to the generic company.

4 ANTI-COMPETITIVE SETTLEMENTS

Can there be settlements which are truly anti-competitive? Yes, assuredly. Where the 'settlement' is not a settlement of a genuine dispute about validity or infringement but in truth involves nothing more than a bribe to induce one party to stop competing, or where the 'settlement' imposes restrictions going beyond the scope of the patent (the patent covers the production of green tooth brushes and the 'settlement' covers the marketing of all hygienic products), or if the original patent was obtained by fraud (the laboratory reports were faked), the public prejudice and anti-competitive effect is

evident. The *Süllhofer*[6] case reminds us that there is no immunity for the terms of settlement agreements just because they are settlements. But that case does not create a duty to litigate!

Litigators are professional combatants. They gather the facts, they test the witnesses, they master the key three or four points on which victory or defeat will hinge, and they anticipate the weaknesses of the opposition and of the client. In a vigorously contested case, only a fool would promise victory. Any prudent lawyer would say something like 'good chances', '65/35', or 'It all depends on Professor Smith'. Any prudent lawyer will initiate with his client discussion of a possible settlement, and in most cases settlement talks will be broached. And it is in the cases where the outcome is most unsure that the pursuit of a settlement makes most sense. It seems troubling to imagine that Commission policy favours litigation to the bitter end, even after defeat at first instance. The policy seems not to distinguish between the situations that are very different. One situation is where for example four weeks before the trial of a litigation which will be vital to the commercial future of the key product of the patentee the trial lawyers feel unsure about the outcome because for example the witnesses are less convincing than when they first gave their story to the lawyers, or the expert has published an article which seems to contradict his technical report. s a result of these fresh uncertainties there is a genuine doubt about the wisdom of going on with litigating an expensive and important case. The second situation is where the patent has been obtained by fraud and the company is keen to avoid scrutiny, and is willing to pay a lot to be left in peace to exploit it. Yet those situations are hugely different and a policy that treats them as equally objectionable seems puzzling indeed.

5 PRE-TRIAL NERVOUSNESS AND UNCERTAINTY

Any practitioner who has conducted litigation will know that the possibility of a settlement is almost always discussed, and often several times, as the case moves forward. It is in finely balanced litigation where the outcome is the most uncertain and where the result may mean life or death for one side or the other that it makes sense to consider the risks and to consider mutual concessions. Roman law[7] and the Bible[8] each favour settlements. In some countries, such as England, an attempt to settle is a legal requirement for initiating litigation. Judges will often agree to delay a hearing to permit the parties to reach a deal. But, if a settlement is reached, it must contractually eliminate the possibility of future disputes on the same topic. All the terms must be borne in mind, not only the ones which prevent a rerun of the dispute.

It is easy to grant competition law blessing where one side is in an overwhelmingly strong position to reach a deal whereby one side wins and the other surrenders,

6. C-65/86 Judgment of the Court of 27 Sep. 1988, *Bayer v. Süllhöfer,* ECLI:EU:C:1988:448, para. 121.
7. *Interest rei publicae ut sit finis litis*.
8. '*As* you *are going with your adversary to the magistrate, try hard to be reconciled on the way, (or your adversary may drag you off to the judge, and the judge turn you over to the officer, and the officer throw you into prison).*' Gospel of St Luke, Ch. 12, v. 58, NIV.

with perhaps some concessions about legal fees. But it is difficult where, for example, the expert who will testify is at risk of not being understood, and the laboratory reports are equivocal, or where there are several cases running in different courts, so that possible victory in France may be too late to prevent generic entry and exports from France to other countries are likely. Yet these are the very situations where concessions are necessary to make the gap bridgeable.

6 THE PUBLIC INTEREST?

There is a potential public interest in the outcome of many disputes – patents over non-pharmaceutical matters, professional negligence, discrimination or harassment in employment, to name but a few. There is equally a strong interest for the parties (either side or both sides) in avoiding public disclosure of their dispute. An arbitration about whether unlawful state aid was granted, or a dispute about the pay of one part-time worker may have huge implications for one of the parties, much wider than the single dispute. So it is not the case that disputes about pharma patents are uniquely unfitted to resolution by settlements.

If there is a public interest in seeing litigation about pharmaceutical patents carried forward to a judicial conclusion, why not apply the same rule to engineering or electronic patents? Indeed by the same logic, there is a public interest in seeing a judicial determination of controversies about harassment in the workplace, dangerous food additives, unhealthy or unsafe premises or negligent lawyers or doctors. It would be surprising to imagine that a settlement of a litigation about any such matter would be anti-competitive if it involved mutual concessions, whereby each party got some advantage.

I suggest that there is a manifest difference between the settlement of a litigation on the one hand, and an agreement to remove a competitor from the market on the other. The first has overwhelming social, legal and economic benefits, at the price of compelling the parties to eschew future combat on the same topic. The second has pro-competitively nothing to commend it. Millions of Euros a year is a lot of money, yet such is the price of a hotly contested patent litigation which is fought out in several countries since patents are enforced nationally in the courts of twenty-eight Member States and imposes ancillary restrictions. We ought not to assume that a deal which ends expensive litigation is no more than a market sharing plot.

7 THE OVERUSE OF THE NOTION OF RESTRICTION 'BY OBJECT'

It is perplexing to see that current policy is moving towards condemning settlements which involve mutual concessions or 'value transfers', without proper enquiry into whether on balance the deal was desirable in competitive terms. Did the litigation about validity continue as between the patentee and other generics, despite the settlement with one generic? Had the generic company valid reason to wish to stop the fight, either because victory would bring it little benefit or would cost too much? Do the risks at stake make any difference? Suppose that the generic did not hope to make

a lot of money even if it won the patent case: Does that excuse its trying to bluff and do an advantageous settlement? Was the threat to the prosperity of the patentee huge, so that it had a high incentive to explore a settlement involving significant concessions? Is the asymmetry of risk (it means a lot to the patentee who hopes to enjoy a full patent term of twenty years in seventeen Member States and fifty in the wider world, but not much to the generic, who will make little or no money unless it can launch its new product legally and quickly) relevant?

I suggest that it ought to be relevant that the parties were confronting genuine business problems that complicated the analysis of whether to continue litigating since there was a fair chance that judicial victory would not confer commercial advantage. Yet it seems the duty to litigate overrides such common sense considerations.

I regret the recently fashionable practice of describing complex contractual relationships as restrictions 'by object'. Such textual condemnations cannot be used casually as a supplementary ground of objection to a controversial practice. I suggest that it is wise to limit the use of the term 'by object' to easy cases where the harm to competition *fait crever les yeux*. Where the merits and demerits of the contract are finely balanced, where it conferred advantages and burdens on each side, where chemical, medical or economic opinion is divided, then slogans are not helpful to the analysis. It is by looking calmly at the effects that one can reach a reliable conclusion. The term 'by object' should not be used as an excuse to avoid precise analysis of what harms and benefits the agreement may confer.

8 WHERE ARE THE LIMITING PRINCIPLES?

It is routine in competition cases about the use and abuse of IP rights for the issue to be presented as a clash between absolutes. The right holder says that it has 'merely' invoked a privilege granted by statute and that to deny it this right takes away the essence of the property right. The complainant points to wholesome competition, the end of abuses, freedom of choice, lower prices and all sorts of other benefits. These slogans are easy to utter. It is indispensable to have clear limiting principles. The seminal cases of *Volvo/Veng*[9] and *Magill*[10] provided such clarifications. But it is quite unclear in the area we are discussing what are the crucial elements whose presence or absence will reveal that the settlement is anti-competitive or not.

'Uncertainty about the outcome' of the litigation is deemed important, but that is a meaningless test since uncertainty is universal on the eve of trial. It is equally risky to settle by mutual concession with a 'value transfer' where the patent is crucial to the company's business even where multiple litigations involving other parties about the same patent continue. The current approach seems to make no distinction between how confident the patentee feels of victory or how objectively strong the patent is thought to be. Of course it is not the job of the competition authority to decide whether

9. C-238/87 Judgment of the Court of 5 Oct. 1988, *AB Volvo v. Erik Veng (UK) Ltd.*, ECLI:EU:C:1988:477.
10. See *supra* n. 4, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Commission*.

a patent is 'weak' or 'strong', but it is strange that the words of the settlement are more important than the reasons to settle. Putting it differently, the merits of the underlying patent dispute seem to make no difference to the analysis of the legality of the terms of the settlement. The fact that it made commercial sense to settle seems likewise irrelevant. Settling after a defeat in court seems no better, since a settlement promises there will be no appeal.

Until clarification has been obtained, it seems to be risky to conclude patent litigation as to pharmaceuticals other than by a total victory or total defeat before a judge.

9 WHAT PRECISELY IS THE ILLEGAL CONDUCT?

If we are going to review the context let us consider all pertinent issues. Does the policy affect litigation only as to pharmaceutical patents, on the rationale that governments pay for drugs? If so, what about patents relevant to the road-building industry or military equipment which would affect the state's budget? If not, is the pharma industry morally inferior or more prone to abuses than other industries? Does the campaign threaten other settlements of other cases where there is a public interest in the clarification of the legal issue in dispute? If the pharmaceutical industry is uniquely in need of the policy, let this be stated and explained.

A related manifestation of the current muddle is prolixity. The decisions in which the European Commission implements its policy are far too wordy. It is impossible to know at the end of 500 pages exactly what conduct was deemed reprehensible. The file may well contain inflammatory emails with military metaphors ('crush them', 'nuke them', 'no mercy', or the like), but they do not define what is unlawful. Email communications which threaten destruction to the competitive enemy may be fun to quote from and colourful to invoke as showing hardness of heart and a harsh approach to competitors. But it is not unlawful to voice competitively hostile thoughts. What is needed is not chapters of 'context' but two pages of carefully articulated explanation of what the offence against competition law consists of, placed fairly alongside all relevant considerations.

If the supposed breach of the law is so clear that it deserves to be damned as a 'by object' infringement, so plain that there is no need to enquire into its effects, then the legal community, the technology community and the world's patentees are entitled to demand intelligible and rational articulation of the core of illegality. Yet the decisions which have so far appeared are hundreds and hundreds of pages too long. This wordiness sows confusion and uncertainty and makes daunting the tasks of judicial review. The *Volvo/Veng* judgment set forth the key findings in two celebrated paragraphs, and the *Magill* decision from the Commission was only nine pages long.

10 A PATENT JUDGE COMMENTS

One of the other contributors to this volume is a distinguished and experienced patent judge, Sir Robin Jacob. I recollect that he was invited to address a large gathering to

mark the Commission's pursuit of its vast enquiry into the pharmaceutical industry. He astonished the listeners by excoriating the assumptions, techniques and conclusions of the sector enquiry. He said it was 'a disgraceful use of the Commission's powers', and of a key theory 'that was entirely nonsense'. Sir Robin said that the preliminary report was 'appalling'.[11] It revealed 'a vast ignorance on the Commission's part as to how the patent system actually works'. He noted that since there is a lot of money involved, generic companies naturally challenge big pharma patents if there is a realistic possibility of winning. And patentees invoke their patents if there is a realistic possibility that they may be held valid. Indeed, I would suggest that there is a structural need for litigation: it is the mechanism whereby the validity of a valuable grant is tested. But there is no merit in compelling those who start a litigation to carry it forward to the bitter end. Sir Robin noted that 'The normal case is where there is a real uncertainty about validity. Neither sides know who would win. The prospective legal battle, if it takes place, will be expensive and time consuming.' However, at the time of the agreement, no one knows whether it is valid or not. That could only be determined by the end of the final appeals in the very battle the agreement is designed to avoid. If these agreements are treated *ipso facto* as anti-competitive, there is only one alternative: litigation to the death. I presume that the Commission would deny any such bleak intention, but it is striking that a very experienced national patent judge asks such basic questions years after the new policy has been adopted, which brings me to a conclusion.

11 CONCLUSION

When I was a young lawyer in Brussels last century, the competition law world was dominated by the parsing of the implications of Article 85 (1) of the EEC Treaty. As then interpreted by the European Commission, its reach was very broad. It caught not just agreements which were intrinsically bad (like a market sharing agreement) but those which had some pro-competitive and some anti-competitive features. This reflected the Commission's understandable nervousness about trusting business people, officials and even judges to apply sound doctrine when applying the unfamiliar concepts of Article 85. The official line was clear: if in doubt, come to the public authority, notify the agreement and request administrative blessing. In reality, the system functioned very differently as practitioners tried to game the system to win procedural advantage, while the Commission found restrictions of competition in almost anything while being reluctant to grant individual exemptions. The system was a procedural curiosity perhaps appropriate to an infant system. Its intellectual flaw was looking at words on a page rather than reality and effects.

I suggest that an excessive reliance on the 'by object' damnation echoes the error of the 1970s and 1980s. Competition takes many forms. It is the consequence of many actions and many phenomena. The reality of how the competitive process works is not

11. R. Jacob, *Competition Authorities Support Grasshoppers: Competition Law as a Treat to Innovation*, available at http://fordhamipconference.com/wp-content/uploads/2014/10/6A-2-Jacob-Robin-paper.pdf.

easy to grasp or to measure. Many actions and many agreements have positive and negative effects. I sell my business and promise not to enter the same line of commerce for five years: that stops my competing with the buyer, earns me a higher price and reassures the buyer that he will be able to approach my customers confident that I have withdrawn. Is that a bad clause or a good clause? It likely has both features: maybe five years is too long, but maybe it is acceptable. A bald promise not to compete for five years is a clear infringement, but such promise as part of a pro-competitive acquisition of my business may be acceptable.

We ought not to revert to the easy days of condemning by reference to words and little else. There can be settlements of sham litigation which are clearly infringements. Those should be challenged robustly. But it is deeply unconvincing to approach the carefully negotiated conclusion of a bitter, costly and uncertain litigation as being inexcusably bad because it involves a 'value transfer' and ended a litigation as to the outcome of which there was 'doubt'. The topic requires much more careful analysis and better examination of all relevant factors. Discouraging the settlement of true disputes by prohibiting the parties from bridging the gap between them is bad policy and ought I suggest not to be good law.