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Win Big Or Lose Big: The Impact Of The Unified Patent Court

by Jo Shorthouse

Decades after it was first mentioned, the updated European patent system – which includes the Unitary Patent and the Unified Patent Court – has finally materialized. What impact will this have on originator and generic pharma?

This year has seen the biggest change to European commercial legislation since the European Commission was established. In June, the Unitary Patent (UP) was introduced alongside the Unified Patent Court (UPC) within which those patents can be challenged or defended. The UPC has exclusive jurisdiction over new UPs, as well as "classic" European patents that have not been 'opted out' of – in other words, withdrawn from – the new system.

This UP and UPC system changes the landscape of European patent law by saving companies time and money. After a European patent is granted, the patent proprietor can request unitary effect which provides uniform patent protection in initially 17 EU member states. UP holders can now obtain protection in all 17 participating member states by filing one single application. Holders of UPs and classic European patents that have not been opted out can now enforce and defend their rights in one centralized court rather than in every jurisdiction in which that patent is held.

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A New Dawn?

"This is the result of a huge push in the market. It's a huge step forward, especially for the commercial world," said Arjan Reijns, an Amsterdam-based legal director at the law firm Pinsent Masons. Indeed, this change has been a long time coming.

Variability in local doctrine and interpretation of patent law overall caused headaches over the

years, said Reijns. “There has been a desire for predictability of outcome, and there has been an incremental harmonization effort from the national courts. Now we're just moving there in an official way,” he told *In Vivo*.

In 1973, the European Patent Convention (EPC) was introduced, under which the European Patent Office (EPO) grants classic European patents. A European patent may be designated in one or more EPC member states, resulting in a ‘bundle of national patents’ rather than one single unitary patent. Patent holders wishing to enforce or third parties seeking to challenge these patents had to bring proceedings in each country of interest, leading to multiple – expensive – national litigations and conflicting legal decisions.

A Community Patent Convention was signed in Luxembourg in 1975. It was never enforced for lack of ratification by member states yet remained in discussion for almost 50 years. In 2000, the Commission put forward a proposal for a Council Regulation creating a community patent. The EC in 2007, stated that the creation of a single community patent continued to be a “key objective” for the European community. The EC’s 2009 Pharmaceutical Sector Inquiry again mentioned the need of a community patent and an accompanying Community Patent Court.

Finally then, in 2023 when the UP and UPC system has finally come into effect, there should be a collective sigh of relief but also anticipation of the streamlined system to come. However, the option to withdraw patents from the system makes

What Is A Unitary Patent And The Unified Patent Court?

A Unitary Patent is granted by the European Patent Office using the same procedure as for classic European patents. Once granted, the patent proprietor may elect for unitary effect to be given for the territory of the EU member states participating in the Unitary Patent system that have ratified the Agreement on a Unified Patent Court.

The Unified Patent Court is a new supranational court that permits the enforcement of, or challenge to, Unitary Patents and classic European patents that have not been opted out of the UPC, across a large geographical market in one action.

At the time of writing, a Unitary Patent and decisions of the Unified Patent Court will cover the territory of the following 17 EU member states: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia and Sweden. Seven countries have signed up to the new arrangement but are yet to ratify. Countries that have not signed up to the system are Spain, Poland and Croatia.

“As soon as the ball starts rolling and it is a fully functional, operational system that

the arrival of this new structure more of a damp squib than the "new dawn" that EPO president António Campinos described just days before it came into force.

Opting Out

The UPC has exclusive jurisdiction for classic European patents unless they have been opted out of the new court system, a strategy by which patent holders can remove their European patents from the jurisdiction of the UPC.

The pharmaceutical industry is one of the heaviest users of the patent system in Europe, well known for filing numerous patent applications for the same medicine to form so-called "patent thickets" to protect a drug from generic competition for as long as possible. Individual medicines are often protected by as many as100 product-specific patent families, which can lead to up to 1,300 patents and/or pending patent applications across the EU Member States. It comes as no surprise then, that the pharma industry tops the list of those opting out of the system.

creates reliable and predictable decisions, the UPC is likely to become more attractive to those countries that have not yet ratified," predicted Reijns. "This means that when more countries ratify, UPC decisions will take effect over an even wider territory in the future."

The Unified Patent Court comprises of a Court of First Instance, a Court of Appeal and a Registry. The Court of First Instance has local, regional and central divisions. Infringement actions will usually be brought before the local and regional divisions. Revocation actions and actions for declarations of non-infringement will usually be brought before the central division, which has seats in Paris and Munich, and from June 2024 is expected to have a third seat in Milan. The Court of Appeal is located in Luxembourg.

Data shared with *In Vivo* from the UPC show that, at the time of writing, the number of opted out patents stood at 563,761. In total, just over 5,000 pharmaceutical products have been opted out so far according to data from law firm Simmons and Simmons, which also shows that Procter and Gamble is the applicant that occurs most frequently on the opt out application list with over 3,000 opted out patents.

Opting out of the UPC has been a subject of much discussion during the ramp up to the system being introduced, and patent holders are taking different approaches, including an increasing turn to licensing agreements.

A lot of pharmaceutical clients were approaching this as an opportunity, said Reijns. "To take the sword and shield approach had become a bit outdated, from a general commercial perspective. Some pharma companies are also finding benefit from licensing agreements and monetizing via licenses, especially with US-based companies that don't have a foothold in the EU," he said.

“However with the UPC, pan-European litigation has now become a much less cumbersome endeavor.”

“Within pharma, there's a process of constant readjustment and reassessment of patent portfolios and strategy going on,” said Reijns. For the last year, many companies have been assessing which patent families they have, and which to opt out of the UPC. The transitional period of an initial seven years means that those companies that have opted certain classic European patents out of the system can still withdraw that opt out.”

“The stakes are high with the UPC, but so are the potential rewards,” said Reijns. “The UPC is a European court that can grant relief – including injunctions and damages awards – over a large market. The fact that opt outs can be withdrawn means that many patent holders have chosen to wait and see how the case law evolves – at least in the early days of the court. However, a number of pharma companies are testing the new system, having filed UPC cases in the first few months of the court, and we have already seen a number of opt out withdrawals.”

Patent Clusters

The patent clusters created by pharma have been used for years to protect innovative drugs from generic attack. It aligns well with biopharma’s strategy to keep the patent system convoluted and protracted for commercial and competitive gains. Instead of streamlining this situation, some argue that the UPC could in fact, make it worse.

In the pharmaceutical field, there is a parent patent and different divisional patents. There is now the possibility to maintain a patent in one system, and to put a patent from the same ‘family’ of patents into another system.

“My fear is that originators that have created patent thickets will now split granted patents of the same family into one unified patent and opted out patents, which means that the UPC would just be one additional court where generics have to litigate. It’s not a reduction, but an additional accord which is expensive,” explained Corinna Sundermann, senior vice president of intellectual property for Fresenius Kabi, which markets generics, biosimilars and proprietary products.

It is a possibility that originator pharma will opt out their weaker patents to extend legal uncertainty, essentially an extension of the patent strategy identified in the Pharmaceutical Sector Inquiry of 2009 that outlined the competitive strategy of patent thickets, and which called for a community patent court to tackle this strategy.

There is nothing to say that, legally, a company cannot employ this strategy. Companies are focused on increasing shareholder value, and one day more of exclusivity can mean millions of dollars in revenue. “We need clear guidelines from competition law about where the line is between normal business conduct and abuse of dominance,” said Sundermann.

Cost, Clarity, Competition

"I welcome the introduction of the UP and the UPC. Concerning the UP, I welcome the reduced annuity cost," said Sundermann. "Every year, we assess the need of specific national patent equivalents for cost control reasons. One year, we needed to drop Portugal and Bulgaria, for example. And the next year, we will drop the Netherlands and Belgium. It's a process that we're doing all the time. Under the UP system this will be extinguished," she said.

However, the UPC gives with one hand and takes with another. Litigating in the UPC is expected to be costly, exceeding the multimillion cost of litigating in UK courts. This will block small companies, Sundermann told *In Vivo*, adding that one litigation in the UPC may cost €5m to €10m ($5.3m to $10.6m). She expects that this increased litigation cost will lead to more settlements, the kind more frequently seen in the US.

"I am fully convinced that a fair and reliable patent system fosters innovation," said Sundermann. "My view is critical towards the influence companies may get in the patent system, in cases where they have unlimited resources."

An advantage to those companies wishing to opt in to the UPC is the expedited timelines for decision making. After a year, a first instance decision is made, something rarely seen in national accords, notes Sundermann. This will allow generics companies to reach legal certainty early and quickly.

Offense The Best Defense

What steps should a company take when creating a defensive strategy around a patent? The most important aspect is to observe patent grants, according to Sundermann. Opposition to a patent must take place within nine months of that patent grant and be brought before the EPO. This can be done for 1% of the cost of a UPC litigation and covers not only the countries that have ratified the unitary patent, but also covers the UK and Iceland. "It's a really powerful tool, with one case you can reach all the patents," advised Sundermann.

After the nine months are up, a company would have to go to national courts or the UPC with revocation actions. This action could cost millions compared to the €50,000 for an opposition. "It's just a completely different story," said Sundermann.

This should be part of a long-term development strategy. If a company sees that a patent is granted in its field, it should oppose that patent if it cannot exclude that it may be relevant to its business in the next decade or more. "Look into the crystal ball and ask yourself if this is relevant or not to your business in the next 15 years, because you don't get a second chance," explained Sundermann. If the opportunity passes by, take next steps in the UPC system, and select a location," she said.

Untested System

It would certainly be a brave decision to opt a multi-billion-dollar patent into an untested system, and over the next seven years industry observers will have mounting case law to inform commercial decisions.

UPs and classic European patents that have not been opted out of the system can be revoked in the UPC, which is a risk to patent owners but an opportunity for generics companies.

It is thought that UPC revocation actions will be fast, so could be an excellent tool for use by generic and biosimilar companies, as well as innovators seeking to revoke patents that might hinder a product launch. If companies have been slow to opt patents out of the system, it could prove to be a fruitful monitoring endeavor resulting in revocation actions through the UPC.

Other considerations for generic or biosimilar launches include the location of first launch in this still untried system. “If you are launching a generic or a biosimilar, where you launch is important because UPC infringement actions are generally likely to be brought before the court where the infringement happens. We’re not sure how judges in the UPC’s local divisions are going to apply the UPC rules and navigate their own national doctrines and practices,” said Reijns.

“As there is no robust body of case law at the moment, you might as well choose to file a UPC action in one of the court’s divisions that you think might be positive for your business,” he explained.

Case law will develop in the next decade. There may not be a mass move to the UP system, especially from pharma, as a historically risk-averse industry with a great deal of money to lose if things go wrong. But success may come in different forms. While smaller companies will benefit from the agile litigation promise, big pharma will benefit from keeping the status quo that has helped the industry to reach its multi-billion dollar balance sheet.