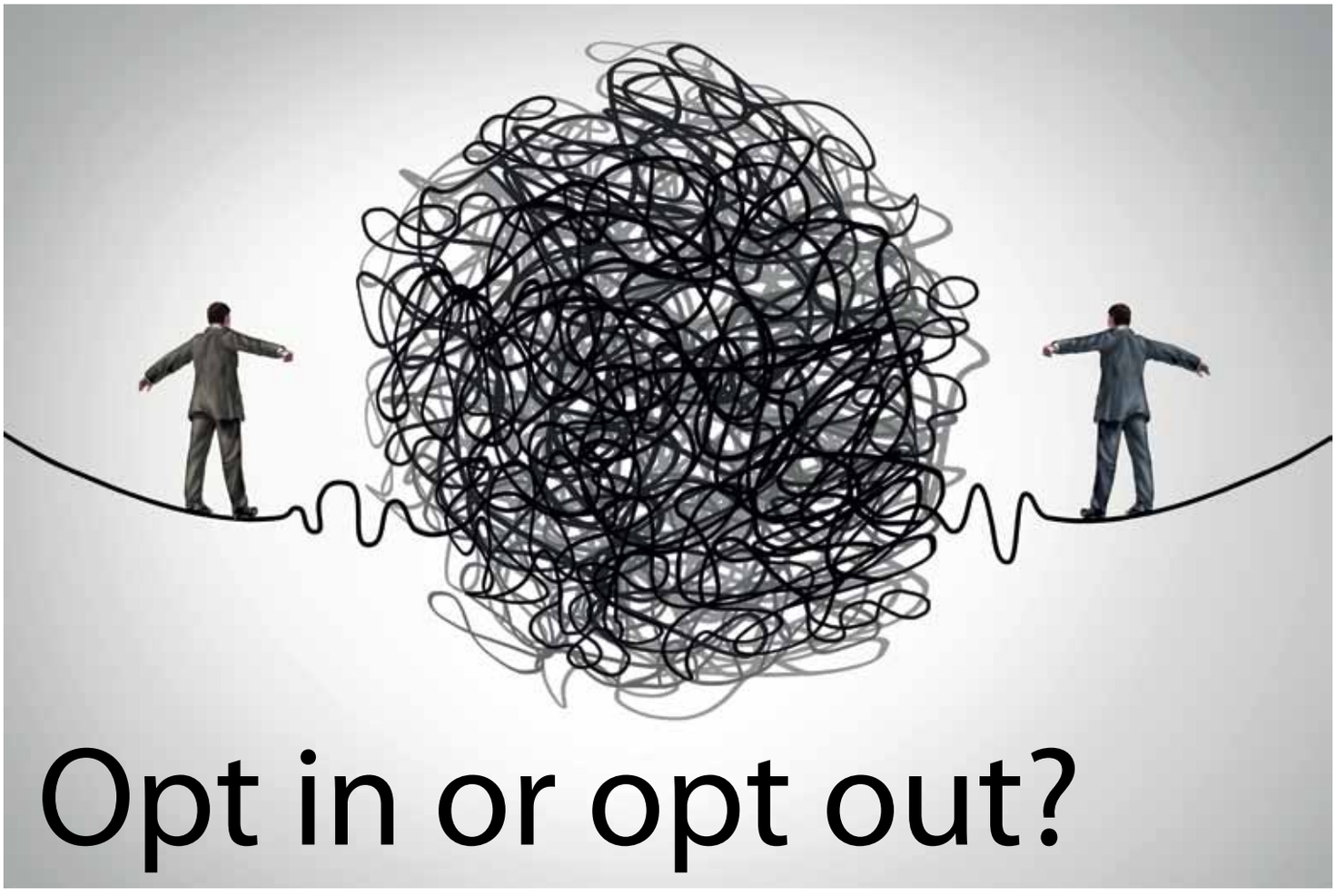

Opt in or opt out?

Changes to European patent law raise a number of questions for the industry

The Unitary Patent (UP) and Unified Patent Court (UPC) will fundamentally change the way patents are granted and enforced in Europe. Currently, patentees must maintain their patents in each European country - or at least in their key national markets. These patents must be enforced or revoked as necessary in each of these different jurisdictions. Like the current European patent (EP), the UP will be centrally filed and examined. However, the UP will also be centrally granted, in English, German or French. There will be no further translation or other requirements. But there is more: through the UPC, a UP (and an EP that has not been opted out, see below) will be challengeable and enforceable in one single court. A pan-European injunction (whether preliminary or permanent), as well as a pan-European revocation, will therefore soon become a reality.

Although it will probably take another year before the UPC is up and running, stakeholders have no time to waste. The Rules of Procedure of the UPC have been finalised and confirm that the management and enforcement of European patent portfolios will require pro-active planning and may involve drastic strategy changes. A UPC audit will be particularly useful for patent and patent litigation driven industries, such as the pharmaceutical industry.

First question to answer: patent in or out

The first question to be answered when proceeding with a UPC audit can be summarised as follows: do we or do we not want to 'play' in the UPC? It will be possible for existing European patents to opt out of the UPC system for a period of seven years from the launch of the UPC (it is possible that this period will be extended by an additional seven years). Important to note: while an opt-out can virtually

DNA of the UPC

- Up and running in 2017?
- One title for protection and enforcement
- One decision on validity and/or infringement, directly binding
- Covered market = 1.6 x US market
- One strike, no duplication of actions
- Specialist patent judges
- One-day trial, no jury
- English dominant language for litigation
- Specific evidence measures, no discovery
- Several ex parte options
- Protective letters
- No treble damages
- Recovery of attorney fees
- Extensive but incomplete Rules of Procedure
- Many practical questions unanswered
- Vast choice of strategic options
- Regional differences expected

always be reversed, the opposite is not possible. On the other hand, a European patent that is the subject of litigation before a national court can no longer be opted in. Although there are many authors who claim that the pharma sector will collectively opt out all of its patents, we have heard other rumours. This is not surprising. Opting out may be interesting for weaker patents that cover blockbuster products: as a result they would not be subject to the jurisdiction of the UPC and would have to be challenged separately in every single UPC contracting state. Opting in however is an appealing option for a strong patent, in particular if the patentee has only limited enforcement means available: one single UPC court case could lead to a virtually pan-European injunction. Other factors such as the timing of a planned product launch, the economic value of the pharmaceutical covered by the patent, the existence (or not) of divisional patents, etc are also factors that can influence the answer to this deceivingly simple question.

Check your licence agreements

Under the UPC system, licensees will have significant rights, in particular if their licenses are exclusive and do not include specific reference to the UPC . Indeed, unless your licence agreement explicitly excludes the possibility of applying to the UPC, an exclusive licensee will be able to initiate the vast majority of proceedings before the UPC without the consent of the licensor. The latter need only be informed of such actions. Where technology is being exclusively licensed to multiple parties in different parts of the EU, it will be particularly important to ensure that these parties do not develop their own, mutually incompatible litigation strategy. On the other hand, those patent holders who rely on their non-exclusive licensees to help protect their interests will have to explicitly authorise them to do so in the licence. As most licences will not contain provisions dealing with the consequences of the UPC, a patentee will have to have this conversation with its licensees in addition to the 'opt in/out' audit mentioned above. For similar reasons the owners of Supplementary Protection Certificates (SPCs) and the owners of the patents on which these SPCs are based (even if those patents have expired) will also need to agree on a UPC strategy.

First mover advantage

Where it is decided that a relevant pharmaceutical patent is to be subject to the jurisdiction of the UPC, the owner and/or authorised licensees and any pharmaceutical companies that are likely to be accused of infringing that patent will have to decide if they want to take an active or passive approach. In this regard, it is important to recall the following: (i) that proceedings before the UPC are front-loading (all the available evidence and arguments are to be submitted at the outset of the proceedings), (ii) that there are several decisions to be made (for example, concerning the language to be used and the division of the UPC to be applied to) and, most importantly, (iii) that the defendant has only three months to reply to the action taken by the plaintiff. In other words, the first mover has time on its side when preparing a case (for the collection of all the required evidence, the preparation of the carefully chosen experts, the careful selection of language and location, etc); the other side will have only three months to do essentially the same work, and to come up with a possible counterclaim. It may even have to conduct parallel settlement discussions at the same time.

(Pre-empting) preliminary strikes

The availability of preliminary measures (both those involving a hearing of all parties, and in particular those that are conducted ex parte) is probably the biggest enforcement asset under the UPC system. A competitor can be denied access to 500 million potential European consumers and this for the duration of the proceedings on the merits (expected to take one year). The UPC Rules of Procedure state that the court should carefully consider the position of the plaintiff and defendant before deciding on a request for preliminary relief. In practice, however, it may be that certain divisions of the UPC will be somewhat patentee friendly and therefore more inclined to award such measures. In the run-up to the launch of the UPC, pharmaceutical companies that fear that they might be targeted by such a preliminary measure should identify the patents that might be invoked and consider filing protective letters. Contrary to what is currently the case in many UPC countries, protective letters are not a custom accepted by the UPC, but a means of defence that is explicitly dealt with in the Rules of Procedure. In essence, a protective letter explains to the UPC why the patent that is to be the subject of the request for preliminary relief is invalid, or at least why the behaviour of the author of the protective letter does not amount to an infringement. These letters can also be used to pre-empt requests for pre-trial discovery and seizure (so-called 'saisie').

> 'Management and enforcement of European patent portfolios ... may involve drastic strategy changes'

Not just time, but also money

It should be clear that properly preparing for the launch of the UPC will require a fair amount of time and effort. In addition, besides the budget required for a proper UPC audit, stakeholders should also plan for a litigation budget. Although the overall cost of UPC proceedings should generally not be more expensive than classic European patent litigation in multiple EU countries, there are several new elements that will have an impact on a UPC litigation budget. In several UPC contracting states the usual court fees for patent litigation are low. Moreover, there is often little possibility for the prevailing party to recover attorney costs and fees. This will not be the case before the UPC. Although there has not yet been a final decision regarding costs and fees under the system, it will most likely be scale-based and the amounts will be heavily influenced by the value of the action. Based on the currently available information and taking into account that in the vast majority of pharmaceutical UPC proceedings a market worth many millions of euros will be at stake, it is likely that court fees will often exceed several tens of thousands of euros. In addition, it will be possible to recover attorney fees and costs up to several hundreds of thousands and sometimes even millions of euros.

There are many other aspects of the Unified Patent package that may influence the future thinking of life sciences companies as regards European and even global patent litigation: Bolar, SPCs, financing of litigation, damages, etc. It is impossible to address all of these issues in an article such as this one, where the aim is not to be complete but rather to raise awareness of this subject area. One lesson should be clear: any life sciences company that takes the UP and UPC seriously has no time to lose in putting together a multidisciplinary team of specialists to address the many practical questions that appear as soon as one scratches the UPC surface.

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