

# Patents and the EU medtech sector: a slumbering volcano

The patent situation regarding medical devices in the EU may not be as volatile as that of their pharmaceutical counterparts, but litigation in the sector appears to be on the increase. Whilst the European Commission's focus on competition in the pharmaceutical sector may begin to fade, there are suggestions that it may turn its gaze towards medical devices. In addition, a more contentious issue has arisen that is likely to have a significant impact on both sectors, writes Faraz Kermani, principal analyst at Informa Business Information



Faraz Kermani

On December 4 2009, the Swedish Presidency of the European Union secured an agreement from the Member States to the key elements of a single EU patent and a unified European Patent Court. This was announced as an initiative that would enable inventors and companies to protect their innovations in the EU more cheaply and easily. The agreement was a clear political breakthrough in negotiations that have been ongoing for a number of years, and

marks a significant step towards a final accord. The next move will be for the European Parliament to adopt a position on the proposal. "Obviously, there is still some way to go on the legislative front, but if it finally goes through, it will be extremely interesting for all the industries that use patents a lot, as the devices industry does," says Stephen Bennett, a partner in the Intellectual Property Practice at Lovells in London.

A unified EU patent system will be valid across a market of some 500 million people, be cost-effective, and provide a remedy for the current situation, where getting patent protection in the EU is more expensive than in other competing markets. Protection in 13 Member States currently costs 11 times more than a patent in the US. Industries that litigate patents on a frequent basis are by no means welcoming this development with open arms. "There is a certain fear of the unknown, as the Court will be staffed by judges who are as yet not well known, and there is therefore a concern about the quality of any forthcoming decisions," says Mr Bennett.

The Court as such would consist of two instances. The first instance level would be regionalised and any subsequent appeal would be centralised. "But even the centralised system is not yet in use and is therefore an unknown commodity," he adds.

Should the new legislation succeed, a single European Patent Court will try cases on both the EU patent and existing European patents. The Presidency maintains that this will bring about a considerable improvement, compared to the current fragmented system where patent processes have to be conducted in each individual Member State, even when they are for the same invention. Current parallel processes translate into a cost increase of €480,000 (\$712,540) in a typical case. A single court could mean annual savings of up to €290m for European companies, the Presidency claims.

"Medical devices are big enough products to justify the expenditure of multi-jurisdictional patent litigation and the fact that we have a unified European patent system in the pipeline

could lead to an increase in the level of patent litigation," says Tim Worden, a partner in Taylor Wessing's Life Sciences and Healthcare Group.

He agrees that the development of the unified patent Court had implications across many areas, including the medical devices sector. "It has significant implications for companies looking to protect their medical technology in Europe and it also makes enforcement [of their IP rights] easier," he suggests. Although he acknowledges that companies may be concerned about the competence of some of the judges set to be appointed to the new court, he suggests that this must be weighed against the negative issues that existed under the current system, including the variations of competence in different Member State jurisdictions.

As for having a single unified jurisdiction, Mr Worden adds: "From a cost perspective, in terms of defending one action rather than a number of actions, this may be beneficial." However, although substantial progress has been made in discussions surrounding the patent court and the single European patent, these are still at a relatively early stage, he warns. "The devil is in the detail, as always," says Mr Worden.

The unified patent also has implications for medical devices approval in the EU. The current system of medical devices regulation in Europe is very different from that of medicinal products, based on CE marking through a notified body. Indeed, once the CE mark has been applied, by a single notified body in one Member State, the product can be marketed throughout the EU. In order for a drug to achieve this, it has to be centrally authorised.

The proposed unified European patent system is more in line with a European approval, Mr Worden pointed out. In terms of a medical device, if a national patent were to fail, this in itself would not affect a company's ability to market a product in other European jurisdictions, as the CE mark alone would preserve this right. "A single European patent should make life easier as they will have a greater degree of alignment with the CE mark," Mr Worden suggests.

## Increased litigation

Mr Bennett notes that over the past 18 months, the medical devices sector has witnessed a significant amount of litigation. "There has been a glut of cases in the medical devices area, covering a range of technologies," he said. Of the 235 patent cases issued in the English courts since April 2008, about 4% concerned medical devices. In the previous 18 months, less than 1% of the patent cases reported were related to medical devices. The reasons behind the sudden rise are not at all clear.

With this in mind, it is important to look at the sources of litigation. There are some significant differences between the medical devices and the pharmaceutical sectors in this

area. For example, on the whole, there is no regulation of prices in the medical devices sector. What's more, there is a distinct difference in the way in which litigation arises in both sectors. In the pharmaceutical sector, most of the litigation is a result of competition between originators and generic medicines manufacturers. "This has an almost pre-programmed timeline to it; everyone knows when the basic patent will expire," Mr Bennett explains.

The medical devices sector differs in that cases pit innovators against each other and there is no innovator/generic split. "This means that both sides approach it with a 'higher stakes' attitude," he suggests. Cases often involve one innovator having filed for a broad patent for an invention. Another innovator may be developing in parallel but may have reached the patent process at a slightly later stage. Both sides would then launch competing products, but the early mover with the broad-based patent will then accuse the second entrant of infringement "Because both sides are active in the patent area, this tends to be the case, but it could also be that the second entrant could file for infringement against his competitors products," Mr Bennett says. Essentially it is often a question of who gets to the patent office first.

Given the recent eruption of patent litigation between medical devices manufacturers, the temptation is to link this situation with the current economic crisis. However, Mr Bennett suggests that this is unlikely to be the case. "The timing, with regard to how long the cases take to get to court, suggests that a lot of them would have been started before the crisis actually came about, because it is at least a year to eighteen months to get to trial," he says. There is an ongoing debate amongst patent lawyers as to whether an economic downturn does in fact encourage litigation. "It seems to have its own clock, which is not so dependent on the economic cycle," he notes.

In half of the medical devices patent cases heard before English courts over the past 18 months, the patent in question was held to be invalid. The patents were upheld in four cases and in the remaining case, two patents were invalidated and one patent was upheld. To summarise: of the total 12 patents reviewed by the courts, seven were found to be invalid and five valid, representing a fairly even split.

Of the 10 medical devices cases brought before the English courts over the past 18 months, three of them focused on stents: *Edwards Lifesciences v Cook Biotech; Conor Medsystems v Angiotech Pharmaceuticals*; and *Abbott Laboratories v evYsio Medical Devices*. The Conor/Angiotech case – in which the House of Lords reversed judgments of the Patents Court in 2006 and the Court of Appeal in 2007, and upheld Angiotech's patent – has reverberated around Europe.

This is because the Court of Appeal had initially upheld the judgement from the English Patents Court, which had

determined that Angiotech's patent for a stent coated with the drug taxol, was obvious and was therefore invalid for lacking inventive step. A day later, in a parallel case heard before the District Court of the Hague in the Netherlands, the Court upheld the Angiotech patent, claiming it had been infringed by Conor Medsystems.

In his lead judgement from appeal to the House of Lords – in the English case – Lord Hoffmann noted that, due to the number of differing jurisdictions within Europe, it was inevitable that courts would arrive at different decisions. However, at the same time, he suggested it was undesirable for European courts to differ in principle in patent litigation cases. Although the Dutch and English courts have now arrived at the same conclusion, the case has increased calls from some sectors for a unified patent court.

**Competition and the Commission**

The research-based pharmaceutical industry has of late been in the spotlight due to the European Commission's investigations into suspected anti-competitive practices. In certain cases, this concerned the building of secondary patents, so-called "patent thickets", around products in an attempt to extend their patent life and prevent generic competition. Some commentators have expressed concern that, once the pharmaceutical sector has been dealt with, the Commission may turn its attention to medical devices.

"I think it is only a matter of time before the devices industry will be more firmly in the spotlight. You can see that the relevant industry bodies are already aware of the need to try to head that off with self-regulation," Mr Worden suggests. He points out that the ABHI in the UK has put in place a code of practice to ensure that its members operate ethically, and this is in turn based on the code of practice published by the European medical devices industry association, Eucomed.

The possibility of medical devices being targeted by the Commission is by no means far-fetched, Mr Worden maintains. "Medical devices are big enough products to justify the expenditure of multi-jurisdictional patent litigation and the fact that we have a unified European patent system in the pipeline could lead to an increase in the level of patent litigation," he says. Indeed, some of the settlements that emerge from such litigation, which affect access to market and thereby competition within it, could prompt the Commission's scrutiny of the sector.

There is a feeling that, ahead of any real political consensus on the single European patent and the unified patent court, and threatened by the shadow of a potential Commission investigation, the medical devices sector is somewhat of a slumbering volcano. There are signs that it is beginning to awaken, as litigation increases, but the real eruption may not be for a few years to come.

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