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Generics

"Dolphins caught in the tuna net" – the deadly effect of the proposed IP enforcement directive on EU generic industries

By **Veronica Lowe***

Have you ever bought “designer goods” in an Asian night-market, or downloaded music from the Internet? Have you bought cheap DVDs only to find that they are poor reproductions, or “branded” software with potentially harmful viruses?

This June, the European Parliament adopted a declaration against counterfeiting and piracy, reaffirming the importance of intellectual property rights to the European economy. The declaration is the fifth adopted during the life of this Parliament, and calls for the governments of member states to prioritise tackling IP theft and its links with organised crime within the EU and the accession states.

The draft directive

Currently before Parliament is a draft directive setting out what are rather drily called “measures and procedures for enforcing IP rights.” The directive’s rapporteur, Janelly Fourtou (a French MEP on the Parliament’s Committee on Legal Affairs and the Internal Market) is about to report back on potential amendments. A strong proponent of the directive as a weapon to combat product piracy, she is hoping for an unopposed first reading in the autumn.

This wish is unlikely to be realised as industries are lobbying heavily either to toughen up or water down the proposals. Parliament’s own Committee on Industry and External Trade has expressed serious concern about its potentially damaging effect on healthy competition within the EU.

Sometimes being attacked by both sides is a guarantee that stakeholder interests are in fact being kept in balance. That is not the case with this directive, which apparently fails to deliver what the victim industries want while threatening to damage irreparably other industries competing legitimately with innovator companies.

Despite its unmemorable title, the directive contains measures that could inadvertently have a disastrous effect on the EU’s valuable generic industries, ranging from pharmaceuticals to automotive components. Its anticompetitive nature could also stifle small innovative companies at the mercy of abusive litigation by larger deep-pocketed rivals.

Designed to combat commercial-scale counterfeiting and piracy, the directive provides an array of drastic injunctive measures to IP rights holders and high levels of penalties for any infringe-

ment of their rights. As the directive applies to patent infringements in the normal course of product development, as well as to the abuse of trade marks, copyright and design rights more often associated with counterfeiting and piracy, innovator companies with patents to protect can wield this powerful weaponry against legitimate competitors.

How has this happened?

In 2000, Parliament unanimously endorsed the green paper, “Combating Counterfeiting and Piracy in the Single Market.” It highlighted the economic and social cost, and the dangers posed to public health and innovation. Effectively, these fraudulent activities were comprehensively endangering consumer rights, innovative companies’ research and development efforts, shareholders’ profits, member states’ tax-take, and their job markets.

This web of stakeholder interests underpins the popularity of measures to combat counterfeiting and piracy, and the intense pressure from a number of quarters to create a legal arsenal of prohibitory measures.

Parliament was troubled by the legislative patchwork in member states on IP protection, which it perceived as enabling pirates to take advantage of weak and inconsistent national laws to escape detection and prosecution in “piracy havens.” Moreover, there was a strong belief that piracy should not be imported from accession countries that apparently have twice the level of such fraud, set against a backdrop of poorly-enforced or non-existent IP protection law.

Also expressed was a concern that these evils were viewed as low-risk white-collar crimes for which only the larger household names stood to be ripped off by enterprising free-traders. Parliament was keen to stress that organised crime corporations running things like drug-trafficking and money-laundering in fact dominate these activities. Some 65-70% of music industry piracy is said to involve organised crime, instead of the peer-to-peer file-trading that comes to mind.

The Commission was charged with preparing the directive. The final draft was published in January 2003 – as the rapporteur remarked, three years after Parliament had called for urgent action.

However, the Commission took its task seriously. In fact, it appears to have gone beyond what Parliament asked for.

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Counterfeiting and piracy

On the issue of counterfeiting and piracy, which sparked off the call for the directive, the Commissioner for the Internal Market, Frits Bolkestein, said:

The Single Market must be a safe and secure environment not only for inventors or creators but also for consumers and investors. This is why all available means must be used to combat this scourge. The action plan being put forward is ambitious, but it needs to be in view of what is at stake.

The Commissioner's use of the word "scourge" is oft-repeated, for example by the rapporteur in April 2003:

Counterfeiting and piracy are an international scourge that needs to be tackled as such.

It has now been taken up by the industry alliances seeking to toughen up the draft, which is seen by them to be "unambitious" despite Commissioner Bolkestein's promises.

"Epidemic" and "blight" are also freely used, supported by a statistical snowstorm. In 2000, Commissioner Bolkestein referred to counterfeiting and piracy representing 5-7% of world trade amounting to €200-300 billion a year, of which the loss to EU businesses was up to €800m in the EU and €200m externally. Worldwide, 200,000 jobs were lost.

The major victim industries suffering counterfeiting and piracy were:

- data processing at 39%
- audio-visual, music and textiles at 10% and above
- vehicle spare parts and sports/leisure goods at 5-7%

In support of the directive, the industry alliances (often with overlapping memberships) provide details of alarming increases, although these are difficult to substantiate.

The Business Software Alliance claims that software piracy amounts to 37% in the EU, worth €2.7bn, and 80% in eastern Europe. A 10% reduction would create €20bn in additional tax revenue, double the European IT sector and, rather implausibly, provide 2,450,000 new jobs.

The IFPI (music) says that counterfeiting reduces the EU's GDP by €8bn a year, with piracy rates of 50% in the EU and up to 95% in eastern Europe.

The Alliance against Counterfeiting and Piracy claims that IP crime leads to a loss of 17,000 jobs a year in the EU, and that customs seizures have increased by 900% since 1998-2001.

The Anti-Piracy Coalition of Authors and Composers estimates that creative industries lose more than €4.5bn a year. The copyright associations believe that 100 million optical discs (CD, CD-ROM and DVD) are pirated annually in the EU.

The rapporteur, in her reference to the three-year interval before production of the draft directive, described an increase in 2000-2001 of customs seizures of illicit products amounting to 39%. Three quarters of this figure related to foodstuffs – an unappetising prospect. She also highlighted increased piracy levels in Spain, Italy and especially Greece. The accession countries were acknowledged to have average levels of 50%. This again reinforces the theme that, unless there are draconian legal measures readily available against counterfeiting and piracy, the unacceptable levels in the EU and its neighbours will drain the life-blood away from innovation.

Faced with this welter of statistical detail on what is clearly a major economic problem, how can anyone object to the directive?

Saturation coverage

As usual, the devil lies in the detail. The directive, while having a laudable objective, is a flawed morass of ill-thought-out drafting and conflicting objectives. Above all, it equates patent infringements, which can occur during the normal course of commercial product development, with fraudulent counterfeiting and piracy.

It does this in the name of harmonisation by roping in all types of IP on the basis that they must be the same and call for the same enforcement methods. It then compounds that error by imposing on any infringement a regime of injunctive measures available on a very low standard of proof and harsh punitive penalties, without any gradation for type or gravity of infringement.

If an infringement occurs during the course of commercial activity (such as product development), it will by definition be "serious" and warranting punitive action, notwithstanding the complexity of the research process or the existence of legally disputable patent claims.

Some may say that that should not matter in the defence of legitimate rights. However, as the directive provides for an innocent infringer to be forced to pay compensation to an IP right holder, whatever the disparity of power or resources between them, that arguably infringes a right that is far more important to society than a property right.

There are ostensible safeguards against abusive litigation built into the draft – a recognition at least that it could occur unless specifically checked. Unfortunately, as drafted, these are meaningless against a well-resourced innovator company that is being handed, in the guise of an enticing codification of options, a stick with which to beat smaller legitimate competitors. These, whether multinational generic companies or "one-product" inventors, are the dolphins caught in the tuna net of the directive.

Given that it was first mooted three years ago, and that the green paper was the subject of wide consultation, one may feel entitled to greet criticisms of the directive with scepticism. How could this have happened without a public outcry?

The final draft has only been available for six months, but has already attracted censure from innovator industries for being insufficiently rigorous by concentrating on commercial as opposed to individual infringers. Generic industries have criticised it for being grossly anticompetitive.

However, it is perhaps understandable that the music industry has the greater lobbying fire-power because of its demonstrable losses from counterfeiting and piracy, and the fact that most EU citizens and their representatives have been exposed to examples of "lookalike" goods. Many have been victims, but equally many have been knowing consumers.

The case of generics

The case for generic industries is less obvious, partly because of the myth that generic products are merely cheap "copycats" of branded products, robbing the innovator of legitimate profits and a justified return on its expensive R&D effort. Sadly, the directive does everything to bolster this false impression by equating competitive product development with counterfeiting and piracy.

In fact, Europe's generic industries produce affordable versions of branded products on which the patent has expired. In the

pharmaceutical industry, generic medicines are competitively priced versions of tried and tested products, which benefit national healthcare systems and patients alike.

For example, my own company specialises in developing and manufacturing complex oncology drugs, particularly for the advanced stages of cancer. Its objective is to be first to market after patent expiry with improved drug delivery and formulation systems. These are often aimed at better patient acceptability, such as coating technology to reduce nausea on taking antibiotics, and the development of once-a-day morphine pellets.

If an EU citizen is asked if they have ever taken aspirin or know of someone being treated with a more patient-friendly version of an established drug, they will instantly perceive the value of generic medicines. This applies as much to patients with cancer or heart disease as it does to those with a bad cold or upset stomach. If their doctor or national healthcare system were unable to supply improved and cheaper bioequivalents because of the directive, there would be a public outcry in the member states – but too late.

For example, according to the European Generics Association, more than 40% of medicines prescribed in Germany are generics, and 18% in the UK are covered by NHS computerised generic purchasing. Germany, the Netherlands, Denmark, Portugal, Spain and France all have systems in which generics must be prescribed where available, or may be substituted by the pharmacist.

Moreover, 100,000 people are employed in the EU generic pharmaceutical industry alone.

Intellectual property

The lack of publicity on the damaging effects of the directive can also be ascribed to its subject-matter – IP rights. Although the *raison d'être* of the directive – misguidedly – is the protection of IP rights *per se*, only counterfeiting and piracy grab the headlines. Most right-thinking citizens can find a better use for their time than studying the differences between types of IP rights and accompanying infringements.

Again, by ignoring the differences, the directive does nothing to disabuse the public of the view that the rights or infringements must all be of equal value and require equal treatment. This soft focus derives not simply from the worthy aim of combating counterfeiting and piracy, but also from the less obvious agenda to harmonise national laws on the enforcement of IP rights as such, even though it is questionable whether the EC itself has the regulatory power to intervene in the civil law systems of member states.

As the Commission put it in the introduction to the final draft of the directive:

... the disparities between the national systems of penalties for IP rights were having a harmful effect on the proper functioning of the internal market. The interested parties expressed the desire for this question to be tackled energetically and for far-reaching measures to be taken at the level of the EU ... The Commission announced that it would be presenting a proposal for a directive aimed at harmonising the legislative, regulatory and administrative provisions of the member states on the means of enforcing IP rights, and at ensuring that the rights available enjoy an

equivalent level of protection in the internal market. That is the aim of this proposal.

So on the back of justifiable concern about counterfeiting and piracy comes the Commission's desire for "horizontal harmonisation" (its own term). The draft then indicates why the Commission is using a short-cut method to achieve this.

Harmonisation of IP rights has only so far covered trade marks, designs, some aspects of copyright, and biotechnological patents. The draft outlines the other matters on which the Commission has "intervened" that fall short of being able to lay down mandatory EU-wide rules. Non-biotech patents are completely excluded and fall within the province of the member states' legal systems, with the civil jurisdiction usually used for claims of infringement within commercial product development.

Why are patents so different from trade marks and copyright? Is this not special pleading on behalf of "non-creative" industries?

First, it is a misapprehension that industries outside those lobbying for a directive do not value IP rights and do not suffer from counterfeiting. Generic companies believe in the ongoing protection of IP rights to foster vigorous innovation. They often have IP of their own that needs protection.

For example, my own company spends €20m a year on R&D, employs 200 scientists, and has invested €150m in its research facilities. The cost of each innovation is up to €7m, with R&D on improving previously-branded products taking six years. The important issue is to balance protection with competition – it is only by encouraging the latter that new products are developed.

Generic medicines are also sometimes counterfeited, but the serious public health implications are dealt with by strict regulatory controls applied by the national medicines agencies. These apply to generic and branded products alike and they, not IP rights jurisdiction, are the first line of defence.

As to the different nature of patents, and the importance of excluding them from the directive's draconian measures, two illustrations suffice.

Whilst it is difficult for a counterfeiter to have an innocent explanation for possession of commercial quantities of copied branded goods, patent infringements may occur in product development due to the complexities of patent claims drafted in highly technical language. Innovator companies also erect a "picket-fence" of 200-300 patents, ranging from the raw material to many alternative methods of use, around the much smaller area to be commercialised.

The difficulty of determining patent infringement, even for experts, is demonstrated by the "Epilady" case. In 1990, the inventor of Epilady, a popular depilatory device, started infringement proceedings against the inventor of "Smooth and Silky." The former used a coiled spring to trap hairs, whilst the latter substituted for the spring a tube with a comb-like action. To circumvent the innovator's patent, this was called a "helical spring."

Most consumers would not have been able to differentiate, as the result was the same. In three member states, the claimant won and, in one member state (the UK) and one EEA state, the defendant won.

This was a case of commercial product development. It would have been capable of attracting the following consequences under the directive.

Remedies and penalties

On showing “reasonably available evidence” that infringement is occurring or imminent, the claimant will be able to obtain an *ex parte* injunction that the court will not be obliged to review automatically. The injunction could be lifted if the claimant did not file the main suit within a month – highly damaging to a generic company whose competition is based on being first to market.

Companies could also be crippled by the additional *ex parte* orders available for production of the defendant’s commercial information to the claimant and seizure of all banking, financial or commercial documents (neither tied even to obtaining an injunction) and seizure of goods, *i.e.* freezing all commercial activity.

It will be possible to require the claimant to lodge an “adequate” guarantee when seeking an injunction, or pay “adequate” compensation if infringement is ultimately not proved, but there are no definitions. As the guarantee could be set *ex parte*, a court will have no guidance except from the claimant. There is no attempt to equate compensation with actual loss, including damage to reputation. Any compensation will be cold comfort to a company kept off the market for months or bankrupted by a spurious claim. Nothing is on offer to any losers among national healthcare budgets.

On finding actual infringement, a court will be able to order

- recall of all goods
- disposal of the goods, raw materials and means of production “outside the channels of commerce”
- destruction

Compensation will be payable even where the infringer has

acted “without fault or negligence.” Double compensation, lost profits and damages for “moral prejudice” will be available if the infringer knew or had reasonable grounds for knowing there would be infringement.

Involvement in infringement is to be treated as a criminal offence if it is intentional and committed for commercial purposes. Given that all product development is commercial and the result of intentional acts, this will criminalise commercial disputes on patent validity.

Is this what Parliament wanted?

Parliament asked for a definition that “distinguishes between various kinds of infringement, thereby taking into account that wilful and fraudulent elements are inherent in counterfeiting and product piracy,” thus differentiating between product piracy and product development, and arriving at appropriately graduated remedies.

Instead it has been given a juggernaut of a directive impelled by the might of the music industry and its allies and by the Commission’s desire for harmonisation at all costs. No one can doubt the importance of the original objective, but the non-newsworthy generic industries of Europe risk being crushed under its weight.

Reference

Proposal for a Directive of the European Parliament and of the Council on measures and procedures to ensure the enforcement of intellectual property rights (COM (2003) 46(01)), 30 January 2003
http://europa.eu.int/eur-lex/pri/en/lip/latest/doc/2003/com2003_0046en01.doc

US amends legislation on generics

On 19 June, the Senate approved rules amending the procedure under the Hatch-Waxman Act of 1984 for approval of generics. Some of its features gave rise to potential antitrust abuse, as was illustrated in the case brought by the Federal Trade Commission against Bristol-Myers Squibb that was settled in March (*CLI April 2003*, p.9). The amendments are designed to correct these defects, among other things.

Under the Act, a manufacturer applies to the Food and Drug Administration for approval of a generic drug, declaring that any existing patent for a bioequivalent drug either is invalid or will not be infringed by the generic. First filing gives the applicant a 180-day period of marketing exclusivity after entry.

Patents are listed in the FDA’s “Orange Book” but the FDA verifies neither the listing nor the assertion made in the generic application. A patent owner may then object by bringing an infringement action, but need not show the proof of infringement that would normally be needed to secure an interim injunction. The filing of the suit is enough to result in automatic suspension of the generic application for 30 months. There has so far been no limit on how many times this may be done.

This system offers two opportunities for abuse: filing unmeritorious infringement suits, and listing patents simply in order to block generics, possibly after the filing of a generic application.

The amendments, which were largely inspired by the Federal Trade Commission’s work on the topic, seek to alleviate the position of generics manufacturers without unduly damaging the incentive to do the costly and uncertain research that is underpinned by the patents system.

There will be only one automatic 30-month stay allowed for each generic. Moreover, the period will run alongside the FDA’s examination of the generic application. Since this takes 18-25 months on average, the period of suspension may become relatively trivial.

Patents of two types – metabolites and product-by-process – have been forbidden by the FDA rules, and information must be filed in support when listing patents for polymorphs.

More contentiously, the amendments will also allow a generics maker to file a suit against the owner of a listed patent for frivolous listing in the Orange Book.

The record of litigation between patentholders and generics makers seems to reveal a balance of merit on the side of generics. According to the testimony of FTC Chairman Timothy Muris, a survey showed that lawsuits were filed against 72% of the generic applications made. Of those, 70% had gone to judgment or been settled. Of the rather more than half that went on to judgment, the generic applicant prevailed in 73% of cases.