Policy Paper PP12/11

IPO consultation on experimental use and Bolar exemption

Introduction

The Federation represents IP intensive companies in the United Kingdom – a list of members is attached. Our member companies are extensively involved with IP in Europe and internationally. Not only do our companies own considerable numbers of IP rights, both in Europe and elsewhere, but they are affected by the activities and IP rights of competitors. They may be either plaintiffs or defendants in IP related court actions, here and elsewhere.

The consultation

The Intellectual Property Office (IPO) launched a consultation on 6 June 2011 to investigate the impact, if any, of UK patent legislation on the conduct of clinical and field trials involving pharmaceuticals in the UK. This consultation is being run in response to concerns from some stakeholders, including the IP Federation, that the current UK regulatory framework can put them at risk of patent infringement when carrying out clinical and field trials involving pharmaceuticals, resulting in an unwillingness to conduct such trials in the UK.

Responses to the consultation need to be made by **31 July 2011**.

IP Federation comments

The IP Federation welcomes this initiative, which we have been seeking for some time. Most recently, in our response dated 4 March 2011 to the Review of Intellectual Property and Growth: Call for Evidence, we said:

> Liberalisation of the 'Bolar' provision in S.60(5)(i) of the Patents Act would be desirable, so that all clinical trials would be exempt from patent infringement, rather than just clinical trials aimed at producing a generic medicine.

Specific questions

Our answers to the questions posed in the consultation are as follows:

1. Does the current legislation strike the right balance between the exclusive rights granted to a patent holder, and the need of the pharmaceutical industry to carry out clinical and field trials, where the risk of patent infringement may be an issue?

No. The legislation does not strike the right balance.

Those seeking regulatory approval for a generic pharmaceutical product are permitted under section 60(5)(i) (which transposes EU law) to perform certain activities which, in the absence of that provision would otherwise infringe a patent. Depending on the activity concerned, the position of those seeking to develop innovative products is either unclear or not within the experimental use defence or Bolar exception.

Thus, in this situation, the UK's patent law encourages copying and not innovation. We favour change to increase certainty and promote innovation.

2. Are there any particular circumstances in which you are, or have been, at risk of infringing a patent when carrying out clinical or field trials? Do any particular types of clinical and field trials give rise to an increased risk of patent infringement *e.g.* using comparators, trials for combination drugs, biosimilars?

The IP Federation is an association of companies. Our individual members are better placed to answer this.

3. How often does the risk of infringement influence your decision to use the UK as a base for clinical and field trials? Does this risk increase the likelihood of you conducting trials elsewhere in the EU and beyond? It would be useful if you could quantify your response *e.g.* as a proportion of all such trials you run.

Our individual members are better placed to answer this question.

4. If the risk of patent infringement when carrying out clinical or field trials in the UK was removed would this influence your company strategy on placing such trials in the UK? If so, would this translate into a positive impact on the activities, the people, or the amount of work done in the UK, including work done by Clinical Research Organisations (CROs)?

Again, our individual members are better placed to answer this.

The options

There follows our answer to the final question posed in the consultation:

5. If sufficient evidence is forthcoming to establish that there is a problem, there may be several options available to address the problem. Please rank the following options in order of preference and give reasons for your preference.

1. Ultimate aims

The ultimate aim should be:

b) Change EU legislation, not necessarily to give an equivalent to the US situation, but to harmonise law throughout the EU in this area.

The first option would also be acceptable:

a) Change EU legislation to match the current US situation as determined by case law.

The IP Federation has always supported efforts to find common ground for international agreement on a number of substantive aspects of intellectual property law. The current situation, where infringement rules vary from state to state with in the EU, means that companies are using this as a basis to decide whether to conduct clinical trials, rather than evaluate where the best facilities and expertise are to be found. It can also force companies to conduct clinical trials outside the EU, if they do not feel confident in doing so in EU states where potentially dominating patents exist, even if such patents bear little relation to their eventual intended marketing activities.

2. IP Federation proposed option

However, in the acceptance that neither of these is going to happen in the near future, we favour the next option:

c) Change UK patent law unilaterally to exempt from infringement all activities relating to regulatory approval of a drug product.

Any development which will encourage investment into research and development in the UK is to be welcomed.

3. Unacceptable options

Totally unacceptable is the next option:

d) Change UK patent law to exempt from infringement all activities relating to public health issues [e.g. including studies required by National Institute for Health and Clinical Excellence (NICE)].

This is too broad and too vague, and could arguably exempt from infringement manufacture and sale of otherwise infringing products on the grounds that, because it could decrease health spending, this is a purpose relating to public health.

The final option would not be possible to enforce, so is not desirable:

e) Agreements within industry which govern practice on the issue of patent infringement in clinical and field trials, either in particular cases or more generally.

Conclusion

We strongly support efforts any change to the law that will improve the current UK regulatory framework by removing the risk of patent infringement when carrying out clinical and field trials involving pharmaceuticals. Such measures will encourage innovation within in the UK, and discourage copying.

IP Federation
29 July 2011

IP Federation members 2011

The IP Federation (formerly TMPDF), represents the views of UK industry in both IPR policy and practice matters within the EU, the UK and internationally. Its membership comprises the innovative and influential companies listed below. It is listed on the joint Transparency Register of the European Parliament and the Commission with identity no: 83549331760-12.

ARM Ltd
AstraZeneca plc
Babcock International Ltd
BAE Systems plc
BP p.l.c.
British Telecommunications plc
British-American Tobacco Co Ltd
BTG plc
Delphi Corp.
Dyson Technology Ltd
Eli Lilly & Co Ltd
ExxonMobil Chemical Europe Inc
Ford of Europe
Fujitsu Services Ltd
GE Healthcare
GKN plc
GlaxoSmithKline plc
Hewlett-Packard Ltd
IBM UK Ltd
Infineum UK Ltd
Merck Sharp & Dohme Ltd
Microsoft Limited
Nokia UK Ltd
Nucletron Ltd
Pfizer Ltd
Philips Electronics UK Ltd
Pilkington Group Ltd
Procter & Gamble Ltd
QinetiQ Ltd
Rolls-Royce plc
Shell International Ltd
Smith & Nephew
Syngenta Ltd
The Linde Group
UCB Pharma plc
Unilever plc