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PHARMA AND BIOTECH PATENT LITIGATION

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EXPERT FORUM

PHARMA AND BIOTECH PATENT LITIGATION

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Douglas R. Nemec concentrates on intellectual property litigation and related counselling, including providing intellectual property advice in connection with corporate transactions. Mr Nemec has litigated numerous cases in a wide range of technologies, from pharmaceuticals and other chemicals to IT and electronics. He has particular experience in life sciences matters, including patent litigation under the Hatch-Waxman Act. Mr Nemec also is registered to practice before the US Patent and Trademark Office, where he represents clients in patent interference proceedings and other matters.

CD: What key trends are you seeing in patent litigation in the pharma and biotech sector? How are these developments leading firms to re-think and adjust their patent litigation strategies?

Bell: In the past, the classic situation has been one in which a litigated patent read on an entire pharmaceutical product. With increased patenting of product features, methods of use, and manufacturing technologies, that type of circumstance has become less common. Instead, companies are routinely faced with complex considerations bearing on how an allegedly infringing product is manufactured, marketed or used. In this context, issues relating to the availability of non-infringing alternatives are more prominent than ever. Challenges in proving damages also arise, for instance in showing that a patented feature was the basis for demand of the product, or that consumers attributed significant value to a feature relative to technologies that may have been used previously.

Schüssler-Langeheine: Traditionally, litigation in the pharma and biotech sector has been widely dominated by disputes between originators and generics companies concerning the generics' strategies of entering the market for established drugs earlier than their competitors – for example, either by challenging patents protecting profitable products or entering the market at their risk or by premature marketing activities which the generics believe are either difficult for the proprietors to become aware of or can be argued as not infringing. We still see a lot of these actions. Actions against parallel traders and counterfeiters are another part of ongoing litigation activities in this sector. Infringement actions of that kind focus on legal rather than technical questions, on the interpretation of the law rather than on claim construction: what kind of preparatory steps for market entry result in an imminent threat of infringement and justify a preliminary injunction? Does an offer for delivery after patent expiry infringe the patent before its expiry? Can API suppliers rely on their customers' Bolar exemption? Also, intelligence, fact finding and securing evidence are key. However, the pharma and biotech sector is slowly undergoing a fundamental change. The low hanging fruit has been harvested. The patent cliff has been left behind. Fewer blockbuster drugs will be approved. As a result, litigation strategies will have to reflect the legal uncertainties associated with claims, the construal of which by a court is not reliably predictable. In our experience, litigation strategies in the pharmaceutical and biotech sector increasingly require a broader perspective, more creativity, and a mechanism to ensure tight and effective coordination.

Nemec: A flurry of proposed legislation in the US Congress aimed toward curbing perceived problems with patent litigation has caught the attention of the public, and may be having an adverse impact on the general perception of patents in the US legal system. While there are certainly examples of so-called non-practicing entities engaging in sharp practices, the debate is unfolding in such a way that virtually all patent plaintiffs are cast in a negative light and a pall is cast over the strength of all patents. These perceptions, or more accurately *misperceptions*, erode public confidence in the entire patent system. The pharma and biotech industrries, which are intimately tied to a strong patent system, may be disproportionately disadvantaged by certain of the reform efforts that are underway.

"A flurry of proposed legislation in the US Congress aimed toward curbing perceived problems with patent litigation has caught the attention of the public. "

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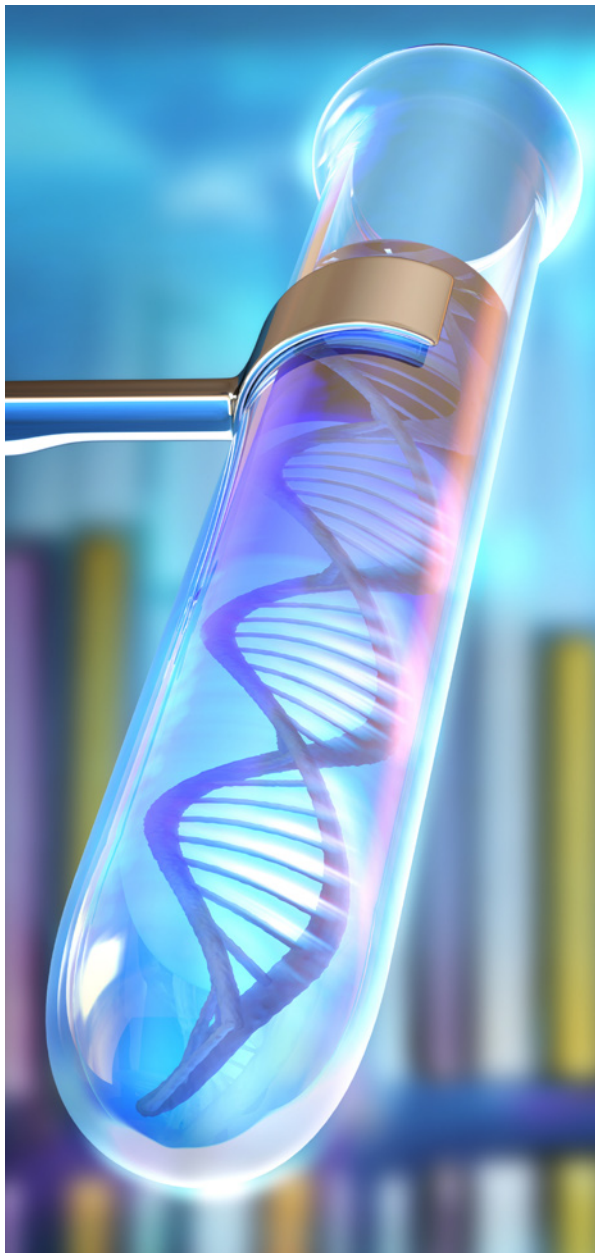
CD: What regulatory and legislative developments have unfolded in recent years? What factors have driven these changes and how have they impacted the pharma and biotech sector?

Schüssler-Langeheine: The EU commission's sector inquiry is certainly still in the heads of patent professionals, in particular when it comes to the enforcement of patents and SPCs with validity not beyond a reasonable doubt. The recent case law of the Court of Justice of the European Union on SPCs has not exactly increased legal certainty. Much caution is being used when drafting and sending warnings and requests and when taking legal action or entering into settlement agreements. Complaints with the EU commission are a popular defence by alleged infringers. Even though the EU Commission has not been overactive in terms of prosecuting allegedly abusive patent threats and actions, the sector inquiry has had its impact on the overall litigation strategies pursued by originators. But the focus of the EU Commission's endeavours is on identifying and sanctioning settlement agreements they perceive to be anti-competitive. The total fine of almost €150m imposed in June for what the EU Commission considered an agreement to delay generic market entry was the latest of a number of actions that have left a lasting impression on both originators and generics. Draft settlements are

thoroughly scrutinised before being communicated or even entered into.

Nemec: The involvement of the US Department of Justice and Federal Trade Commission in pharmaceutical settlement agreements will no doubt intensify in the wake of the Supreme Court's *FTC v. Actavis* decision regarding 'pay-for-delay' settlements. There are few issues on which both the brand name and generic drug industries agree, but the difficulty of settling pharma patent disputes without drawing antitrust scrutiny is certainly one of them. Adding to the difficulty is the fact that the Supreme Court provided no bright line rules in *FTC v. Actavis*. As a consequence, brand and generic drug companies attempting to settle suits will always face some risk, and thus may be less inclined to settle.

Bell: A big development in the US and the EU has been the emergence of a regulatory pathway for biosimilars, which are copies of branded biologic products. While patent litigation between innovators and generics is a well-trodden area in the small-molecule drug space, different issues arise when biosimilars are considered. For instance, a biosimilar may be subject to relatively high development costs; it may be differentiated from the reference product vis-à-vis clinical attributes or indications; and it may be expensive and complex to manufacture. All of these may lead to a competitive environment between the reference product and the biosimilar



that is very different from what we would expect based on experience with small-molecule generics. Patent litigation involving biosimilars is to a large extent uncharted territory, but there is every reason to believe it will involve confronting a range of new and complex issues.

CD: In terms of patent litigation, have there been any recent major recent cases of note? What insights can we draw from their outcome and what precedents have been set by recent case law?

Nemec: The Supreme Court's *Myriad* decision, holding that isolated human DNA is not patentable, represents a setback to the biotech industry. Biotech companies for years have been relying upon precedent that such inventions are entitled to patent protection, and the US Patent & Trademark Office has issued countless such patents over the years. The initial outcry cooled somewhat, as it has become clear that in many cases claims directed to isolated DNA sequences were accompanied by claims of differing scope that would satisfy the *Myriad* standard for patentability. The Court's decision in *Myriad* reveals some consistency in thinking with other recent cases on patentable subject matter, such as *In re Bilski*, in which the Supreme Court has shown a reluctance to allow the patenting of abstract concepts.

Bell: As an economist, I have a special interest in cases that result in a ruling discussing damages issues. There continues to be a lot of time and effort spent on grappling with the additional value created by a particular product feature within the context of an overall product that may be complex, embodying numerous other features. This is a tricky issue from an economic perspective, and it is one that courts are paying more attention to. In some cases, courts have even excluded testimony by experts deemed not to have used reliable methods. It may be that the use of survey evidence similar to that used for market research becomes more common here. In any event, my expectation is that these types of issues will become even more prominent as we see more patent disputes involving large-molecule drugs with complex attributes.

Schüssler-Langeheine: In Europe, interesting new developments are occurring with regard to the question of the conditions under which patent term extensions can be obtained by way of Supplementary Protection Certificates (SPCs). Decisions of the Court of Justice of the European Union (CJEU), such as C-210/ Glaxosmithkline Biologicals, C-322/10 Medeva, C-130/11 Neurim, and the more recent decisions C-493/12 Eli Lilly, C443/12 Actavis, and C-484/12 Georgetown University have clarified some pressing questions and, at the same time, raised even more new ones. Current hot topics concern the protection of an active ingredient

by a general claim and conditions for protecting drug combinations. SPCs can only be granted for one active ingredient or a combination of active ingredients if these are "specified/identified" in the claims of the basic patent. In C-493/12 Eli Lilly, the Court held that this may include functional definitions provided they "implicitly but necessarily and specifically" relate to the product. What this exactly means is uncertain, however, and remains a matter to be determined by national courts on a case-by-case basis. Interesting consequences are expected, for example, for biosimilars should the originator of the active ingredient rely on the MA for the biosimilar of its competitor to apply for an SPC for its basis patent.

CD: What actions are you seeing pharma and biotech companies take to protect their patents? What are the first steps towards initiating patent litigation?

Bell: The most pressing issue for patentees, whether in the pharma and biotech space or elsewhere, tends to be obtaining an injunction. In the US, the Supreme Court has clarified what needs to be shown in order for a permanent injunction to be granted. One of the prongs of this test is a showing of irreparable harm. Because this can be a particularly fact-intensive issue – and because the same types of issues tend to arise in the context of preliminary proceedings under the Hatch-Waxman regulations – companies seek to assemble the necessary arguments and evidence relatively early in the litigation process. This can involve evidence on the degree of substitutability between the patented and infringing products, and lost market share, revenues, brand recognition, goodwill in the marketplace, and so forth.

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Schüssler-Langeheine: Litigation in the pharmaceutical and biotech field is inherently global or covers, when conducted in Europe, at least a number of countries because local markets can in principle easily be entered separately on a country-by-country basis based on the harmonised system for obtaining marketing authorisations. Patent enforcement and generic defence across Europe requires early and thorough preparation and

coordination. As long as unitary patent protection and enforcement is not available, holders of pharmaceutical patents must carefully define where and how to start legal action on the basis of their European patent. This is a multi-factor decision. Which court will decide how quickly and which impact will that have in the other jurisdictions? Where can evidence be obtained in seizure or inspection proceedings that can be used for actions in other countries? Which counter-strikes can be expected and where? Based on these and further considerations, it is our experience that patentees develop an action plan often only after having obtained knowledge of infringement or after having been served a revocation action. On the other hand, companies intending to launch their product prepare for litigation by taking into account the possibility of being stopped in one country – that is, they provide for alternative manufacturing sites and supply routes.

Nemec: Pharma and biotech companies have always been among the savviest of intellectual property owners, which stands to reason given the US regulatory structure that rewards strong patent protection. While actions involving non-practicing entities, or 'patent trolls', now account for over 50 percent of patent infringement lawsuits in the US, pharma is one of the few industries where the vast majority of lawsuits are between competitors. Venue choice for pharma disputes is a more important strategic consideration than ever, as the existence of specialised patent rules intended to streamline cases and front-load contentions can make a jurisdiction unsuitable for the unique nature of pharma patent litigation.

CD: What is your advice to firms on preparing for patent litigation?

Schüssler-Langeheine: In view of the multi-jurisdictional character of most patents disputed in the pharma and biotech sector in Europe, it is important to set up an overall strategy and a concrete action plan for the litigation as early as possible, considering the specifics of each country involved. As a first step, a team of in-house and external litigation experts should be established and the team's functions and working procedure must be defined at a very early stage. Local counsel and experts should also be chosen, contacted and retained early. Using their local and technical expertise, Standard Operating Procedures (SOPs) should be drafted, agreed on and explained to the national enforcement teams. Short and transparent ways of communication should be established to ensure an efficient and consistent approach out and in front of the courts. Further evidence may be secured in accordance with the SOPs on a national basis to the extent possible using generally accessible sources and private investigators. Draft

complaints and requests for provisional injunctions should be prepared early.

Nemec: The prevalence of electronically stored information (ESI) has had a dramatic impact on the cost and complexity of patent litigation. It is not uncommon for a single party to produce hundreds of thousands of pages of emails and other electronic documents. Considering the cost of gathering and reviewing that volume of data, millions may be spent just to put documents in the opponent's hands. Notwithstanding that effort, satellite disputes over what documentation was *not* retained arise with regularity. Firms preparing for litigation should undertake efforts to locate and preserve ESI as soon as litigation is contemplated. Even if ESI is not physically collected before a suit is filed, knowing where all relevant material is located and having IT personnel at the ready to gather the material will pay dividends when the case is instituted.

Bell: Companies will want to employ competent, experienced counsel who will help them ensure that their liability – validity, claim construction, infringement – and damages positions are mutually consistent. It can frequently be helpful to engage damages and technical experts relatively early in the process, especially when damages are likely to depend on complex technical issues. Also important is arriving at a realistic view of the potential damages award or exposure, as this can, and should, bear on the resources devoted to the case. Companies often find themselves in a 'win-at-all-costs' situation, but this may not be justified given the stakes in a particular lawsuit.

CD: What difficulties might companies face when attempting to enforce patents in emerging markets? What steps are these countries taking to strengthen their IP laws and procedures?

Nemec: As a US-based practitioner, I have had little exposure to the challenges of enforcing patents in emerging markets. However, my experience in the US tells me that a strong enforcement system begins with a strong examination system. If we put our faith in the policies behind patent protection as a stimulant to innovation, then emerging countries should be vigilant in ensuring ready access to patenting for inventors of all shapes and sizes, along with quality examination procedures and personnel. Recent changes in the US Patent & Trademark Office embrace these principles, by easing fees on 'micro' entities and adopting procedures that allow start-up companies to secure patents swiftly and efficiently, in recognition of how critical IP protection can be when a firm is at a fledgling stage.

Schüssler-Langeheine: Among the emerging markets, India, China and Brazil have recently come into particular focus. While the decision *Novartis v.*

Union of India (Gleevec) has been widely perceived as being detrimental to the innovation environment in India, China and recently also Brazil have been very active in improving protection of intellectual property in their countries. Living beings and parts thereof, and naturally-occurring biological material, or therapeutic, surgical and diagnostic methods remain excluded from patentability in Brazil. However, genetically modified microorganisms and modified DNA sequences or genes are patentable, as well as chemical compositions even if characterised by functional features. The Chinese patent law, too, has been significantly improved over the years since it came into force in 1984. Problems with enforcement still occur, in particular with respect to obtaining evidence, the long duration of proceedings, high costs versus the small amount of awarded damages and limited effect of deterrence.

CD: The proposal of a Unified Patent Court has caused considerable debate in the European Union. Could you provide an overview of the proposals and how companies might prepare for future developments?

Schüssler-Langeheine: It is not exactly a proposal anymore. The Agreement on the Unified Patent Court (UPC) was adopted in early 2013. It has already been ratified by France, Austria and Malta and will enter into force when Germany, the UK and eight other Member States deposit their ratification instrument. Optimists say that the UPC will take up its business in 2015, but 2016 seems more realistic. This court will hear infringement and nullity actions relating to a newly established European patent with unitary effect throughout all Member States. However, it will also hear actions based on 'traditional' European patents and SPCs, which so far can only be enforced and nullified on a country-by-country basis. During a transitional period of initially seven years, such actions can still be brought before the national courts at the plaintiff's discretion. Patentees can even exclude the jurisdiction of the UPC for such actions if they opt-out in time – namely before individual European patents or SPCs are challenged before the UPC. Companies must

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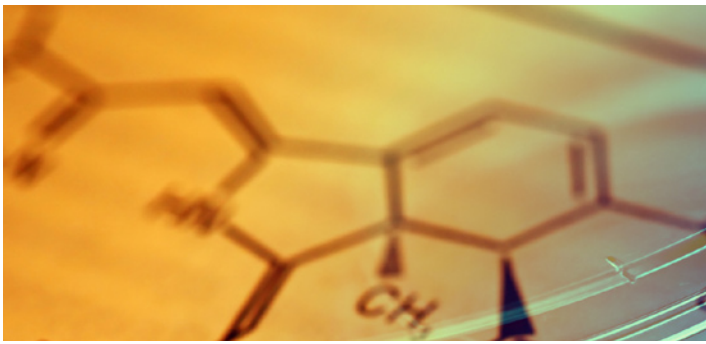
Dr Dirk Schüssler-Langeheine, Hoffmann • Eitle



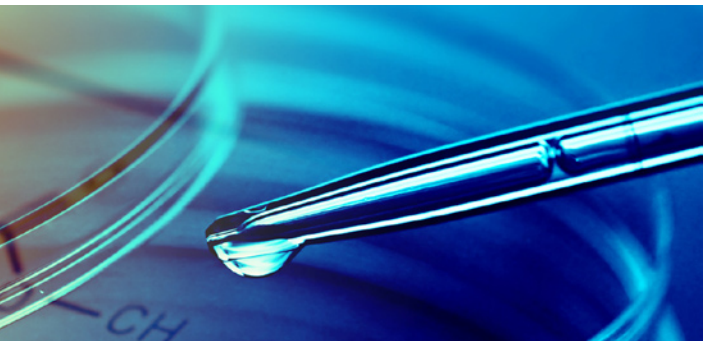
scrutinise their portfolios and analyse their options under the new system at an early stage, in particular to avoid being attacked by way of a pan-European revocation action where this is not desirable.

Bell: The current EU patent system is seen as suffering from excessive complexity, in terms of securing protection in different jurisdictions and then enforcing rights on a country-by-country basis. Recently, there has been broad but tentative agreement on a proposal for a single 'unitary' patent. A prospective patentee would apply for the unitary patent via a single, central application at the EPO, and a Unified Patent Court would have exclusive jurisdiction for enforcement of these patents. It is still not clear when and if all signatory states will ratify the agreement. Since firms will still be able to choose to apply for, and enforce, patent protection on a national basis, it will be interesting to see what drives the choice between unified and national patenting. For example, one might expect larger, less resource-constrained firms to diversify their risk by filing patents on a national basis, leaving open the option of filing multiple national actions.

Nemec: I am not conversant in the details of the Unified Patent Court proposals, as my litigation experience is concentrated on the United States. However, in general I applaud efforts to achieve uniformity in both the procedures for resolving patent cases around the world and the substantive law of patents. Global companies could recognise enormous efficiencies if a decision in one jurisdiction could provide greater predictability of the outcome in another jurisdiction. At present, for example, an EPO determination cancelling claims in an opposition proceeding will in all likelihood not even be admissible in a US case, even if the claim language is identical to that being litigated in a US court. The Unified Patent Court would not resolve this particular example, but it is a step in the right direction.

CD: Looking ahead, what are your predictions for the patent litigation landscape over the next 12-18 months? What major issues – such as gene and stem cell patents – do you see on the horizon as sources of conflict?

Bell: Patent litigation involving biosimilars is going to be a big deal. We might expect to see a fair number of biosimilars launching 'at risk' – that is, before all actual or potential patent disputes are resolved. In part, this is due to the difficulties that may arise in simply identifying the relevant set of patents at issue. Also, since biosimilars are likely to be priced closer to the reference products than small-molecule generics, the potential damages



exposure may be less. Given the complexity of patent issues in the biologic space, another issue to keep an eye on is the possible emergence of patent assertion entities, or 'trolls'. These companies or individuals may seek to purchase patents in order to assert them against originator or biosimilar manufacturers. We have seen a lot of troll activity in telecommunications and electronics, and it may be that conditions are becoming more favourable for them in the biotech and pharma sphere.

Schüssler-Langeheine: We believe that the entire biotech sector will gain an even more important role. In the future, there will be more drugs and, as a result, more patents and more cases, increasingly involving disputes between originators, and patents with broader claims potentially covering a greater number of various products. For example, claims for antibodies, antibody fragments or receptors binding to specific targets may cover a whole class of active agents. On the procedural side, the opportunity to use mediation or arbitration proceedings to solve in particular multi-jurisdictional patent disputes in the pharmaceutical and biotech sector seem to be underexplored. This may be a sign that the court system is perceived to function rather well, but we are also under the impression that parties are hesitant to deviate from the jurisdiction of the national courts and instead to put all of their eggs into one basket, possibly fearing that this may raise questions regarding the motivation for such a move when the overall outcome of the arbitration should be negative. As far as Europe is concerned, we believe that we will see more patent litigation in Eastern Europe over the coming years. Courts in Eastern Europe had the reputation of being against patentees, but we see an increasing number of cases where patents are enforced quickly and effectively in Eastern European countries. Since the Eastern European markets are also of increasing size and significance, this will probably translate into a growing litigation activity, at least until the pendulum might swing against patentees some time in the future.

Nemec: There is little doubt that Congress will pass some form of patent litigation reform legislation within the next 12-18 months. Given the proposals currently under consideration, there is a strong likelihood that such legislation will make it more difficult for pharma and biotech companies to enforce and protect their patents. For its part, the Supreme Court is continuing a nearly decade-long streak of patent decisions, the vast majority of which have cut back on what may be patented or raised the bar for successfully asserting patents. This is a troubling trend for an industry that relies so heavily upon patents to fuel innovation. CD

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Founded in 1965, **Charles River Associates** is a leading global consulting firm that offers economic, financial, and business management expertise to major law firms, corporations, accounting firms, and governments around the world. CRA has extensive experience in international arbitration, including both commercial and investment treaty claims, and has been engaged in some of the most complex and high-profile disputes of recent years. The firm provides expert testimony and analytical expertise in a variety of industries, including life sciences, metals and mining, financial services (including banking, finance, and insurance), energy, and telecommunication and other media.

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