CLEARY GOTTLIEB

Life Science Sector And International Arbitration: Risks And Opportunities

Commercial Arbitration And The Life Science Sector

WHY ARBITRATION?

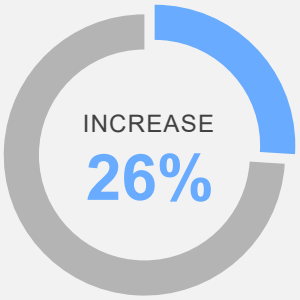
— **Efficiency** and **neutrality** of international arbitration, as single forum

— **Expertise** of international arbitrators

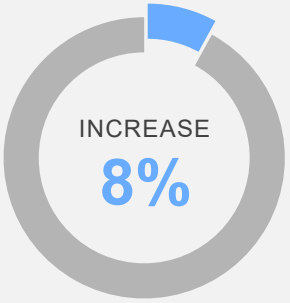
— Other typical advantages of International Arbitration: greater ease of **enforcement** of arbitral awards; **confidentiality** of the proceedings; procedural **flexibility**; specific regime for **emergency relief**

Recent Numbers of Arbitration Cases in the Life Science Sector (2020)

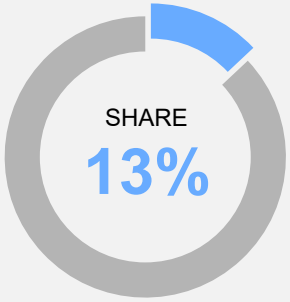
International Centre for Dispute Resolution (ICDR)
Healthcare sector



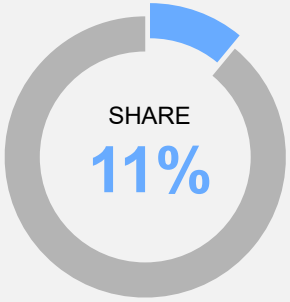
International Centre for Dispute Resolution (ICDR)
Life Science sector



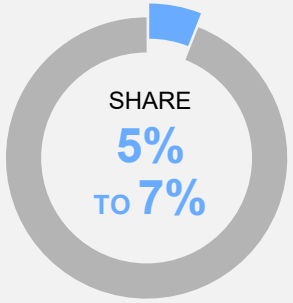
Swiss Chambers Arbitration Institute
Pharma/Life Science cases



Singapore International Arbitration Center (SIAC)
New cases registered



ICC International Court of Arbitration
New cases registered



Types Of IP-related Claims

Contractual Claims

Breaches of **various types of contracts**: research and development (joint or for-hire), licensing, know-how, settlement, co-promotion or distribution, agency.

Non-contractual Claims

Ownership disputes, **validity disputes**, **contentious matters** related to the **achievement of milestones**, **supplementary protection certificates**, **trademark and design rights**, **inventor's rights**, **regulatory matters**, **data exclusivity**, etc. Whether such disputes fall within the scope of arbitration agreements (and/or are arbitrable) should be determined on a case-by-case basis.

COVID-19 RELATED CLAIMS

The pandemic will trigger claims against private parties as well as State entities related to countries' measures to fight the outbreak, including State policies that required **disclosure of confidential trade secrets**, **unpermitted use or access to IP rights**, **compulsory purchase**, **non-performance or delay** due to State-ordered lockdowns, and other **supply-chain disruptions**.

Importance Of Interim Measures And Emergency Relief In Life Science Claims

WHY?

Interim measures are used to **preserve the parties' position pending resolution of their dispute**. They are particularly important in IP disputes, including in the Life Science sector, as they allow an **immediate stop to infringement**, disclosure of trade secrets, or the use of IP rights without permission.

WHO?

Under most arbitration rules, interim measures may be granted by **the tribunal at any point before the issuance of the final award**, or even before the constitution of the tribunal by an **emergency arbitrator**, the arbitral institution, or by a national court.

WHAT?

Interim measures will typically seek to **maintain or restore the *status quo***, to preserve assets or evidence, or to prevent prejudice to the arbitral process.

HOW?

Most arbitration rules contain provisions relating to interim measures and emergency relief (including the rules of the ICC, LCIA, ICDR, AAA, CIArb, WIPO, CPR, JAMS, SIAC, SCC, HKIAC, CIETAC and SCAI).
Some institutions have issued **rules tailored to IP disputes**, including on interim measures and emergency relief (e.g., the AAA Resolution of Patent Disputes Supplementary Rules, Art.3(5)(h)).

RECURRING ISSUES INCLUDE:

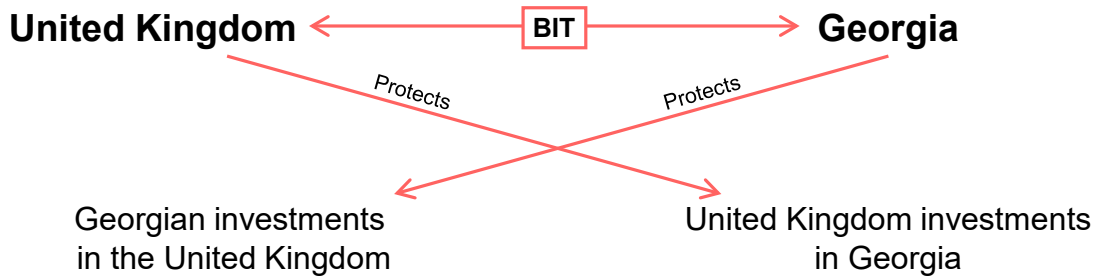
- Is the preliminary relief sought covered by the applicable arbitration rules?
- Who can grant it?
- What needs to be established to obtain such interim measures?
- Is testimony or disclosure from third parties needed?
- How can the interim measures or emergency relief be enforced?

How Investment Treaty Arbitration Works

A **limited but increasing** number of investors in the Life Science sector are making use of one of the 2600 investment treaties in force, including for purpose of **negotiation leverage**.

RECIPROCAL PROTECTION

Example:



SUBSTANTIVE PROTECTIONS GRANTED BY INTERNATIONAL INVESTMENT AGREEMENTS (IIAS)

- Protection against **Unlawful Expropriation**
- **Fair and Equitable Treatment ("FET")**
- **Full Protection and Security**
- Protection against **Arbitrary** and **Discriminatory Conduct**
- **National Treatment**
- **Most Favored Nation Treatment ("MFN")**
- **Observance of Contractual Undertakings ("Umbrella Clause")**

PROCEDURAL REMEDIES

- Access to **fair and neutral** mechanism for resolution of investor-State dispute
- **Party-appointment** of arbitrators
- **Final and binding** award on all parties
- **No appeal** mechanism
- **Enforceability** of award (under either the ICSID Convention or the 1958 New York Convention)

Examples Of Investment Treaty Claims In The Life Science Sector To Date

- Regulation on patented medicines and mandatory prohibition order against generic competitors
- Refusal to renew marketing authorizations
- Denial of justice
- Harassment and discriminatory conduct by regulators
- Arbitrary invalidation of patents
- Wrongful termination of long-term sales contracts
- Discriminatory issuance of import alerts
- Disclosure of know-how to competitors

Recent Trends: Compulsory Licenses And COVID-19

Some countries have been considering resort to **compulsory licenses to fight against COVID-19**.

Can compulsory licensing be challenged by the holders of patents before investment arbitration tribunals?

— Patent holder Novartis issued a notice of intent against Colombia challenging the compulsory licensing of cancer drug Glivec announced by the government in 2016. The case was settled.

Some IIAs include "*carve-outs*" excluding from their scope compulsory licensing as provided in other IP conventions. Examples include:

Australia-Chile FTA 2008:

> 5. This Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such revocation, limitation, or creation is consistent with Chapter 17 (Intellectual Property).

Singapore-India FTA 2005:

> 6 This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights to the extent that such issuance, revocation, limitation or creation is consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights.

Arbitral tribunals will need to assess the **applicability of such IP conventions**, both in cases where the applicable investment treaty contains a carve-out and where it does not. Tribunals will also need to consider states' **right to regulate to preserve public health**.

Advantages Of Investment Arbitration

Neutral forum	Party appointment of arbitrators	Mitigation of sovereign risks for investments	International and simplified recognition and enforcement of arbitral awards

ENFORCEABILITY

— The majority of treaty-based investment arbitrations are under the ICSID Convention. Monetary awards under the ICSID Convention are enforced as final judgments of domestic courts.

— Limited grounds to set aside award or resist enforcement of non-ICSID awards under the 1958 New York Convention on Foreign Arbitral Awards.

ANNULMENT

— The annulment regime for ICSID awards is limited. Only 2% of awards under the ICSID Convention have been annulled since 2011.

EXPERTISE

— Investment tribunals have dealt with a number of arbitrations relating to IP rights and/or involving the Life Science industry.

Financing International Arbitration Claims

Third-Party Funding Arrangements

— Claimants are increasingly turning to **third party funders (TPF)** to finance arbitration proceedings.

— TPF provide **non-recourse financing** of all or part of legal fees and costs in exchange for share of proceeds.

— TPF is **not limited to impecunious claimants.**

— TPF take into consideration a number of criteria including:

- The **merits** of the claim
- Any **enforcement risks**
- **Amount** of funding required
- **Return** on the investment

— TPF may also **monetize** already-issued awards.

Award on Costs

— Tribunals in international arbitration generally follow three approaches in the allocation of costs:

- "Loser pays": the loser must compensate the winner for its costs
- "Pay your own way": each party must bear its own costs and half of the tribunal and administrative costs regardless of the outcome
- "Allocation *pro rata*": tribunal allocates costs in a manner that is proportionate to the relative merits of all claims and defenses raised

Key Contacts

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Laurie Achtouk-Spivak's practice focuses on international arbitration and litigation, with a particular emphasis on public international law.

Laurie represents investors and sovereigns in investment treaty arbitrations under ICSID, UNCITRAL, ICC and other arbitration rules. She acts as an arbitrator and is a CEDR-accredited mediator. She also advises companies on investment treaty structuring.

Laurie teaches a university course in investor-State dispute settlement. She is a member of the ICC Commission on Arbitration and ADR, as well as the ICC Task Force on "Addressing Issues of Corruption in International Arbitration." Laurie is widely published on investment treaty arbitration and is co-director of The Paris Journal of International Arbitration's annual investment arbitration case law review.

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Larry Dembowski's practice focuses on international arbitration and litigation.

He has represented sovereign and private clients in a diverse range of disputes, including international arbitrations under the auspices of the Permanent Court of Arbitration (PCA), the International Chamber of Commerce (ICC), the International Center for Settlement of Investment Disputes (ICSID) and others, as well as litigation before federal and state courts in the United States, both at the trial level and on appeal. His arbitration and litigation experience has included matters involving bilateral and multilateral investment treaties, United States antitrust and securities laws, and a variety of civil causes of action.

Larry joined the firm's Washington, D.C., office in 2002 and became a senior attorney in 2013. From 2008 to 2011, he was resident in the Frankfurt office.

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Cameron Murphy's practice focuses on international arbitration, as well as public international law. He also has extensive experience representing clients in investigations.

Cameron represents investors and sovereigns in international arbitrations based on bilateral and multilateral investment treaties before various arbitral institutions, and he acts as counsel to both claimants and respondents in commercial arbitrations. Cameron also represents multinational corporations in regulatory and criminal investigations involving allegations of fraud, money laundering, environmental harm and violations of the Foreign Corrupt Practices Act.

Cameron joined the firm's New York office in 2003, relocated to the Paris office in 2007, became counsel in 2012 and now practices in the London office.