

## Not so unified: Brexit means uncertainty for European patent law



[Elizabeth Cairns](#)



### **Unitary patents are important for the biopharma sector, but might be even more crucial for medtech.**

The UK's ratification last week of the international treaty to set up a Unified Patent Court for Europe was without doubt a positive move for life sciences companies, which are now closer to being able to obtain wide-ranging, cost-effective intellectual property protection in Europe.

But the ongoing Brexit process means much is still unclear. "The UPC agreement, as currently written, only allows for EU member states to participate in the new unitary patent and UPC system," says Victoria Bentley, legal director at Pinsent Masons. There is still a risk that when the UK leaves the EU, the unified patent will not cover the fourth largest biopharma and third largest medtech market in Europe.

Unitary patents are intended to make it possible to get EU-wide patent protection by submitting a single request, making the procedure simpler and more cost-effective for applicants – particularly SMEs. They will be able to register their patents across participating countries more cheaply than under the current system, and enforce them through a centralised court system rather than multiple local courts.

The importance of this to the biopharma sector is obvious, but it might be an even bigger deal for medtech. A single medical device often relies on many patents covering different parts of its technology, whereas IP protection of a drug often stands or falls on the basis of its composition of matter patent. In short, it is probable that medtechs could save more money than biotech under the new system.

"For life sciences and medtech and many businesses, it's a positive step," says Ms Bentley. "It offers greater geographical coverage for medtech companies in particular who might want to make a single application ... this is going to be a more cost-effective way of getting that coverage than with the current European patent system."

### **Bundesverfassungsgericht**

The move towards the creation of EU-wide patents overseen by a single court has had a long gestation, and it had always been the UK's intention to ratify the agreement – indeed, the UK was one of the three core EU member states that needed to ratify before it could proceed, the others being Germany and France.

The results of the Brexit referendum of June 2016 cast that into doubt. "Most people thought that the decision

to leave the EU meant that [establishment of the UPC] wasn't going to move forward," says Ms Bentley. "So the news was really quite a momentous step."

One hurdle has been jumped, but another lies ahead. Germany is yet to ratify the UPC agreement – and there is a holdup. A complaint has been made to the country's constitutional court, the Bundesverfassungsgericht, arguing that the proposed reforms for the UPC are unconstitutional.

A decision might be reached in that case by the end of 2018, Ms Bentley says. "It is really now in Germany's hands to get this over the line."

### **London in; the UK out**

The UK's ratification of the UPC agreement moves the unitary system a step closer to coming into effect. When it comes to whether the UK will itself be part of that system, however, the ratification changes nothing.

If Germany resolves its constitutional complaint and ratifies the treaty in good time, it is still unlikely that the system will come into effect before March 2019 – the point at which the UK will leave the EU.

This means unitary patents will be less appealing than they might otherwise have been. The UK is a huge market for both drugs and medical devices; if the unitary patent does not have force in the UK drug and device makers will have to get UK patents on top of the EU-wide ones, undermining the entire argument for the new system.

And another rather odd situation could arise. One of the three seats of the UPC – the seat that will rule on patent disputes in pharmaceuticals and life sciences – will be in London. That decision is independent of whether the UK is a member of the EU or not.

It is therefore possible that disputes over patents covering drugs and medical devices will be litigated in the capital city of a country that does not recognise those same patents.

Of course, the UPC agreement could be amended to allow non-member states, or perhaps former member states, to participate. This will be one of the many issues that will have to be negotiated as the UK proceeds with Brexit.

"Overall in the UK we're all quite hopeful – subject to what's happening in Germany – that there will be potential to find a way to accommodate the UK post-Brexit," Ms Bentley says. It is in the interests of almost everyone, and certainly the European life science industry, that this accommodation is made.

*To contact the writer of this story email Elizabeth Cairns in London at [elizabethc@epvantage.com](mailto:elizabethc@epvantage.com) or follow [@LizVantage](https://twitter.com/LizVantage) on Twitter*

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