IPLA - Working Group on Patents and Related Rights in the Post-Brexit Era

Objective

The aim of this short note is to summarise briefly the output of the IPLA working group on Patents and Related Rights in readiness for guidance from the UK Government as to how it would like to progress the next steps in relation to shaping the landscape for intellectual property in the post-Brexit era.

The Basis of Patent law in the UK

The principal legislation governing patent law in the UK is the Patents Act 1977 (as amended) ("the Act"). The Act is framed in large part to align with the European Patent Convention 1973. This convention is unconnected to the European Union and therefore continued alignment is not inconsistent with delivery on Brexit.

However, the Act is not the only legislation which impacts on patents and related rights in the UK. The landscape is far more complicated than that.

IPLA Work on Patents to date

When the IPLA patents working group met in mid-July 2016, we identified the following areas beyond the Act which required separate detailed consideration and assigned a small group of lawyers to each area:

- **SPCs/Paediatric Extensions and related rights**: Brian Cordery (Bristows), Andy Bowler (Bristows), David Rose (Mishcon de Reya) and Steven Baldwin (Allen + Overy)
- **Orphan Drug Regulation and other healthcare regulation issues**: Nigel Jones, Yohan Liyanage and Kathy Berry (all Linklaters).
- **Brussels Reg/Rome II and Service issues:** Tim Powell and Zoë Butler (both Powell Gilbert)
- **Patents and Competition Law/Compulsory Licences/Settlement**: Laura Balfour (Slaughter + May) Campbell Forsyth (Dentons) Gordon Harris (Gowling WLG) and Hiroshi Sheraton (Baker + McKenzie)
- **Plant Varieties** – Rebecca Halford-Harrison (Kemp Little)
- **Biotech Directive and Related Issues** – Andrew Sharples (EIP) and Rebecca Halford-Harrison
- **Customs** – Chris Sharp (Herbert Smith Freehills) and Vicky Bentley (Pinsent Masons)
- **Transitional Provisions** – Adam Cooke (DLA Piper)

By early September, most of the groups had supplied a report to the co-chairs of the IPLA Patents Working Group - Gordon Harris and Brian Cordery. A condensed verbal summary was given to the IPLA meeting on Monday 12 September 2016. It was noted that the reports supplied to the co-chairs varied considerably in length, content and style.

As noted above, this note provides a short, more homogeneous summary of those reports whilst the IPLA seeks guidance from the UK Government as to how it can best assist with the process of preparing the IP landscape for Brexit.

A "total exit" model, in which the UK exits the EU and is not a member of the EEA or EFTA, entails the greatest legislative upheaval. This summary focuses upon the position regarding total exit.

1. Supplementary Protection Certificates ("SPCs").

In broad overview, SPCs provide a patent holder with an additional period of up to 5½ years of legal exclusivity after expiry of patent protection for a medicine or a plant protection product. SPCs are vital to the research-based pharmaceutical industry because of the length of time that inevitably lapses between the filing of the patent and the obtaining of a licence to sell the medicine. SPCs are wholly based on EU Regulations. These Regulations are not the model of clarity and, in the view of many practitioners, the CJEU has added to the uncertainty with confusing and inconsistent decisions. However, even though it is not perfect, the system is nevertheless regarded as generally fit for purpose.

IPLA recommends that at the very minimum, the SPC Regulation is adopted in its entirety into UK legislation. In time, it may be possible to conceive of and adopt a different system but this would seem a goal too far at this stage. The UK Government must ensure that the transitional provisions are framed such that there is no gap in protection between the cessation of the application of the EU Regulations and the entering into force of the new UK law.

If the UK becomes an EFTA or EEA member, further considerations will apply as set out in the note prepared by the subgroup.

Finally, it should be noted that the law of SPCs sits on the interface with healthcare regulation law and so any revised SPC regime must be prepared in harmony with revisions to that part of the law as well.

2. Orphan Drug Regulation and other healthcare regulation issues

Whilst there are many Brexit issues arising out of healthcare regulation, many of them are outside the scope of this document as they are primarily regulatory issues rather than patent and SPC issues. However, three key areas are:

(i) exemptions to patent infringement in relation to acts which are for the purposes of medicinal product assessment. In particular, ss60(6D) – 60(6G) Patents Act 1977 (as amended) incorporate definitions from Directives 2001/82/EC and 2001/83/EC. These references therefore need to be amended to set out the definitions or refer to equivalent new post-Brexit legislation. S60(5)(i) Patents Act which also refers to the same two directives should be repealed as it provides no additional exemption over and above that in ss60(6D) – 60(6G);

(ii) legislation which allows applicants for marketing authorisations for generic medicinal products to exclude parts of the summary of product characteristics which are protected by second medical use patents (resulting in so called “skinny labels”). The relevant EU legislation is Article 11 of Directive 2001/82/EC, Article 14 of Directive 2001/83/EC and Article 3(3)(b) of Regulation 726/2004. The relevant provisions would need to be transposed into post-Brexit UK law, if the UK wants to continue to allow such skinny labels; and

(iii) orphan medicines. Articles 36 and 37 of Regulation 1901/2006 allow market exclusivity for orphan medicinal products to be extended by two years if certain conditions are met relating to paediatric studies, but at the expense of a standard paediatric extension to the SPC. Post-Brexit, legislation will be needed to maintain the exclusivity already enjoyed by orphan medicines, but taking into account the post-Brexit regulatory and SPC regimes. As with SPCs, in due course, this could be revisited by considering systems in other jurisdictions

3. Brussels Reg/Rome II and Service issues

On Brexit, the EU rules on jurisdiction and enforcement (as primarily laid down in the Recast Brussels Regulation (1215/2012/EU)), on choice of governing law (Rome II Regulation (864/2007/EC), and also EU rules which exist to improve cooperation and cross-border transfer of judicial documents and evidence, will cease to apply in the UK and need to be replaced by alternatives. This is relevant not just to patents or IP, but to civil and commercial disputes more generally.

Of particular interest in the patents sphere is that the EU rules on jurisdiction specify that if the validity of a patent is put in issue, the Court of the Member State where the patent is registered has exclusive jurisdiction to determine its validity. In addition, whereas the general rule is that an action is to be commenced in the member state in which the defendant is domiciled, in patent disputes an exception is relied on which is that an action may be brought where the act of infringement takes place. On jurisdiction, the UK could follow Switzerland, Norway and Iceland in signing the Lugano Convention, which is largely consistent with the Recast Brussels Regulation. Alternatively, the UK could ratify the Hague Convention on Choice of Court Agreements, or enter bilateral/multilateral agreements.

4. Patents and Competition Law/Compulsory Licences/Settlement/Parallel imports

The EU laws relevant to patents in the context of competition law, compulsory licensing and settlement are:

- Article 101 of the Treaty on the Functioning of the European Union ("TFEU"), which prohibits arrangements between undertakings which have the object or appreciable effect of preventing, restricting or distorting competition within the internal market of the EU, and which may have an appreciable effect upon trade between member states;

- The so-called "block exemption" Regulations, which provide "safe harbour" provisions in respect of Article 101 for parties below a certain market share: the Technology Transfer Block Exemption Regulation 316/2014 ("TTBER"); the Research and Development Block Exemption Regulation 1217/2010; the Vertical Restraints Block Exemption 330/2010; and the Specialisation Regulation 1218/2010

- Guidelines of the European Commission in relation to vertical restraints, horizontal agreements and the TTBER are also of relevance, although they are not binding

- Article 102 TFEU, which prohibits one or more undertakings holding a single or collective dominant position from abusing that position insofar as it may affect trade between member states

- The EU Merger Regulation 139/2004 ("EUMR"), which requires mandatory notification to and clearance by the European Commission of certain "concentrations" of a certain size, including mergers, acquisitions and full-function joint ventures; and

- Articles 34 to 36 TFEU, which prohibit Member States from imposing unjustified barriers to cross-border trade.

Upon a total exit, UK businesses would remain subject to the potential application of Articles 101 and 102 TFEU where their commercial activities were implemented in the EU and had as their object or effect the distortion of competition in the EU and produced an effect on interstate trade. Settlements involving UK firms and/or UK patents (including EP(UK)s) will therefore remain subject to EU law where the relevant conditions are met.

Likewise, concentrations involving UK firms which satisfy the relevant jurisdictional thresholds would remain subject to the application of the EUMR and the jurisdiction of the Commission. Such concentrations would also be subject to UK law in parallel as UK mergers would no longer benefit from the 'one stop shopping' principle of the EUMR.

Aside from this, competition law and merger control would, in the UK, be governed by the UK's national laws.

The UK's national laws prohibiting anti-competitive arrangements and abuses of dominance (modelled upon Articles 101 and 102 TFEU) are contained within the Competition Act 1998 Chapters I & II and would remain in force in the UK upon a total exit.

However, the various EU "block" exemption Regulations would cease to have effect in the UK unless equivalent UK Regulations were put in place establishing an equivalent domestic exemption regime.

In the event of a total exit it is assumed that UK intellectual property rights would not be exhausted by sales in the EU or EEA and that parallel imports into the UK from the EU would be prevented. Customs legislation (on which see below) would need framing accordingly.

The IPLA recommends that, at least, a provision akin to section 10 of the Competition Act 1998 is put in place in order to create an equivalent domestic exemption regime mirroring the EU block exemption regime. Consideration should also be given to whether section 60 (regarding the interpretation of such rules) should be replaced.

5. Plant Varieties

Council Regulation EC/2100/94 on Community Plant Variety Rights, as amended (the "CPVR Regulation") governs EU plant variety rights. They endure for 25 or 30 calendar years following the year of grant (30 years being available for trees, vines and potatoes). The rights are subject to annual maintenance fees. In limited circumstances, an additional 5 year extension to the CPVRs may be granted by the Community Plant Variety Office.

Plant Breeders' Rights are the equivalent UK right and are governed by the Plant Varieties Act 1997 ("UK PBRs"), as well as several pieces of secondary legislation that deal with narrow issues such as fees, information notices, and naming. There is an appeal system where appeals are to the UK Plant Varieties and Seeds Tribunal (and appeal on points of law to the High Court system). Rights endure for up to 25 years following the date of grant, except for trees, vines and potatoes, which have a duration of up to 30 years following the year of grant. Compulsory licences are available, for example, where a registered right is not exploited and has not been surrendered. Propagating material must be maintained by the rights holder whilst the right is maintained on the register.

The CPVR Regulation would automatically cease to have effect in the UK assuming the UK exits the EU. For new PVRs, UK PBRs could be filed, which are equivalent to CPVRs, bar the slight difference in duration (25/30 years post date of grant for UK PBRs; 25/30 calendar years post the year following grant for CPVRs (the longer period for both rights applying to trees/vines/potatoes)). CPVRs and UK PBRs can, in principle, be extended by an additional 5 years. However, for existing CPVRs, or pending applications, there will need to be transitional provisions to enable transition of EU registered CPVRs into PBRs in the UK. In the event that the periods of duration between CPVRs and UK PBRs are not harmonised, there may be an issue around duration, because the rights holder will potentially lose a (in most instances small) part of its period of protection as a result of transition to a UK PBR,

including where the CPVR has been extended by an additional period by the CPVO. Other issues arise in relation to compulsory licences, representation (in relation to CPVRs and UK PBRs) and translations.

6. Biotech Directive and Related Issues

The Biotech Directive (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions) has been transposed into national UK law and into the EPC. Therefore there are no relevant EU Regulations which would need to be transposed into UK law on Brexit.

Consequently, even once the UK is no longer a Member State of the EU, provisions equivalent to those of the Biotech Directive will continue to apply to both GB patents and EP(UK) patents. Following current UK Supreme Court rulings on following the EPO approach, the UK will likely not deviate from the EPO's approach in relation to EP(UK) patents, although it may be that differences in interpretation will arise over time as there would be no appeal to the CJEU . The UK could potentially amend UK legislation so that the law diverges in relation to UK patents, but there does not seem to be an obvious advantage in doing so.

7. Customs

The Customs Enforcement Regulation 608/2013 (the "Customs Regulation") grants powers to customs authorities in all EU Member States to detain, seize and destroy products which are suspected of or found to infringe certain intellectual property rights.

Upon a total exit, the Customs Regulation would no longer have effect in the UK. There are no national legislative provisions conferring upon the UK's customs authorities (HMRC and Border Force) equivalent rights. A replacement regime would need enactment into UK law.

The UK Government would therefore have the opportunity to legislate carte blanche to establish its own powers and procedures in this area, particularly by engaging with the HMRC policy team to improve upon deficiencies identified in the current system.

8. Transitional Provisions

Adam Cooke reported to the team that to him, it made sense to consider transitional provisions after a proposal was made in relation to each of the rights. This seemed sensible to us.

Brian Cordery and Gordon Harris
London
18 October 2016