ARBITRATION: BIG PHARMA, BIG PLAYER

Franz Schwarz and **Santiago Bejarano** of **WilmerHale**

examine how the use of international arbitration by the global pharmaceutical industry is changing, and how the ensuing challenges are being managed as a result

The pharmaceutical industry has established itself as a big player in international commercial arbitration. **The International Centre for Dispute Resolution** and the international division of the **American Arbitration Association** (AAA), have dedicated arbitration services that cater to pharmaceutical companies, including a specialty roster of arbitrators with expertise in pharma-related disputes. According to Jean Baker, vice president at the AAA, the number of international arbitrations related to the pharma industry is growing steadily: 26 cases in 2009, 33 cases in 2010, 37 cases in 2011, 42 cases in 2012 and 47 cases in 2013.

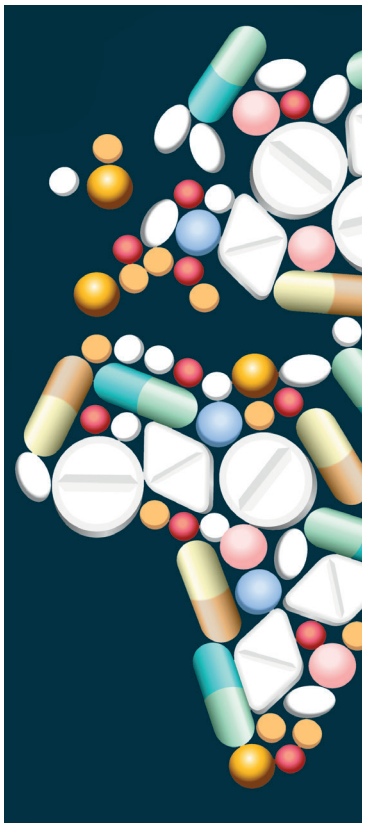
She notes while "[t]he case numbers are small … the size of the claims tend to be very large". The cases are also varied in nature, ranging from licensing disputes, to commercial claims common to many other large industries – these include joint venture, partnership, distribution, manufacturing and breach of contract claims.

The **International Chamber of Commerce** (ICC) similarly reported the pharmaceutical industry as a strong player in arbitration in its statistical reports. In 2004, for example, arbitrations involving the pharmaceutical industry accounted for 6.2% of its caseload.

The use of commercial arbitration to resolve disputes in the pharmaceutical industry often raises particular issues of public policy. For example, in *Teva Pharmaceutical Industries v Proneuron Biotechnologies* (2011) – the Israeli Supreme Court confirmed a decision of a Tel Aviv district court which refused to stay proceedings and submit the parties to a **London Court of International Arbitration** (LCIA) tribunal, as provided in the licensing agreement between them. In the court's view, the dispute – which related to the alleged breach of a drug licensing contract arising from a negligent clinical study – raised issues of public policy and health and was therefore not subject to arbitration.

Although this decision certainly appears to be an outlier, similar and broader policy concerns exist in Europe, given the size and competitive position of some pharmaceutical companies. In *GSK Spain v European Commission* (2006), for example, a decision affirmed by the EU courts, the General Court confirmed that agreements between pharmaceutical companies are subject to competition law if they may limit competition to the detriment of the final consumer. This broad concept would cover many licensing agreements. In *Eco Swiss China Time v Benetton International* (1997), the European Court of Justice held that the application of EU competition rules by arbitrators is a matter of public policy. Therefore, the failure to address competition laws and to apply them correctly could render an award unenforceable in the European Union.

In the US, since the Supreme Court's decision in *Mitsubishi Motors v Soler Chrysler-Plymouth* (rendered in 1985), courts have rejected the argument that claims involving issues of federal antitrust law can only be decided by courts. *In Baxter Int'l, Inc v Abbott Laboratories* (2003), **Abbott** initiated arbitration against **Baxter** under a cooperation agreement alleging that it precluded competition, and was successful on the merits. Baxter sought to have the decision overturned by a federal court, but the Seventh Circuit in 2003 affirmed the district court's decision that the authority of courts under the Federal Arbitration Act precluded the court's ability to "second-guess" the tribunal's determinations and the suit was dismissed.



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Other courts in the US have also affirmed the notion that pharmaceutical claims are arbitrable. In *Sanofi-Aventis Deutschland v Genentech* (2013), the US Court of Appeals for the Ninth Circuit affirmed a decision of a district court in California refusing to enjoin arbitration between **Sanofi** and **Genentech** over a dispute involving allegations of patents. The court considered that ICC arbitration and the application of German law was permissible, even if the result would have been different under US patent law.

Similarly, in *Infinity Indus v Rexall Sundown*, an early decision dating back to 1999, the Second Circuit rejected the plaintiff's argument that "arbitration is not the normal forum for disputes in the pharmaceutical industry" and compelled the parties to arbitrate in accordance with their agreement.

Therefore, it is likely that arbitration between pharmaceutical companies will continue to increase in number, especially in the US. Even in Europe, the fact that competition law issues may be involved does not preclude these disputes from being submitted to arbitration, although particular caution must be exercised by tribunals to ensure the correct evaluation and application of EU competition law.

Investor-state claims

Claims in the investor-state field remain an attractive possibility for pharmaceutical companies, despite recent awards rendered under the North American Free Trade Agreement (NAFTA). The use of investor-state arbitration by pharmaceutical companies is a more recent development. To date, seven disputes brought by pharmaceutical companies have been publicly reported: three were brought by **Apotex** and one by **Eli Lilly** against the US under NAFTA; one claim was brought by **Merck** against Ecuador, one brought by Italy on behalf of Italian investors against Cuba, and a claim by a major French pharmaceutical company was brought against Poland.

Two of the Apotex claims were decided by an award rendered on June 14 2013. The

first dispute alleged a breach of NAFTA resulting from the decisions of US courts relating to Apotex's effort to introduce Sertraline, a generic version of a big-name antidepressant, into the US market. The second claim related to the US Food and Drug Administration's (FDA) decisions on the development and introduction of a generic heart disease medicine. The tribunal dismissed the claim, considering that Apotex had no investment as defined under NAFTA. The tribunal rejected the argument that the development and production of a drug in Apotex's Canadian plant could constitute an investment in the US. Likewise, the tribunal rejected Apotex's argument that the hefty costs and expenditures involved in applying for clearance at the FDA to commercialise the drugs could be viewed as an investment, since no property right was vested because approval was not definitive and was subject to revocation. The tribunal also dismissed claims alleging that litigation costs could fall under the definition of investment under Article 1139 of NAFTA.

The third Apotex claim was also recently dismissed in August 2014, and was the first NAFTA award to apply the doctrine of res judicata. In its claim, Apotex alleged that the US breached the NAFTA protections by issuing an "import alert", through the FDA, which prevented Apotex's US subsidiary from importing drugs produced in two of Apotex's Canadian plants. It alleged a discriminatory treatment of its investment. The tribunal gave res judicata effect to the holding on the prior Apotex investment claims and concluded that Apotex had no covered investment.

Although it identified that Apotex did suffer less favourable treatment compared to other foreign plants, it rejected the most favoured nation treatment claims by considering that there were no "like circumstances" between Apotex and the other plants, because they each raised different health concerns for the US.

Eli Lilly followed Apotex and filed a NAFTA claim against Canada. In its claim, it argues that the treaty protections were breached when a Canadian court allowed a Canadian generics manufacturer to produce and launch a generic version of Zyprexa, a drug patented to Eli Lilly. The arbitrators have not issued an award, and it remains to be seen whether the tribunal will take a view similar to the one in the Apotex arbitrations, and reject the claim.

Despite the negative NAFTA result for Apotex, a recent case brought by French pharmaceutical giant **Servier** against Poland could set a positive precedent for Eli Lilly and others who seek investment protection. The award, issued in February 2012 and which has been partially published, was the result of the government's denial to renew the authorisation for two drugs produced by Servier, while while at the same time approving local companies to produce generic alternatives to these.

The tribunal took the view that there had been an expropriation of Servier's investment, and discrimination against the French pharmaceutical company, while the state had taken steps to aid local competitors, and to expedite their licensing process. It considered the measure discriminatory and disproportionate, and an unlawful expropriation of the investment. This award is a landmark for the pharmaceutical industry, and is likely to be the subject of considerable reliance by future tribunals and claimants.

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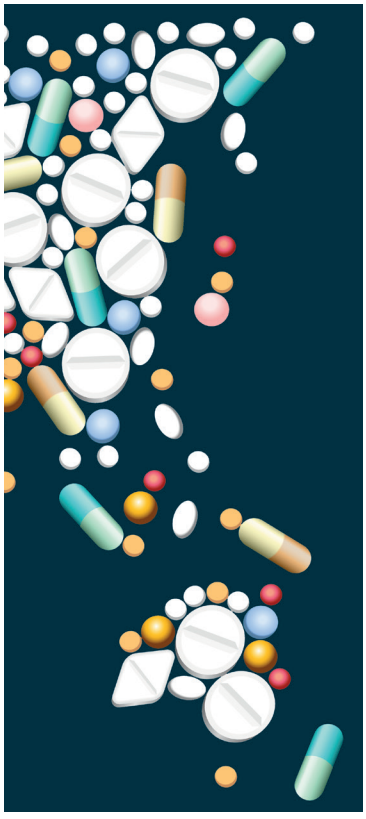

Conclusion

Statistics demonstrate that pharmaceutical companies continue to use arbitration as a means for settling disputes. They do so in respect of their commercial disputes and, increasingly, as a way to procure relief from host states where they produce, commercialise and distribute their products. ■

About the authors

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