ARBITRATING PHARMA DISPUTES ON THE RISE – PLANNING AHEAD MAKES SENSE

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Legal Briefings – By **Chris Parker and Lizzie Reeves**

Pharmaceutical companies risk coming up against complex and high value disputes in their everyday dealings and operations, and we are increasingly seeing arbitration being used to resolve those disputes. Here we discuss the kinds of disputes pharmaceutical companies face and why international arbitration is well-suited to resolving those disputes.

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WHAT KINDS OF DISPUTES DO PHARMACEUTICAL COMPANIES FACE?

Leaving typical IP disputes to one side, pharmaceutical disputes do not necessarily fit within the same bucket. However, they commonly arise out of contractual relationships, whether "one-off", such as acquisitions, or ongoing, such as collaborations for drug development or co-promotion agreements.

Contractual disputes are increasingly common in the sector, including from R&D collaborations and co-promotions.

As in other sectors, M&A can give rise to a variety of disputes, relating, for example, to inherited liabilities and warranty claims.

Pharmaceutical companies also enter into a vast range of ongoing commercial arrangements, including R&D agreements, licenses, co-promotion contracts and supply or distribution agreements. While most of these contracts are performed amicably, they can be ripe for dispute if the parties' commercial interests fall out of alignment.

For example, co-promotion, co-marketing, joint development or license agreements in relation to a particular drug can bring together companies of significantly different size, with expertise in different segments of the market and different geographical reach. The idea, of course, is that the parties share an interest in successful commercialisation of the product. Their interests may not, however, always align – particularly if the agreement (as is often the case) places primary responsibility for the costs of development or promotion of the product on one party or the performance of the product is not in line with expectations.

These collaborative agreements commonly include some form of endeavours or efforts obligation, such as a requirement for one party to exercise commercially reasonable efforts to develop a particular product. In our experience, these kinds of obligations provide fertile ground for dispute if the parties' commercial relationship deteriorates. In particular, what a particular endeavours or efforts obligation requires is often a complex question, from a legal perspective and in terms of industry practice and the product and markets in question. We also find that these obligations can be vague and ill-defined – for example, in the absence of key performance indicators, what should be the reference point to determine whether a company is doing enough to satisfy its obligations to work towards a certain objective? In a co-promotion agreement, should the focus be on the investment committed, the number of details performed, reflection rates or something else entirely? There are often good reasons for drafting an endeavours obligation in broad terms – for example, because the development pathway for an early stage drug is uncertain. However, the vaguer the drafting, the more scope there will be for conflicting interpretations and disputes further down the line.

Further, when these disputes do arise, they can be very high value (hundreds of millions of dollars), with the claiming party alleging significant lost revenues in the form of lost royalties or lost sales, covering many years. Needless to say, this can result in the agreement in question receiving a much higher level of scrutiny – by lawyers and tribunals, but also internally – than was ever anticipated when it was signed. It also brings into focus clauses often considered as boilerplate – including, in particular, limitation of liability provisions and arbitration clauses. A well-crafted and enforceable limitation clause will preclude a high-value, speculative claim, and could be critical in enabling a commercial resolution to any dispute.

> In a 2013 survey on dispute resolution in technology-related disputes produced by the WIPO Arbitration and Mediation Center (the "2013 **WIPO Survey**", available here), one respondent from an R&D institution in Germany estimated that in two years the institution had concluded approximately 2,000 non-disclosure agreements, 6,000 R&D agreements, 900 licenses, cross-licenses and pool licenses and 10 agreements on settlement of litigation.

The 2013 WIPO Survey suggests that disputes arise more commonly from license agreements as compared to other contractual relationships: respondents from the pharmaceutical / biotechnology sector identified license agreements as most commonly giving rise to disputes, at 26%, followed by R&D agreements at 20%.

In the 2013 WIPO Survey respondents from the pharmaceuticals / biotechnology sector were asked to identify their preferred dispute resolution clause for use in commercial contracts – the results placed arbitration in second place (at 24%), not far behind court litigation (at 33%). Respondents were also asked about their key considerations when negotiating dispute resolution clauses – those who used arbitration more frequently in international agreements identified time, enforceability, quality of outcome and forum neutrality as more important considerations compared to respondents using litigation most frequently. Respondents also indicated that they spent more time and incurred significantly higher costs in litigation than in arbitration and mediation.

ARBITRATION OF PHARMACEUTICAL DISPUTES IS ON THE RISE AND SET TO GROW

We are seeing increasing use of international arbitration to resolve pharmaceutical disputes, primarily in the context of cross-border commercial arrangements, where a deal or relationship spans multiple countries. This increasing move towards arbitration is likely down to the fact that, as we explain below, arbitration has a number of advantages over national court litigation in the context of cross-border agreements in this sector. With the pharmaceutical industry continuing to grow and increasing awareness of the benefits of arbitration for the resolution of pharmaceutical disputes, we expect the use of international arbitration in this sector to continue to rise.

Arbitral institution caseloads also indicate that the use of arbitration for pharmaceutical disputes is on the rise. For example, the number of pharmaceutical disputes before the American Arbitration Association (the "AAA") steadily grew year-on-year from 2009 to 2013, increasing from 26 to 47 cases, and in 2016, pharmaceutical and healthcare disputes were the joint sixth largest industry contributor to the LCIA's caseload.

WHY AND WHEN TO CHOOSE ARBITRATION FOR PHARMACEUTICAL DISPUTES

A neutral forum for resolving multi-jurisdictional disputes

Commercial arrangements in pharma increasingly span many countries and involve parties of different nationalities. Recent years have also seen increasing expansion of global pharmaceutical companies into emerging markets. By 2015, emerging markets had overtaken the "EU5" economies (Germany, France, Italy, the UK and Spain) in pharmaceutical spending (see McKinsey, "*Pharma's next challenge*", July 2015, available here). The activities of a number of the global pharma companies also demonstrate significant investment in emerging markets: Bernstein analysts have estimated Pfizer's 2017 emerging markets growth as the fastest, at +7.8%, and average emerging markets exposure for big pharma at 22% (as reported here).

Although there has been significant growth in emerging markets and growth prospects remain attractive, growth has been less explosive than previously forecast (as highlighted by Deloitte in "*Pharma and emerging markets: Unlocking the potential of emerging economies*", available here). This stall in growth is owed in part to economic conditions, but it is likely to also be attributable to a number of other factors, such as pricing pressures, lack of IP protections and regulatory challenges. Nonetheless, the long-term potential for pharmaceutical companies in emerging markets remains, particularly with the shifting epidemiological profile in developing countries and the upward trend in chronic diseases (as reported by PWC in "*Pharma 2020*: The vision", available here).

PREFERRED DISPUTE RESOLUTION CLAUSE

Pharmaceuticals / biotechnology sector were asked to identify their preferred dispute resolution clause for use in commercial contracts

COURT LIGITATION

ABITRATION

Arbitration is an attractive option for resolving any disputes that arise from these cross-border arrangements. Arbitration provides a neutral forum: for example, an English party and Japanese party may agree on arbitration in Paris or Singapore as a neutral forum in which to resolve any disputes, without submitting to the jurisdiction of courts with which they may not be familiar. It also provides an alternative to the local courts of the country where the activity is taking place – a key consideration in emerging markets, where the rule of law may be less rigorously applied and national courts may not have the necessary expertise or resources to deal with complex, high-value disputes.

Enforceability

In the cross-border context, enforceability of arbitration awards or court judgments is a critical consideration – a favourable judgment that cannot be enforced against the counterparty's assets will often represent a pyrrhic victory. Here, arbitration awards have a significant advantage over court judgments, with the New York Convention providing a regime for the enforcement and recognition of arbitral awards within its 157 contracting states. While enforcement may be refused on limited grounds, this means that in the vast majority of jurisdictions, a successful party will have better (and often much better) prospects of enforcing a foreign arbitration award than a foreign court judgment.

It is, however, important to note that some jurisdictions impose limitations on the arbitrability of patent disputes, which may impact enforceability. For example, the French courts will not enforce an award on the validity of a French patent, but will recognise a decision on civil action for infringement.

Preserving confidentiality

In our experience, pharmaceutical disputes frequently concern IP issues and sensitive technical and commercial information. Confidentiality is therefore often a critical concern. While arbitration is not always confidential, it can be. Parties who choose to arbitrate can opt for an arbitral seat or institutional rules (for example, London or the LCIA Rules) which impose a duty of confidentiality on the parties in relation to documents, submissions and evidence provided in the arbitration, or they can include an express confidentiality obligation in the arbitration agreement.

The collaborative nature of many commercial relationships in this sector also means that it is often to the benefit of all parties to preserve an ongoing relationship, and to continue working towards the aim of the collaboration, pending resolution of a dispute. The possibility of maintaining confidentiality in arbitral proceedings may mean this is more achievable, mitigating the risk of publication and external comment exacerbating the dispute.

Selecting a procedure that is suited to the dispute

Our clients value the greater flexibility that arbitration generally offers to parties to tailor a dispute resolution procedure to suit a specific dispute. Arbitrators have greater discretion than judges in civil litigation to adopt a procedure that is best suited to the dispute in question, as they are not bound by detailed procedural rules. Further, parties are also able to choose their own arbitrators, and can choose candidates with experience in pharmaceutical disputes, a scientific background and a degree of familiarity with the sector. Some arbitral institutions (such as the International Centre for Dispute Resolution) offer panels of arbitrators with specific life sciences experience to assist parties in selecting the most appropriate candidates.

Arbitration may also offer the parties to a dispute the opportunity to resolve it more quickly by way of expedited or emergency procedures. This may be of particular benefit where resolution of a dispute is time- sensitive, for example, where it is important that a dispute causes minimal disruption to the development of a specific drug.

2013 WIPO SURVEY

The results of the 2013 WIPO Survey highlight the cross-jurisdictional nature of commercial arrangements in technology-driven sectors such as the pharmaceutical industry. The survey revealed that:

- 90% of respondents concluded agreements with parties from other jurisdictions;
- 80% of respondents concluded patent-related agreements with parties from other jurisdictions on technology patented in at least two countries;
- 71% of WIPO mediation and arbitration cases have been international in scope; and
- 92% of patent-related WIPO arbitrations and mediations have been international in scope.

Finality of the arbitral award

Arbitration awards are final and subject to appeal only on very limited grounds (which do not typically include alleged errors of fact or law). In turn, this increases the possibility of the dispute being brought to a timely conclusion and reduces the risk of the parties incurring further costs. Of course, the counter-argument is that everything then turns on the decision of the arbitral tribunal.

DRAFTING EFFECTIVE AND ENFORCEABLE ARBITRATION CLAUSES

When parties do opt for arbitration, it is critical to get the arbitration clause right: a badly drafted clause can (at best) cause delay and increase costs if there is a dispute or (at worse) be ineffective.

To keep things simple and minimise the risk of challenge, **we suggest using the relevant institution's model arbitration clause as a starting point and tailoring it (if appropriate and with care)** to suit the agreement in question.

The arbitration clause should contain a mandatory reference to arbitration and set out the parties' agreement on the seat, language of the arbitration, the applicable institutional rules, the governing law of the arbitration agreement (typically either the governing law of the contract or the law of the seat) and the number of arbitrators.

Parties should **take care in selecting the arbitral seat**, which determines the national law that will underlie the arbitration and the national courts to which the parties will turn if they require court intervention in support of the arbitration or wish to challenge the tribunal's award. Certain places are commonly considered "safe" seats because they benefit from a legal framework that limits the scope for court intervention and from strong, "pro-arbitration" local courts. Seating an arbitration in a less arbitration-friendly jurisdiction can have significant consequences; for example,
there may be increased risk of local court intervention, either during the arbitration or in lengthy challenges to the tribunal's award. There can also be negative practical consequences: for example, certain jurisdictions prohibit international counsel from appearing as advocates.

It is important to **bear in mind how the agreement to arbitrate will work in practice**. For example, including in the arbitration clause strict qualification requirements for the arbitrators can cause delay, lead to the challenge of arbitrators (on grounds that they do not meet the criteria) and limit the pool of potential arbitrators.

Parties should also **consider whether multi-contract or multi-party scenarios should be taken into account** in the choice of arbitral institution and in the drafting of the arbitration clause. For example, where there are multiple interrelated contracts, it is often advisable to include a consolidation mechanism and consent to disputes arising under the different agreements to be resolved together.

Finally, **tiered dispute resolution mechanisms are increasingly common**, requiring negotiation or mediation before an arbitration is commenced. The attractions are obvious, but a tiered clause like this arguably precludes either party starting arbitration until the tiered clause has been complied with. The drafting should therefore be clear that either party may commence arbitration after a certain number of days (whatever has happened or not happened) – and parties should only include this sort of mechanism if they are prepared to let it play out if a dispute does arise.

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KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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