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ARBITRATION IN THE LIFE SCIENCES AND PHARMACEUTICAL SECTOR

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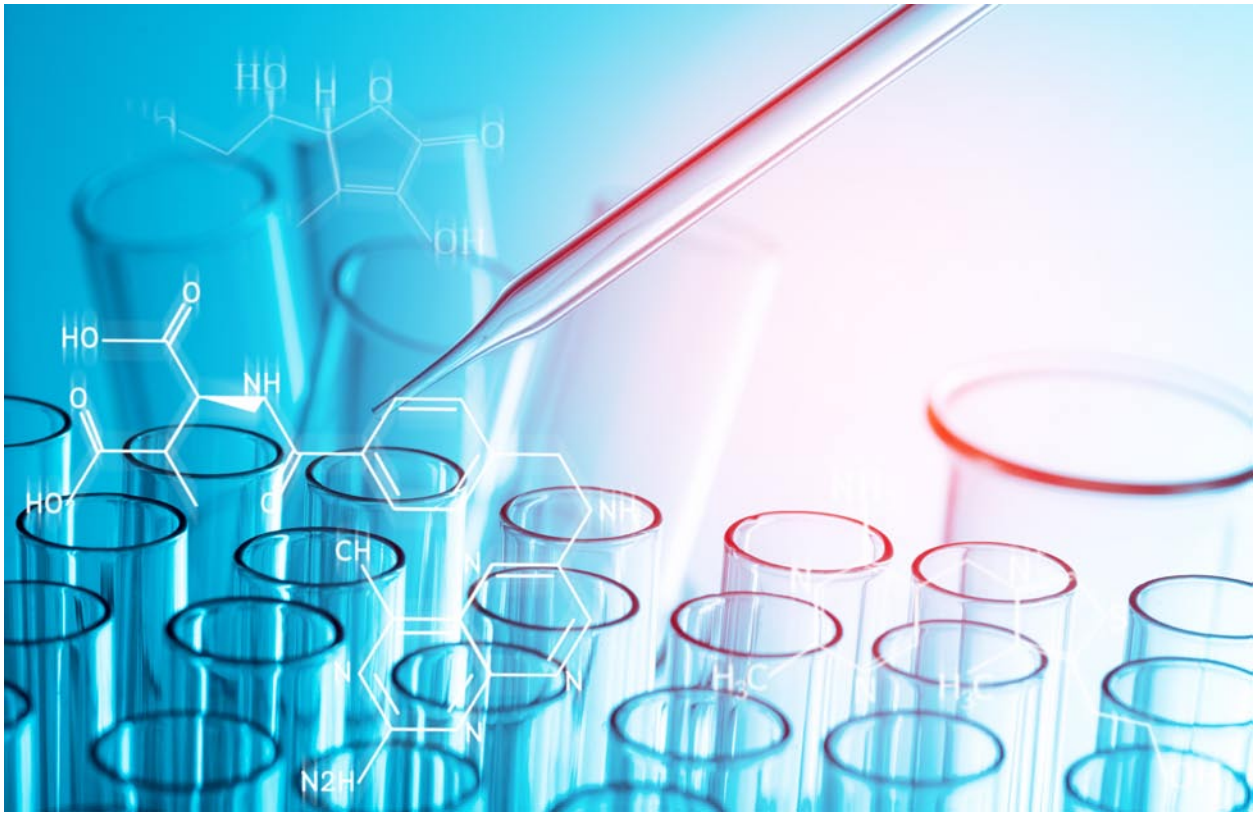
HOT TOPIC

ARBITRATION IN THE LIFE SCIENCES AND PHARMACEUTICAL SECTOR



PANEL EXPERTS

Lauren Lindsay
Senior Associate
Allen & Overy
T: +44 (0)20 3088 2365
E: lauren.lindsay@allenovery.com

Lauren Lindsay is dual qualified in both law and biology, with a specialisation in genetics. Her Masters in Law considered the interplay between parental consent, children's rights and genetic testing, with a particular focus on the dignity of the child. Ms Lindsay has experience in numerous large commercial arbitrations involving life sciences issues and also has a background in civil litigation in the IP sector.

Philipp Groz
Partner
Schellenberg Wittmer Ltd.
T: +41 44 215 5252
E: philipp.groz@swlegal.ch

Philipp Groz is a Zurich-based partner of the Swiss firm Schellenberg Wittmer Ltd. He is part of the firm's dispute resolution team and heads the IP and life sciences practice groups. He represents clients before state courts as well as in complex international arbitration and mediation proceedings. He also sits as an arbitrator. His experience spans a broad range of sectors, with a focus on the life sciences industry. He is a board member of the Licensing Executives Society Switzerland.

Santiago Bejarano
Senior Associate
Wilmer Cutler Pickering Hale and Dorr LLP
T: +1 (212) 937 7270
E: santiago.bejarano@wilmerhale.com

Santiago Bejarano is a senior associate in Wilmer Cutler Pickering Hale and Dorr's LLP international arbitration practice, focusing on commercial and investor-state disputes with parties involved in a wide range of industries, including oil & gas, energy, luxury goods and life sciences.

Leandro Toscano
Legal Officer
WIPO Arbitration and Mediation Center
T: +41 22 338 8247
E: leandroemilio.toscano@wipo.int

Leandro Toscano holds an LL.M. in International Dispute Resolution from Queen Mary University of London and University College London. He was admitted as an attorney by the Bar Association of Buenos Aires following studies in law at the University of Buenos Aires. Before joining WIPO in 2008, he was in private practice in intellectual property and information technology law. Mr Toscano was the Center's representative at Maxwell Chambers in Singapore from 2011 until mid-2014.

CD: How would you describe the appetite among companies operating in the life sciences sector, to use arbitration to resolve their disputes?

Lindsay: Our perception is that the appetite for arbitration is on the rise. The WIPO Arbitration and Mediation Center (WIPO Center) reports approximately 15 percent of its current case load as involving the life sciences industry. The ICC International Court of Arbitration and American Arbitration Association's (AAA) International Centre for Dispute Resolution (ICDR) recorded an average of 30 international arbitration cases relating to health, pharmaceutical and body care matters submitted annually between 2011 and 2015. There are a number of features of arbitration that make it suitable for the life sciences sector, including the confidential nature of proceedings, the possibility of appointing arbitrators with sector-specific expertise, the bespoke nature of the arbitration agreement and the greater ease of enforceability of arbitral awards internationally than court judgments.

Toscano: The growth in the use of arbitration among entities operating in the life sciences sector may be related to the advantages that it presents, such as confidentiality, the ability of parties to control procedures and to select decision makers with expertise, the ability to resolve multiple national disputes in one forum and international enforcement of arbitral awards. To date, 15 percent of arbitration and mediation cases filed with the WIPO Center have related to life sciences, with a noticeable increase in recent years. Parties to these cases were research institutes, universities, hospitals and SMEs involved in the pharmaceutical, biotechnology and medical devices industries, and they were mainly based in Asia, Europe and North America. While the cases varied in their complexity, the amounts in dispute were as high as $1bn. We have also noted an increase of the referral of life sciences disputes to mediation.

Bejarano: There is an increasing desire to use international commercial arbitration in the life sciences sector, in particular as cross-border licensing agreements become increasingly ordinary in the industry and cross-border multi-billion dollar M&As occurring in the space. For instance, according to Deloitte, the global pharmaceutical wholesale and distribution market has been growing at a steady rate of nearly 7 percent annually since 2014, and revenue in this market is expected to exceed $1 trillion in 2019 alone. Given the size of the industry and the international nature of the companies that operate in this space, including the increasing number of technology-focused startups that are emerging in this market, it is unsurprising that there is an increasing desire to resolve disputes through international arbitration, in particular because of the advantages that come with the confidentiality regimes that may

be applicable to arbitration proceedings. There has also been increased participation of pharmaceutical companies, for example, resorting to international investment arbitration to bring claims against states, under bilateral or multilateral investment or trade treaties.

Groz: I expect the use of arbitration in the field of life sciences to continue to grow in the coming years. Disputes in this industry typically involve more than one jurisdiction and often concern technical, intellectual property (IP) and regulatory issues. Frequently, such disputes also relate to issues that are highly sensitive, such as a company's trade secrets or reputation. These factors will often advocate for the use of arbitration, thereby allowing parties to agree on confidential proceedings in a single neutral forum and to select decision makers with the relevant expertise.

CD: What are some of the typical causes of recent disputes in this sector? To what extent do these disputes lend themselves to arbitration?

Bejarano: The life sciences sector, and in particular the pharmaceutical industry, commonly enters into collaboration agreements covering the different stages of a product's research, development, production or manufacturing and marketing. In this context, disputes often arise around those agreements, whether they concern the use of intellectual property under a licensing agreement, the performance of co-marketing or co-promotion agreements or the performance of distribution agreements covering particular geographies. All of these disputes are essentially commercial in nature and lend themselves to resolution through arbitration, in the same way that disputes in other specialised fields, such as the financial services industry, are resolved through these means.

Groz: Patents and know-how are of primary importance in the life sciences industry. It is therefore not surprising that conflicts often arise out of international IP licence agreements. For example, we have seen several arbitrations in which the licensee argued as a defence to royalty payment claims that it did not use the licensed patents, and that these patents were in any case invalid. Resolving such disputes in front of national courts would be burdensome and costly, as at least the patent invalidity issue may have to be adjudicated in separate proceedings in the jurisdictions in which the patents are registered. By contrast, arbitration allows for the resolution of multijurisdictional issues in a single forum. While some jurisdictions, such as Switzerland, would even permit the arbitrators to declare a patent invalid with effect towards third parties, many jurisdictions, such as the US, at least allow arbitrators to rule on patent invalidity issues with effect among the parties.

Lindsay: There is no standard 'life sciences dispute' fact pattern. Disputes are often contractual, arising out of complex licensing or joint venture agreements. They may result from disagreements over the development, licensing and marketing of a particular drug or product. Alternatively, they may be linked to change in control provisions resulting from a merger or acquisition and a shift in the new entity's priorities. We have seen a number of insurance arbitrations arising out of mass tort litigation claims in the US, where the dispute related to whether the life science company's product liability fell within the scope of its insurance arrangements. Investor-state arbitrations also feature in the life sciences context. These arbitrations are brought by foreign investors against states that take measures interfering with the investor's rights under investment treaties. In *Les Laboratoires Servier v Republic of Poland*, for example, a dispute arose when Poland revoked Servier's marketing approvals upon Poland's accession to the EU. Other disputes may arise out of compulsory purchase arrangements, which prevent a drug company setting its own prices.

Toscano: The significant value of intellectual property rights, together with the increased complexity of cross-border transactions, require entities operating in the life sciences sector to carefully choose a strategy for how to protect and enforce their intellectual property rights, including the way potential disputes will be settled. WIPO caseload in this sector includes disputes related to R&D agreements, distribution agreements for generic drugs, licensing agreements, and settlement agreements of prior court litigation in several jurisdictions.

CD: What are the main issues and challenges facing companies during the arbitration process? Are there any aspects unique to this sector, which companies should consider when preparing for arbitration?

Bejarano: One of the main challenges faced by companies in the life sciences sector when they resort to arbitration is making otherwise highly technical and scientific information accessible to the arbitrators and their own counsel. The resolution of many disputes in this space, particularly those related to intellectual property of medical devices or pharmaceuticals, are necessarily dependent on information that is both scientifically complex and technical. It is, therefore, of paramount importance for the parties to find the right expert witnesses early on, who can assist counsel from the outset in understanding the complexities surrounding the evidence as they prepare to put the case forward, and then down the line they can assist the tribunal in understanding the same concepts and how they are central to the resolution of the dispute.

Lindsay: One feature often relevant to disputes in the life sciences sector is the ongoing business relationship between the parties. Longevity of relationships is often crucial in light of the way big pharmas work together to test or exploit a drug for licensing, or stock their pipeline by collaborating with or buying out smaller biotech companies. What begins as a licensing relationship may well turn into a merger or acquisition. The fact that arbitration is private and viewed as a more consensual process than litigation can be of assistance. Confidentiality is also an important consideration, given the involvement of proprietary information as well as the public profile of many pharmaceutical companies. Parties should consider from the outset whether express confidentiality provisions are required to keep the existence of the dispute out of the public domain. They should also seek to enter into appropriate confidentiality arrangements with each other when disclosing documents or expert reports in the proceedings.

Groz: In life sciences disputes, contractual issues are often intertwined with IP issues. In addition, regulatory aspects frequently play a major role, such as whether a pharmaceutical supplier complied with good manufacturing practices. Finally, an understanding of the market realities and industry practices will also often be required to determine a disputed issue such as whether commercially reasonable efforts were made to distribute a pharmaceutical product. Therefore, the parties' counsel and the arbitrators in a life sciences dispute should ideally not only be seasoned arbitration practitioners, but also familiar with the relevant contractual, IP, regulatory and industry aspects.

"Alternative dispute resolution (ADR) procedures allow tailoring arbitration and mediation proceedings to meet parties' needs."

Leandro Toscano,
WIPO Arbitration and Mediation Center

Identifying appropriate counsel and arbitrators early in a dispute is thus more important than in other industries in which the pool of suitable candidates is usually larger.

Toscano: Alternative dispute resolution (ADR) procedures allow tailoring arbitration and mediation proceedings to meet parties' needs. In some cases, parties streamline procedures by agreeing on shorter timelines for submissions and for the issuing of the award. One of the key elements for parties involved

in life sciences disputes is the choice of arbitrators familiar with relevant legal, technical or business areas. Specific provisions regarding evidence may also be very useful in life sciences arbitrations. The WIPO Arbitration Rules govern the access to samples and testing, determination of the scope of discovery, selection of suitable technical and damages experts, as well as offer protection of trade secrets and other confidential information. Before initiating an arbitration procedure, parties may also consider the possibility and usefulness of negotiation and mediation as time and cost effective alternatives.

CD: Could you highlight any recent, high-profile arbitration cases in this space which have captured your attention? What lessons can the life sciences sector learn from the outcome of these cases, and the ultimate enforceability of the decisions reached?

Groz: In 2016, the Court of Justice of the European Union (CJEU) rendered its decision in the case *Genentech v. Hoechst, Sanofi-Aventis Deutschland*. This case is interesting for various reasons, but I would like to focus on the efficiency and confidentiality aspects of the case. Hoechst initiated arbitration in 2008 for payment of patent licence royalties. The sole arbitrator issued a partial award on liability in September 2012. The Paris Court of Appeal stayed the annulment proceedings against the award and requested the CJEU for a preliminary ruling on an aspect of EU competition law. The CJEU decided in July 2016, almost four years after the relevant partial award was issued. This case serves as a general reminder to parties to agree on a seat of arbitration in a jurisdiction with swift, one-instance annulment proceedings. In Switzerland for example, the Swiss Federal Supreme Court is the only instance to deal with challenges against arbitral awards and typically decides such challenges within four to six months. Moreover, this case demonstrates that even if the parties agree to the confidentiality of the arbitration, arbitration-related state court proceedings, regarding annulment or enforcement, may cause the details of the dispute to become publicly known.

"The Swiss Federal Supreme Court is the only instance to deal with challenges against arbitral awards and typically decides such challenges within four to six months."

Philipp Groz, Schellenberg Wittmer Ltd.

Toscano: A WIPO high-profile arbitration case dealt with the alleged infringement of European and US patents protecting medical devices. Following litigation in several jurisdictions, a European company and an American company signed a settlement agreement including an arbitration clause. Given the importance of the patents in dispute, the parties amended the standard WIPO arbitration clause so that infringement claims of US patents would be heard by a sole US arbitrator, and those relating to European patents by a sole European arbitrator. The arbitrators' awards were also subject to review by an appeal panel of three arbitrators. The US and the EU arbitrators issued their awards within 18 months and the parties agreed not to use the appeal procedure.

Lindsay: One recent case of interest is *Eli Lilly v Canada* – the first international investment-treaty award dealing with patents. Eli Lilly brought a claim for breach of the North American Treaty Agreement (NAFTA), based on Canada's alleged revocation of certain patents which did not meet the so-called 'promise utility doctrine'. Eli Lilly argued the revocation was a radical departure from Canada's traditional patent utility standard – and those applied by the other NAFTA partners – and thus breached the fair and equitable treatment and expropriation, standards of the treaty. In March 2017, the tribunal rejected Eli Lilly's claim because the 'promise utility doctrine' was not a fundamental or dramatic change in Canadian patent law so as to breach the NAFTA standards. It was described instead as an incremental, evolutionary change. The tribunal also reminded the parties that it was not an appellate court for the decisions of national courts, to which it accorded considerable deference. This case shows that international investment tribunals may be an appropriate forum for patent disputes, although they will not interfere with what is seen to be the domain of national courts. Interestingly, just three months after this award, the Canadian Supreme Court handed down a judgment – *AstraZeneca Canada Inc. v. Apotex Inc*. – which effectively did away with the 'promise utility doctrine'.

Bejarano: The *Apotex v. United States* NAFTA arbitrations are interesting cases. Apotex, a Canadian-based pharmaceutical company, brought investment arbitration claims under NAFTA against the US. There were three decisions rendered in that saga, the latest of which is from August 2014. Apotex claimed that the US had violated its treaty obligations – national treatment, most favoured nation treatment and minimum standard of treatment – when the Food and Drug Administration (FDA) issued a series of decisions that effectively prevented Apotex's US subsidiary from importing certain pharmaceuticals produced in facilities in Canada. The US argued that the importation authorisations were incapable of being 'investments' within the meaning of NAFTA. The Tribunal recognised the *res judicata* effect of the prior *Apotex* awards, and held that these authorisations

were not an 'investment' within the meaning of the treaty. This case exemplifies the complexity of life sciences investment arbitration claims, because they often arise in the context of a highly regulated industry. The *Apotex* case is a red light for similar claimants, who must carefully consider what constitutes 'protected' investment and how to frame it appropriately to establish a tribunal's jurisdiction, in particular when the main driver of the claimant's alleged right is a government-issued authorisation to import or market a particular product in the relevant jurisdiction.

CD: What general advice can you offer to companies in terms of strategies to adopt when involved in arbitration proceedings? Are there any recurring issues which parties tend to underestimate, for example?

Lindsay: Although arbitration lends itself well to the international nature of the operations of life sciences companies, its use in the sector has been a comparatively recent development. Accordingly, parties can sometimes underestimate the common procedural and practical difficulties that may arise in arbitration. For example, the lead-time required to secure hearings in front of high profile arbitrators or the procedural wrangling involved in agreeing detailed confidentiality provisions. Arbitration can also be extremely costly if left unchecked and parties should seek to reduce costs from the outset. This may involve the use of an expedited arbitration procedure, limiting disclosure and the number of rounds of pleadings or selecting arbitrators and administering institutions with more reasonable hourly rates.

Toscano: To maximise the benefits of using ADR procedures, parties should not underestimate the efficiency of mediation. The use of dispute resolution escalation clauses – mediation followed in the absence of settlement by arbitration – has proven to be a suitable solution including the need to preserve business relationships between parties. Seventy percent of WIPO mediations have settled, giving parties the opportunity to get back to work in a time and cost efficient way. Effective proceedings, to a large extent, depend on the quality of the mediator,

or arbitrator, in this case, familiar with relevant life science legal, technical or business areas. The WIPO Center maintains a list of mediators and arbitrators specialised in life sciences that parties can appoint in cases under the WIPO Rules.

Bejarano: With respect to technical and scientific information, there is one important issue that is sometimes underestimated in life sciences disputes and that is the complexity of establishing what 'commercially reasonable efforts' clauses entitle a party to. These types of clauses are very common in the sorts of collaboration agreements that are entered into between life sciences companies, and often require establishing best industry practices and local, geographically-specific practices. In the pharma space, for instance, this will involve

establishing what was a reasonable commercial effort in relation to the drug's stage of development and marketing stage. Because pharmaceuticals usually have a lifespan, which involves heavy investment in research and development, and then in marketing during the first few years after a launch, which then generally tends to decline, it will be of paramount importance for the parties to establish, in the particular case, what efforts could reasonably be expected at each stage of the drug's lifecycle.

Groz: Disputes in the life sciences industry tend to involve technical matters, which need to be presented by way of party-appointed experts. In certain areas, few suitable and available experts exist. Identifying and instructing the appropriate experts prior to, or at an early stage of, an arbitration is thus key. Furthermore, even if the arbitrators have, or claim to have, experience with life sciences, parties should not blindly assume any prior knowledge on any relevant topic. In practice, questions of arbitrators during hearings often reveal that their understanding of relevant industry-specific issues is lower than expected. A party, and its counsel, should thus adopt proper case presentation techniques, to ensure that even a layperson would clearly understand the party's arguments. This may include the use of technical tutorials, 3D animations or other types of demonstrative evidence.

CD: What are some of the typical mistakes or problems that you have encountered in practice when looking at arbitration clauses in contracts relating to the life sciences industry?

> **"One of the issues that we have encountered has been arbitration clauses that impose very detailed requirements on the expertise of the arbitrators."**
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> *Santiago Bejarano, Wilmer Cutler Pickering Hale and Dorr LLP*

Groz: Arbitration clauses sometimes specify arbitrator qualifications. For example, "each arbitrator shall have at least 10 years of experience in the pharmaceutical industry". This should be avoided. First, such definitions are often subject to interpretation and lead to disputes and delay once the arbitration is initiated. Second, the qualifications often turn out to be irrelevant to resolve the specific

dispute that ultimately arises. Third, at least the presiding arbitrator should have sufficient arbitration experience, but not necessarily industry experience, to efficiently and fairly conduct the arbitration. Another problematic issue that I have encountered in arbitration clauses is the specifying of unrealistic time limits, such as "the hearing shall be held within 90 days of commencement of the arbitration". Disputes in the life sciences industry are often technically complex and require the assistance of experts. This takes time. Specifying overly short time limits can not only leave one or both parties unsatisfied with the process, but may also endanger the enforceability of the resulting award.

Bejarano: One of the issues that we have encountered has been arbitration clauses that impose very detailed requirements on the expertise of the arbitrators. While it is obviously desirable for the arbitrators hearing a dispute in the life sciences sector to be familiar and knowledgeable in the field, imposing specific requirements on arbitrators – such as the requirement that they have medical backgrounds or are members of certain arbitration rosters – may end up making the arbitrator selection process difficult and burdensome to the parties. It is best to exclude these sorts of requirements so as to allow the parties maximum flexibility when a dispute arises, given that different focuses may be desirable depending on the type of dispute, and the arbitration clause is normally drafted to encompass most, if not all, disputes that may arise in the performance of an agreement. Another thing that is often overlooked is the significance of the arbitral seat in commercial arbitration, particularly because the law of the seat is often looked at by the tribunal to evaluate whether the arbitration clause is valid, and there are still jurisdictions that limit the arbitrability of certain subject-matters that are frequent in life sciences sector disputes, such as patents.

Lindsay: Common mistakes tend to be the same as those made in other industry contracts. For example, failing to specify the seat of the arbitration or confusing the seat with the physical location of the hearing, failing to identify the applicable laws of the contract and, separately, of the arbitration clause where there is an international element to the transaction, using equivocal language instead of making a clear and unambiguous reference to arbitration, incorporating institutional 'rules' for a non-existent institution. Such mistakes can lead to potentially lengthy and costly satellite disputes about the meaning and scope of the arbitration clause, before the dispute under the contract can be heard. We would advise using model arbitration clauses as a starting point, which can be tailored, with appropriate local law advice, to meet the specific requirements of the transaction.

Toscano: It goes without saying that disputes should be anticipated by parties to any type of

contracts, including life sciences. Dispute resolution options and provisions should be carefully considered during contract negotiations. The use of model ADR clauses is encouraged to ensure that the important elements of a dispute resolution clause are provided for and to avoid any ambiguity which may later lead to difficulties and delays in the dispute resolution process. Some typical problems relating to the efficiency of ADR clauses were the restriction of the subject matter submitted to the arbitration, the omission of core clause elements, for example the number of arbitrators, the place of arbitration and applicable law, among others, and incorrect references to applicable ADR rules or the administering institution.

CD: In your experience, is there a particular arbitration institution and seat of arbitration that seems particularly well suited to arbitration in the life sciences sector?

Bejarano: All major international arbitral institutions, like the ICC or the AAA (ICDR) have made efforts to cater to the life sciences sector and are receiving increasing numbers of cases in this field. For instance, the AAA (ICDR) now has a roster of arbitrators with specific expertise in the life sciences field. However, if I would have to single out an institution that may have particular expertise to deal with these types of disputes, it would be the WIPO, which administers a large number of these arbitrations. The WIPO Arbitration Rules contain certain provisions that are specifically tailored to this space, such as rules about the use of experiments, the tribunal's power to order the joint production of technical primers and models or drawings and special rules on confidentiality which may be particularly sensitive in the life sciences area.

Groz: The differences between the arbitration rules of major arbitration institutions should not be overstated. That said, the WIPO arbitration rules may be of particular interest in this field. They contain strict confidentiality provisions and a provision specifically aimed at the protection of trade secrets. Additionally, the WIPO Center has a large database of neutrals with different backgrounds. This may be helpful to find an arbitrator or expert with rare qualifications. There is no specifically suited seat for life sciences arbitrations. As a general rule, parties should always opt for a seat in a jurisdiction with an arbitration-friendly legislation. To the extent that IP issues could become relevant in the arbitration, parties should agree on a seat in a jurisdiction that has a liberal approach to the arbitrability of IP disputes, such as Switzerland.

Toscano: WIPO arbitrations have taken place in several locations, including Amsterdam, Brussels, Geneva, London, Madrid, Munich, New York, Paris, Singapore and Zurich. To ensure the quality of its procedures, the WIPO Center maintains a dedicated

list of mediators and arbitrators familiar with relevant life sciences legal, technical and business areas. The WIPO Arbitration Rules include specific provisions on confidentiality and evidence well suited for life sciences disputes. To optimise dispute resolution practices in the life sciences sector, the WIPO Center also collaborates with relevant stakeholders and organisations around the world.

Lindsay: Any seat that is supportive of arbitration would be suitable. We recommend London, Paris, Geneva, New York, Singapore, Hong Kong and Stockholm, which are all recognised arbitral centres with courts known to support the arbitration process. Frequently recommended institutions include the LCIA, ICC, SIAC, HKIAC and SCC. It is not necessary to match the institution with the seat of the arbitration. Parties should instead look at the different offerings of the institutional rules in key areas relevant to their business or transaction, for example charging structures, arbitrator appointments, confidentiality obligations, scrutiny of the award, emergency and expedited arbitration provisions, consolidation and joinder. There are, of course, specialist institutions like WIPO, which may be of interest. WIPO offers resolution of IP and technology disputes under its own set of arbitration rules, which are considered suitable for contractual disputes requiring rapid resolution. It also maintains a list of arbitrators qualified to deal with IP disputes. While we have experience of pharmaceutical companies providing for ad hoc arbitrations in their contracts, this approach is only recommended for sophisticated parties with significant experience arbitrating disputes.

"WIPO offers resolution of IP and technology disputes under its own set of arbitration rules, which are considered suitable for contractual disputes requiring rapid resolution."

Lauren Lindsay, Allen & Overy

CD: What are your expectations for future trends and challenges concerning arbitration in the life sciences sector?

Toscano: A working group of in-house lawyers and life sciences practitioners coordinated by the WIPO Center recently indicated that they expect to see an increase in outsourcing of originating development work to universities, university spin-offs and start-ups, and contract research organisations.

Increased settlements in court litigation, as well as in arbitration and an increased use of mediation, are also expected. Arbitration and mediation may become more attractive for parties to life sciences disputes as they allow tailored procedures. Moreover, SMEs prefer to avoid court litigation because of high costs and related risks for their business activities. Another interesting trend to mention is the increased referral to mediation by national courts of life sciences disputes pending before them.

Groz: In view of the pressure to cut costs and increase efficiency, I expect that the use of mediation as a pre-arbitration tier will increase. I further believe that the pressure on counsel and arbitrators to specialise in certain industries will grow. In many jurisdictions, it is still difficult to find practitioners with significant experience in both life sciences and in international arbitration. I do not anticipate, however, that further specialisation is required on the side of arbitral institutions. For lack of experience and proven track record, newly created specialised arbitral institutions such as the Patent Mediation and Arbitration Centre – to be established in Ljubljana and Lisbon under the Agreement on a Unified Patent Court – will likely have difficulties becoming attractive to arbitration users.

Lindsay: We expect to see a continuing rise in the number of life science arbitrations, linked to the growth in IP arbitration generally and the increased recognition of the suitability of life sciences disputes for arbitration. The risk of disputes between different entities collaborating in the global commercialisation of drugs is inherent in today's model of drug development. For example, collaborations in certain therapeutic fields, most particularly in the area of immuno-oncology, are booming. Arbitration can be perceived as a less combative approach to resolving those disputes than the courts. It remains to be seen what will come of the relatively recent, but expanding, collaborations between big pharma and tech companies in the development of digital health products, but disputes suitable for arbitration are sure to materialise.

Bejarano: I think we will continue to see growth in the number of arbitrations in this sector. In particular, I believe that the UK's decision to leave the European Union may lead to an interesting increase in the number of patent and IP disputes in this sector involving UK parties that may be submitted to arbitration. CD