
EFPIA represents the innovative pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of about 2,100 companies committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

Intellectual property is of critical importance to the ability to improve health by bringing innovative products to markets and to the economic success of the pharmaceutical industry. It is imperative to the EFPIA membership that balanced, reliable and effective regimes exist for IP rights in the EU. EFPIA applauds the work done with the Directive 2004/48 (the Directive) and agrees that significant progress has been made.

EFPIA is supportive of the efforts of the Commission to continue to improve the standard of IP right enforcement in the EU and welcomes the opportunity to provide feedback on the Report dated 22 December 2010. EFPIA agrees that the internet and the digital environment has provided new scope for infringers and those involved in infringing activities and that this has given rise to a new set of challenges for the courts which could usefully be addressed. However, even outside of the new challenges posed by the internet there are areas where the application of the Directive has varied from country to country and in some instances this has led to failure to achieve the aims of the Directive as set out in the recitals.

These areas would also benefit from a more detailed examination by the Commission in consultation with Member States and other stakeholders. The extent and impact of these differences and deficiencies should be assessed with a view to deciding whether further action at EU level is needed. In conducting this assessment, all factors need to be taken into account including the degree to which it is appropriate to fetter judicial discretion to deal with cases on their specific facts.

On a wider perspective EFPIA observes that it is important to continue to strengthen the cooperation between the Commission’s DGs in charge of reviewing / implementing legislation which may have an impact on the enforcement of IP, e.g. Directive 95/46/EC on data protection, Directive 2000/31/EC electronic commerce, Directive 2002/58/EC and Regulation 44/2001.

1. IMPLEMENTATION /TRANSPOSITION OF DIRECTIVE 2004/48

Before dealing with the areas for focus it is important to address the state of implementation of the Directive as it stands at this time. EFPIA notes with concern the historical late
implementation of this Directive in many Member States (as outlined in Annex 1 to the Staff Working Document accompanying the report). Still further EFPIA has ongoing serious concerns that Greece, even now, has apparently not implemented the Directive in respect of all categories of IP. Critical for the pharmaceutical industry, Greece has not transposed the Directive into law for Patents or Trademarks. It is pointed out that this Directive represents the minimum standard of enforcement of IP rights for a European Union Member State. EFPIA encourages the European Commission to take whatever steps are appropriate to ensure that Greece properly and fully implements the Directive.

2. AREAS FOR CLARIFICATION OF DIRECTIVE 2004/48 FOR A MORE EFFECTIVE PROTECTION OF IP RIGHTS AND A BETTER FUNCTIONING INTERNAL MARKET

Gathering Evidence and Measures To Preserve Evidence

General applicability of Art.6

Art.6, in contrast to Art.7, is silent on whether it is applicable before commencement of legal proceedings. Different Member States adopt different approaches e.g. UK and Spain where it is applied before commencement of proceedings and Italy where it is not.

EFPIA suggest that this is an area that might be suitable for clarification. As is the case in other fields of technology, in the field of pharmaceuticals it is not always possible to ascertain from the publicly available documentation whether an IP right (especially a patent) is infringed or not. Access to technical documents and samples before litigation commences is sometimes required to make a proper assessment of whether there is infringement. This enables unnecessary litigation to be avoided. Failure to allow this would effectively preclude the possibility of a prelaunch interlocutory injunction (hereafter 'pre-launch injunction') under Art.9. The Commission should also consider whether clarification is necessary to the effect that Art.6 includes the possibility to request samples for analysis in respect of patent infringement as well as in respect of copyright and trademark infringement.

In a further point related to samples, under the case-law of the CJEU parallel importers are required to provide the relevant trademark owners with samples of the product that they intend to parallel import and place on the market, so as to enable the trademark owners to check whether the reputation of their trademarks may be harmed by poor labelling and/or packaging. Sometimes these parallel importers deliberately omit to do so or if they do provide them, refuse to answers to questions raised by the trademark owners. However, such failure to provide samples or to co-operate with the trademark owners is not deemed per se as an infringement of trademark rights by the Courts of all Member States. The Commission could clarify that such behaviour by the parallel importers is per se deemed as a trademark infringement, so as to enhance the likelihood that the trademark owners may obtain precautionary measures before the imported product is actually placed on the market.

Interpretation of ‘specified evidence’ Art.6

The Staff Working Document in 2.3.1 final paragraph identifies an area of concern shared by EFPIA with regard to the different levels of information which are required to successfully obtain an order for production of evidence - in one Member State compared to another. Clearly a sensible position needs to be taken protecting the alleged infringer from a ‘fishing expedition’ by the IP rights holder whilst ensuring the provision has utility in each and every Member State. The Commission should give further detailed consideration to this point.
Interpretation of ‘in the control of’ Art.6.

The Staff Working Document at 2.3.1 final paragraph highlights that an issue has arisen around the definition of ‘in the control of’ as it relates to evidence. It is EFPIA’s view that the term ‘in the control of’ extends more broadly than mere ‘in the possession of’ and also more broadly than ‘the need to make a reasonable search’ as proposed in the Staff Working Document. In the pharmaceutical field some companies utilise compartmentalisation to render it difficult and in some cases impossible for IP right holders to get information critical for the assessment of IP right infringement. For example a generic company buying an active ingredient from a company in India may not have in its possession a copy of the manufacturing process details used to make the ingredient but it would often be within its control due to the contractual relationship with the supplier (active substance manufacturer). Courts that apply a narrow definition of ‘in the control of’ risk facilitating deliberate hiding of facts critical for IP right enforcement.

Internet documentation

EFPIA concurs with the Report concerning the increased threat of IP right infringement through the internet. The Staff Working Document highlights a disparity between the courts in the Member States in terms of the form and admissibility of evidence from the internet e.g., if sales of IP infringing medicines are offered on the internet. EFPIA echoes the concerns and suggests that further consideration should be given to whether action is needed at EU level. In particular, as far as trademarks are concerned, practices known as cybersquatting and typosquatting may result in harm not only to the trademark owners but primarily to the patients, who are exposed to deception by those who advertise and sell products bearing identical or confusingly similar trademarks vs. the names of the original drugs, with potential severe risks for public health. EFPIA also supports further voluntary cooperation with relevant stakeholders to address the problem of websites selling counterfeit and illegal medicines, for the sake of patient safety and protection of IP rights.

Injunctive Relief

Provisional and precautionary measures (Art.9)

It is noted in the Staff Working Document (paragraph 2.5.1.1) that these types of injunctions are, for most stakeholders, the main enforcement remedy. EFPIA agrees with this and further highlights that a distinction must be seen between an interlocutory injunction granted after an infringer has been commercialising the infringing product and a pre-launch injunction which prevents the commencement of commercialisation of infringing product. The reliable availability of pre-launch injunctions is of paramount importance to the pharmaceutical industry, in particular since legislation in many member states provides for mandatory price cuts for originator products or creation of reference price groups when generic products enter, regardless whether these generic products are infringing or not.

The speed with which an injunction can be granted is of critical importance to the pharmaceutical industry. The Staff Working Document at 2.5.1.1 states that - ‘With some exceptions, interlocutory injunctions are generally granted rather quickly….’ This is not representative of our experience as an industry. The speed at which applications for such measures are decided varies considerably between Member States. In some countries, it is not uncommon for it to take more than a year to obtain such a decision. There should not be a material differential in timing of injunctions before the courts of the Member States.

One possible suggestion for consideration is that this differential in the application of the Directive between Member States could be addressed by including a maximum time limit
from filing of the interlocutory injunction application to Decision. Precedent for such a maximum time limit can already be seen in the Directive at, for example, Art.9(5).

In addition, the Staff Working Document, 2.5.1.1 second paragraph identifies two major areas of disparity between the application of the Directive in the Member States that are of particular concern to the pharmaceutical industry:

- That the courts of some Member States are “reluctant to grant an injunction unless an infringement has actually been proven as opposed to granting an injunction for preventative reasons”.
- The Staff Working Document highlights that “the level of evidence required by the courts to grant an injunction (interlocutory injunction) differs significantly between Member States and, in general terms is rather high”. Art.9(3) governs the evidence standard but, as the Staff Working Document notes, lack of clarity of that standard is the reason cited by those courts who do not grant precautionary injunctions as to why they are not given. “In these cases, the ‘sufficient degree of certainty’ that is required by the courts is higher than what the applicants can establish in practice”.

This practice by some of the courts in the Member States is self evidently contrary to the literal wording of Art.9(1) (a) of the Directive which explicitly provides for “precautionary injunctions to prevent imminent infringement of an IP right” and out of line with the spirit of the recitals. Also as noted above, the dependable availability of precautionary injunctions is of fundamental importance to the pharmaceutical industry as significant and irreparable harm can result following breach of an IP right even for a small period of time, not only in terms of lost sales and lost profit but also in terms of mandatory price cuts or other negative price effects for the originator product dictated by national price and reimbursement legislation following the launch of the infringing generic product. EFPIA would encourage the Commission to examine in detail the application of Art.9(3) with a view to determining whether further EU action is necessary. In these situations, in terms of imminent infringement, it must be remembered that if the alleged infringer is in fact not intending to commence commercial activities until after the IP right has expired then the presence of an injunction can do him no harm.

Furthermore, and again of significant importance to the pharmaceutical industry, in some Member States there is a strong reluctance to grant interlocutory injunctions (pre-launch or post launch). Staff Working Document at 2.5.1.1 states “.. in cases involving trademarks, designs or copyright the ‘obviousness’ of infringements may be often assumed, in cases of Patent infringement this is rarely the case. -”.

Considering Trademarks, according to our members’ experiences, obtaining an interlocutory injunction against a confusingly similar trademarks is, in practice, becoming increasingly difficult in most Member States (except of course if one is using a name identical to the plaintiff’s trademark). Economic or other non-legal considerations are often used by the Courts to deny the grant of injunctions. This is far from the infringement being ‘assumed’ as put forward in the Staff Working Document.

When patents are concerned however, the Courts are, as noted by the Staff Working Document, even more reluctant to take the responsibility of an injunction. This is even in cases where, from a technical/legal perspective the assessment is not necessarily complicated. For example in pharmaceuticals a patent to a chemical compound is clearly infringed if another company imports and sells a generic medicine containing that compound as its active pharmaceutical ingredient. EFPIA is concerned that it should not become a general excuse that patent cases are ‘too complicated’ to give an injunction. EFPIA encourages the Commission to examine this point carefully to ensure proper application of the Directive. As noted above, the issue of whether there is infringement would be clearer in
many cases if a pre-litigation provision was to be available that allowed the patent holder to obtain evidence including samples ahead of filing for an interlocutory injunction (see section on Gathering Evidence).

Another circumstance that should be taken into account is that preliminary injunctions, if granted more often, could not only prevent the continuation of the specific act of infringement at stake, but also further infringements in general, as well noted by the Commission in para. 2.5.3 of the Staff Working Document, à propos de Case C-324/09 (L’Oreal vs. eBay). Moreover, for unitary EU titles such as Community trademarks or designs, in an attempt to win the reluctance of the national Courts the Commission could clarify that granting cross-border injunctions should be deemed as particularly appropriate.

The Staff Working Document at 2.5.1.2 provides a thorough discussion of the importance of injunctions, in particular interlocutory injunctions against intermediaries. EFPIA agree with this position and highlight that in its members’ views the ability to act against intermediaries plays and important role in the fight against counterfeiting (IP service providers, financial services providers, platforms, carriers etc.). It is crucial that the preliminary injunctions apply to intermediaries regardless of the liability regime which is applicable to them. It is necessary to continue to harmonize the procedural rules and the recognition and enforcement regime against the intermediaries at the EU level since, most of the time, drug counterfeiting has an international dimension.

**Alternative Proposal – Early Resolution Mechanism**

It is clear that the pharmaceutical sector has some unique characteristics in its dynamic between innovator companies holding IP rights (especially patents) and generic companies seeking to launch their copy products in a highly regulated environment. EFPIA recognises that both innovator and generic companies play a part in the benefit to society and the functioning of the internal market. As such EFPIA have proposed an early resolution mechanism that seeks to facilitate resolution of disputes before launch of potentially infringing products. The suggested mechanism seeks to allow patent litigation to be initiated at a significantly earlier stage than is currently possible. It would require that the generic company notify the Patent holder when making its application for marketing approval of its copy products (i.e. well before it is permitted by regulatory law to launch the product). Such notification would be sufficient to allow the initiation of patent infringement litigation if the IP right holder believed that infringement was at hand. If, of course, when providing the notification the generic company gave a binding statement not to carry out infringing activities as long as the patent was in force then no litigation would be required. Any litigation under this proposal would have to be initiated within a specified time limit from notification and the timing of the notification and any initiation of patent litigation arising from it would be such that a full trial on infringement and validity (if that was counterclaimed) could in many cases be concluded and a Decision issued by the court before the generic company would be permitted by the current regulatory law to launch its product. High level details of the proposal can be found in Annex 1. This proposal if adopted would remove to a great extent the issues around disparity of the application of Art.9.

**Corrective and Alternative Measures**

**Recall from the channels of commerce**

The Staff Working Document highlights a disparity in the remedies available for infringement in an interlocutory injunction. As noted above for the pharmaceutical industry the precautionary injunction is paramount. However when this is not possible and the interlocutory injunction is granted only after launch of the infringing product then it is essential that a court should clearly have the power to order recall of the infringing goods
from the channels of commerce. In the case of pharmaceuticals there is a well established and well functioning supply chain involving distributors and wholesalers who have sizeable facilities to store and transport large amounts of infringing goods. Without the possibility of recall these goods would be at risk of continuing their journey through the supply chain to the end user after the order against the principal infringer has been made causing continuing damage to the right holder. The alternative is to always request an interlocutory injunction against the infringer and all intermediaries but identifying these intermediaries is not always practical and this would cause unnecessary proliferation of litigation. The Commission should consider whether clarification is required that recall from channels of commerce is available as a provisional (pre trial) measure.

**Destruction of goods**

The issue highlighted in the Staff Working Document is who should be responsible for paying the cost of destruction of infringing goods when that is ordered by the court. EFPIA agrees that destruction of infringing goods should not be at the expense of the rights holder. The right holder is the party harmed by the infringing goods and it is not equitable that the rights holder should have to pay to have the goods destroyed. The Directive is clear that the cost should be borne by the infringer. However in a number of cases the infringer is indeterminable or uncontactable (supplied a false name and address). In such cases EFPIA believe that there is a good argument that the intermediary - here the carrier or shipper - should be liable for the cost of the destruction of the infringing goods.

**Damages**

EFPIA agrees with the assessment made by the Commission in item 3.5 of the report and believes that the lack of adequate damages in a number of Member States, especially when coupled with the time taken in some Member States to resolve pre-trial injunctive proceedings and reluctance to provide precautionary injunctions leads to a situation where a would-be infringer can, through a programme of cynical calculus, arrive at a profitable business model based on deliberate infringement. This simply cannot be allowed.

EFPIA believes that damages must be fair for the right holder in terms of placing them in the position they would have been had the infringement not occurred and at the same time being dissuasive to would-be infringers.

Art.13 of the Directive sets out two possibilities for claiming damages: (a) actual prejudice and (b) reasonable royalty but there is no guidance for the courts of the member states when these should be applied. This is of significant concern because option (b) at least in the field of pharmaceuticals is vastly inadequate in terms of recompense if the infringement has denied the patent holder of sales of his or her own medicinal product. EFPIA would strongly encourage the Commission to consider clarifying the situation on damages such that the reasonable royalty option (b) should be applicable only in circumstances where the IP right holder - does not have a competing product on the market or when the IP right holder so chooses. In all other circumstances option (a) must be applied.

Even within option (a) it is very frequent that the damages awarded are very low in comparison with the actual harm suffered. This, for the reasons highlighted in the report, namely the need for 'effective, proportionate and dissuasive' is another clear area for focus.

In terms of lost profits, as identified in the Staff Working Document 2.7.3.1 these are difficult to prove and calculate. This is especially so if there is more than one infringer where the market has fragmented and each infringer has to be pursued for damages separately. EFPIA believes that the infringer should be liable for all harm that the IP right holder has suffered that flowed inevitably from the infringement.
In terms of infringer profits, these are most often less than the lost profits for the IP right holder. However, in rare circumstances where the infringers profit is greater then damages of greater quantum should be awarded.

As to moral damages, they are most likely to be suffered in the event of pharmaceutical trademark infringement, when the reputation (and good will) of the infringed trademark may be very hard to restore in the eyes of the doctors, pharmacists and patients. The Courts are very rarely in favour of the recognition of such damages, primarily because the trademark owner has difficulty to prove them. The Commission might consider recommending to adopt a general level of moral damages in addition to the economic damages recognised in the judgment favourable to the IP owner (e.g. + 25% vs. the amount of the other damages found); such “automatic” percentage could vary according to the convincing evidence brought by the defendant or the plaintiff, respectively, in order to decrease/increase the overall amount of damages to be awarded by the Courts.

**Publication of the Judgment**

According to Recital 27 of the Directive, in order to “act as a supplementary deterrent to future infringers and to contribute to the awareness of the public at large, it is useful to publicise decisions in intellectual property infringement cases”.

No doubt the publication of the judgment confirming an infringement is to be seen also as a measure to stop the confusion which is inevitably created at the level of consumers. In the pharmaceutical sector, this is particularly crucial due to the nature of the product involved (drugs) and the potential risks to public health. For pharmaceutical trademarks, this is often the rule. Sometimes the effects of such confusion may be permanent, or quasi-permanent.

The fact that many Courts are reluctant to publish their judgment could induce the Commission to revise Art.15 of the Directive by introducing automatic or semi-automatic publication of such decisions. This would seem more consistent with one of the ancillary purposes of the Directive, which is to protect consumers and dissuade infringers from creating confusion on the market.

**Legal Costs**

The Staff Working Document 2.7.6 final paragraph highlights the issue that costs recovery is highly variable across the European Union. Once again this is a disparity that could usefully be considered by the Commission as an area of focus. EFPIA's position is that at least 50% of the actual legal costs should be recoverable in each and every country.

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