News and Views

The likely impact of Brexit on patents and SPCs in the UK

Summary

The UK is currently on course to leave the European Union at the end of 29 March 2019. With over 21 months having passed since the UK voted for this outcome, and with a year remaining before it becomes a reality, this article assesses likely implications of recent, Brexit-related developments for patents and Supplementary Protection Certificates (SPCs) in the UK.

In summary, our assessment of recent developments is that:

- they will likely lead to little or no change for patents in the UK; but
- whilst there are very good grounds for optimism that UK SPCs will retain effect post-Brexit, there is as yet no clarity on precisely how this will be achieved; and
- the holders of certain "centralised" Marketing Authorisations (MAs) may need to take action prior to Brexit in order ensure that those MAs do not lapse, thereby making any SPCs based upon those MAs (in the UK, or in any EU27 or EEA member states) vulnerable to early expiry.

Brexit: recent developments

This article focuses upon the following developments.

(1) Draft UK legislation (the European Union (Withdrawal) Bill 2017-19) that aims at ensuring that the vast majority of EU-derived legislation retains effect under UK law post-Brexit.

(2) Negotiations between the UK and the EU (as described in a presentation dated 8 March 2018 from a Taskforce of the European Commission), aimed at:

(a) before 30 March 2019, agreeing a financial settlement and the terms of a transitional period during which UK laws will remain in close alignment with EU laws; and
(b) before the end of the transitional period mentioned in (a), signing and ratifying an agreement that sets out how trade between the UK and the EU will be governed in the long term.

Whilst this article focuses upon patents and SPCs, information on the current situation for other IP rights (including trade marks, designs and copyright) may be found in:

- the UK Intellectual Property Office's commentary on "*IP and BREXIT: The facts*"; and
- Section 4.4 of a Briefing Paper from the UK House of Commons Library.

UK Legislation

Amongst other things, the draft European Union (Withdrawal) Bill mentioned at (1) above contains provisions aimed at:

- "retaining" (i.e. incorporating into UK law) the vast majority of EU legislation, including current EU Regulations and Directives;
- providing government ministers with powers to "repair" any retained EU legislation that becomes in any way redundant, inoperative or nonsensical under UK law post-Brexit; and
- changing the legal significance in the UK of decisions of the Court of Justice of the EU (CJEU).

With respect to the latter point, the draft Bill currently proposes to afford pre-Brexit CJEU judgements the same binding effect as judgements of the UK Supreme Court. On the other hand, it is also proposes to make post-Brexit CJEU judgements non-binding on UK courts.

UK-EU Negotiations

Current status

In accordance with a framework imposed by the 27 other EU Member States ("the EU27"), negotiations between the UK and the EU started with a first phase that addressed only the following areas:

- protection of citizens' rights;
- a framework for addressing the unique circumstances in Northern Ireland (in the light of the so-called Good Friday Agreement); and
- a financial settlement.

The first stage concluded in December 2017, when UK and EU negotiators agreed reached "agreement in principle" in connection with these three areas.

The second phase of negotiations are now reasonably well advanced. Indeed, the week commencing 19 March 2018 saw the following developments.

- UK and EU negotiators published an updated text of a draft Withdrawal Agreement, in which various provisions were indicated to be either "agreed at negotiators' level" (those highlighted in green) or "agreed on the policy objective" (those highlighted in yellow). Provisions of the draft Agreement without highlighting are those proposed by the EU, but where negotiators have yet to reach agreement on either details or policy.

  Amongst the provisions that are essentially agreed is Article 121, which indicates that the transitional period will remain in force until the end of 31 December 2020.

- The leaders of the EU27 approved the terms of the draft Agreement, as well as guidelines for the EU's post-Brexit relationship with the EU.

The next stages

With regard to the Withdrawal Agreement, the next steps for EU and UK negotiators will be:

- finalising the terms of the Agreement; and then
- obtaining the consent of the UK and European parliaments to ratify the finalised Agreement.

Only at that point can negotiations begin in earnest on a further agreement that will govern trade between the UK and the EU in the long term.

It remains overwhelmingly likely that the Withdrawal Agreement will be finalised and ratified in due time. However, this does not mean that progress will necessarily be straightforward. For example, it is possible that the UK and/or the EU will face difficulties in persuading their respective parliaments to accept compromises agreed between negotiators on one or more politically sensitive issues (such as the handling of the border between Northern Ireland and the Republic of Ireland, which is the UK's only land border with any of the EU27).

In any event, it is likely that the Withdrawal Agreement will need to be finalised by no later than October 2018, in order to "*allow for the timely ratification by the European Parliament, the Council (Article 50) and the UK, according to its own constitutional requirements*" (see the Fact Sheet accompanying the European Commission's first draft of the Withdrawal Agreement).

Patents in the UK: little or no change

Our assessment is that Brexit will likely have little or no impact upon patents in the UK. This is based upon the following observations.

- The key provisions of the law governing patents in the UK derive from international treaties (the EPC, the PCT and TRIPS) to which the UK will remain a signatory, and whose effects under UK law do not in any way rely upon the UK's membership of the EU.

- The UK's continued membership of the European Patent Organisation means that it will be "business as usual" with respect to the ability of UK-based European Patent Attorneys to represent applicants before the EPO.

- Whilst a small number of provisions of UK patent law (those governing biotechnological inventions and the so-called "Bolar" exemption) derive from EU Directives, it is very likely that the effects of those provisions will be retained under UK law post-Brexit. This is because the European Union (Withdrawal) Bill aims, where necessary, to effectively "cut-and-paste" relevant provisions of the EU Directives into UK law.

Optimism but no certainty (yet) for UK SPCs

In contrast to the situation for patents, SPCs in the UK are governed by EU legislation (Regulations 469/2009 and 1610/96). Further, many UK SPCs rely upon "centralised" MAs granted under EU law. As things currently stand, the legal effects in the UK of such MAs are due to cease upon Brexit.

With this in mind, it is disappointing to note that it is not yet clear how SPCs and "centralised" MAs will be handled in the UK post-Brexit. This is because provisions of the draft Withdrawal Agreement for which negotiators have yet to reach agreement on either details or policy include both:

- Article 56 (which addresses SPCs); and
- Article 91 (which addresses decisions of the European Commission, including decisions to award "centralised" MAs).

Despite this lack of clarity, our view is that the holders of SPCs or "centralised" MAs can be confident that it should be possible to maintain their rights in the UK post-Brexit. This is not least because of the UK government's stated intention to maintain regulatory alignment with the EU, including by seeking associate membership of the European Medicines Agency (EMA; see, for example, paragraph 45 of recent report from the House of Commons Health and Social Care Committee).

Nevertheless, it is clear that there will be at least some changes to the systems for granting MAs in the UK and the EU. For example, Article 123(6) of the draft Withdrawal Agreement (which is "agreed at negotiators' level") would appear to have the effect of preventing the UK from acting as the Reference Member State for applicants seeking MAs *via* the so-called decentralised procedure (DCP). Other, more important (possible) changes to regulatory arrangements are outlined in the EMA's Brexit-related guidance for companies. As discussed below, these changes may require actions to be completed (prior to Brexit) to ensure that certain "centralised" MAs, and the SPCs based upon them, remain in force.

Finally, with regard to the long term, it is possible that the proposed reduction (and then elimination) of the binding effects of judgements of the CJEU could lead to slight divergences between the UK and the EU27 – if only with respect to the *interpretation* of the provisions of SPC law.

Action Required

As discussed in the above-mentioned Brexit-related guidance from the EMA, maintaining certain "centralised" rights (such as MAs and orphan designations) may require various actions to be completed prior to 30 March 2019 – e.g. if necessary, by ensuring that those rights are transferred to a holder that is "established in the Union" (i.e. in a Member State of the EU27 or European Economic Area (EEA)).

If any such actions are necessary to prevent a "centralised" MA from lapsing, then taking those actions promptly will be essential to ensuring that SPCs (in the UK, or in any EU27 or EEA member states) based upon that MA do not become vulnerable to early expiry under the provisions of Article 14(d) of Regulation 469/2009.

Please contact Mike Snodin (at mike.snodin@parkgrove-ip.com) if you would like our advice on these or any other matters.