



WIPO ADR for Life Sciences Disputes

June 21, 2023

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WIPO Arbitration and Mediation Center

- Facilitates the resolution of commercial disputes between private parties involving IP and technology, through ADR
 - Offices in Geneva and Singapore
 - **International neutrality**
- ADR of IP/technology disputes benefits from a **specialized** ADR provider
 - Database of over 2000 WIPO mediators, arbitrators and experts experienced in IP and technology (including open-ended list of experts specialized in life sciences)
- Services: Mediation, Arbitration/Expedited Arbitration, Expert Determination and Dispute Resolution Boards

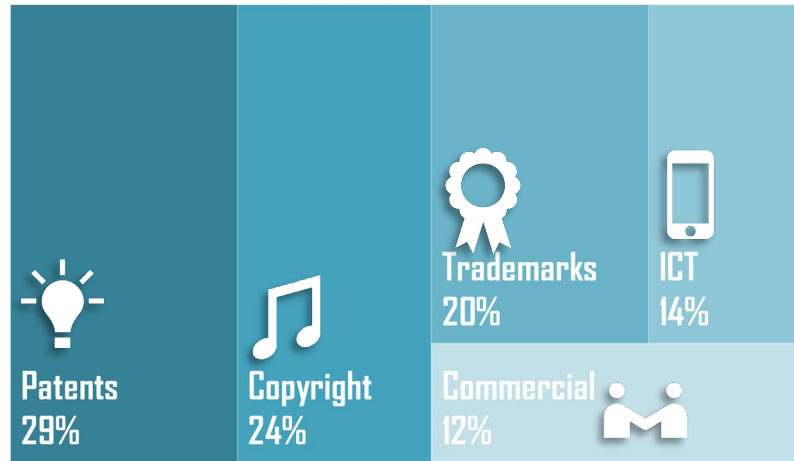


WIPO ADR Procedures

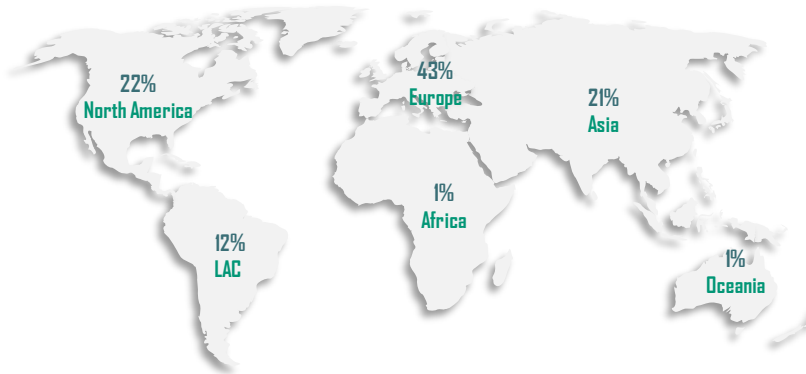
- **Mediation:** An informal consensual process in which a neutral intermediary, the mediator, **assists the parties in reaching a settlement of their dispute**, based on the parties' respective interests. The **mediator cannot impose a decision**. The settlement agreement has force of contract. Mediation leaves open available court or agreed arbitration options.
- **Arbitration:** A consensual procedure in which the parties submit their dispute to one or more chosen arbitrators, for a **binding and final decision** (award) based on the parties' rights and obligations and **enforceable** internationally.
- **Expert Determination:** An evaluative and consensual ADR procedure in which the parties submit a specific matter (e.g., scientific or technical question) to one or more experts who make a determination on the matter. Such determination can be binding unless the parties have agreed otherwise. It can be used on a stand-alone basis, in the context of a broader dispute, or during contract negotiation.

WIPO ADR Caseload

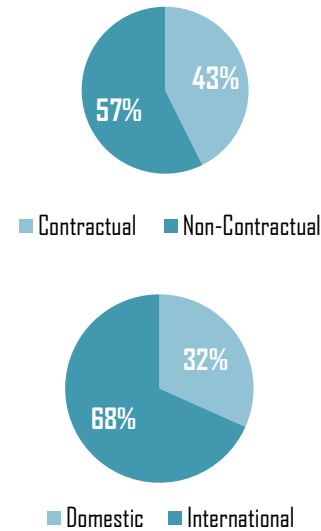
Legal Area WIPO ADR



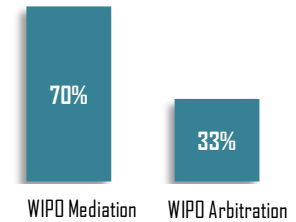
Party Location WIPO ADR



Case Source WIPO ADR



Settlement Rate WIPO ADR



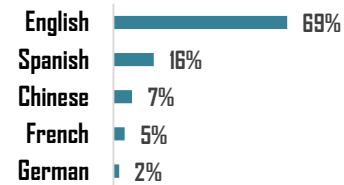
2021-22

Use of **WIPO online case tools**

+45% in 2021

+105% in 2022 (including co-administration of disputes with DNDA (Colombia) and INDAUTOR (Mexico))

Language WIPO ADR



WIPO Rules (2021)

- Pre-structure entire proceeding
 - Flexible: can be modified by arrangement between arbitrator and parties
- Appropriate for all commercial disputes, domestic or international
 - IP and technology specific elements, e.g., confidentiality, technical evidence, interim relief
- Recent updates
 - Singapore Mediation Convention
 - Electronic filing and online conduct of WIPO ADR proceedings
 - Disclosure of third-party funding

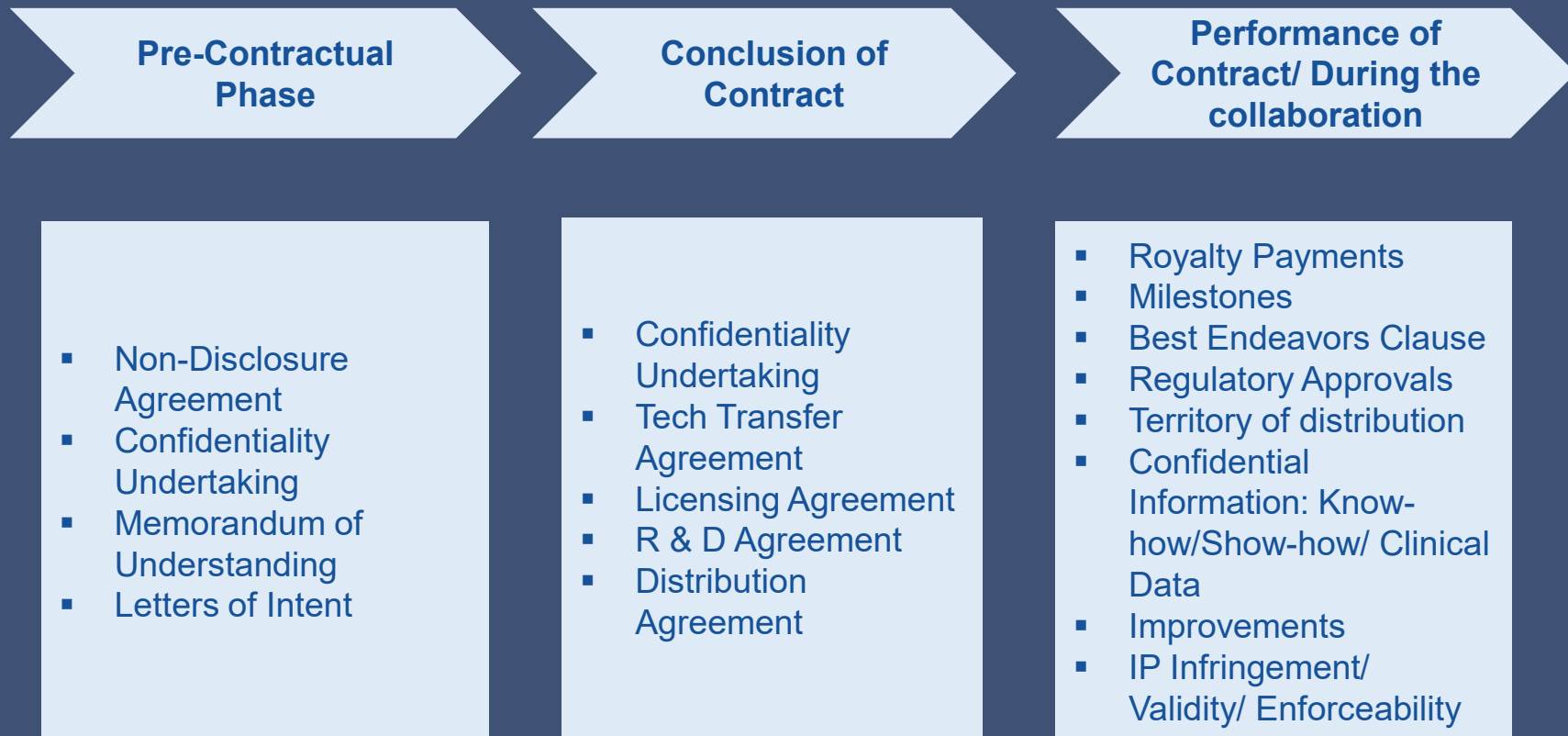
WIPO Mediation,
Arbitration,
Expedited Arbitration
and Expert
Determination Rules
and Clauses

Alternative Dispute Resolution

WIPO ADR Services for Life Sciences

- Approximately 15% of arbitration and mediation cases filed relate to Life Sciences
- Disputes are often international and may be contractual/non-contractual
- Disputes may relate to wide range of issues including:
 - non-disclosure agreements
 - material transfer agreements
 - R&D agreements (including clinical data)
 - patent licensing (including trade secrets i.e. know-how/show-how)
 - manufacturing and distribution agreements

ADR to resolve Disputes relating to Life Sciences Contracts and Collaborations



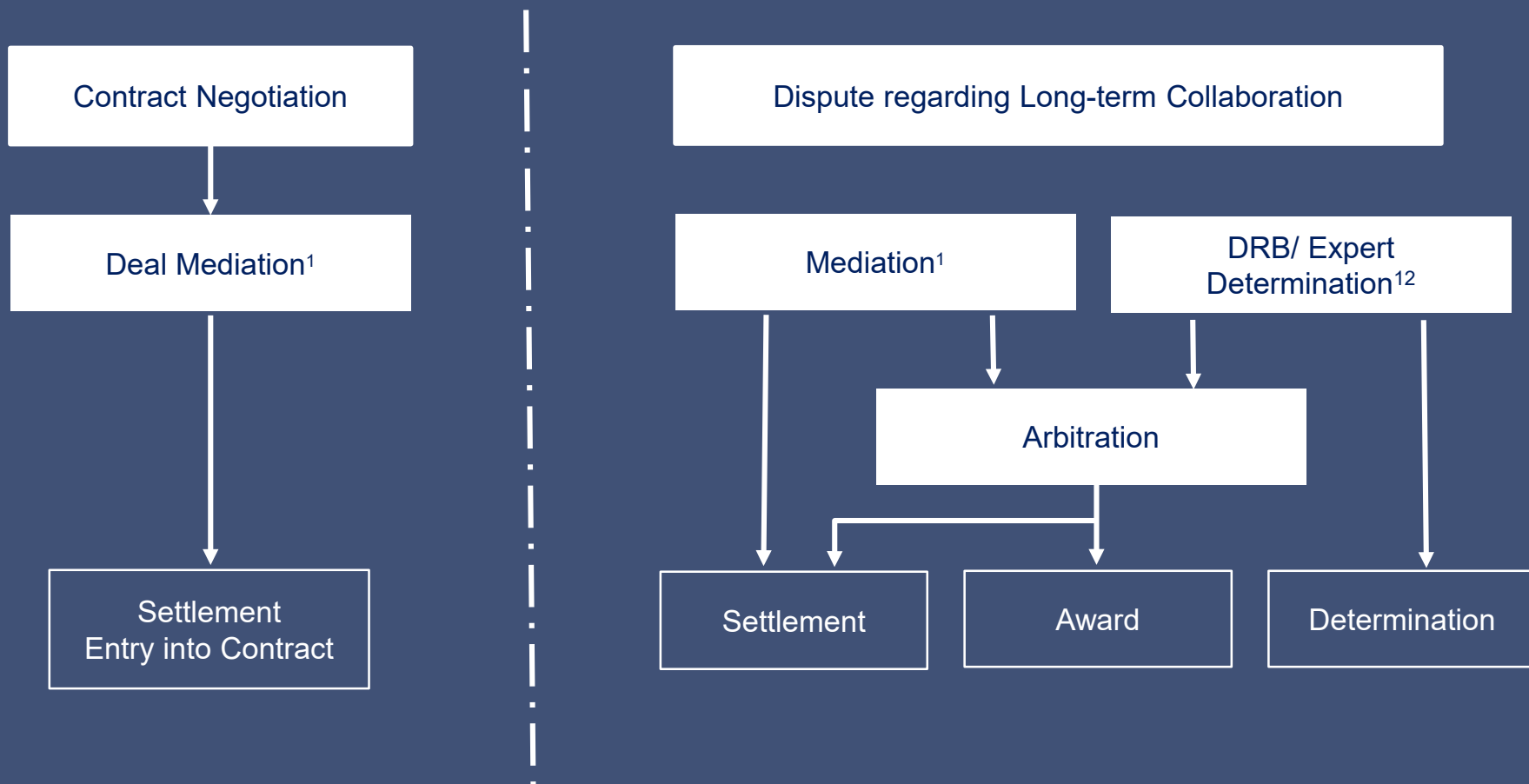
WIPO ADR Services for Life Sciences

- Potential stakeholders to disputes include:
 - biotech companies
 - originator companies
 - generic companies
 - medical devices and diagnostics companies
 - universities and tech transfer offices
 - start-ups
 - government agencies, IGOs, NGOs
 - funding bodies

WIPO ADR Services for Life Sciences

- WIPO Mediation
- WIPO Arbitration/Expedited Arbitration
- WIPO Expert Determination
- New Tailored WIPO ADR Options for life sciences developed in consultation with industry experts:
 - WIPO Deal Mediation (including Unilateral Request under Article 4)
 - WIPO Dispute Resolution Boards (“DRB”)

New Tailored WIPO ADR Procedures for Life Sciences Disputes

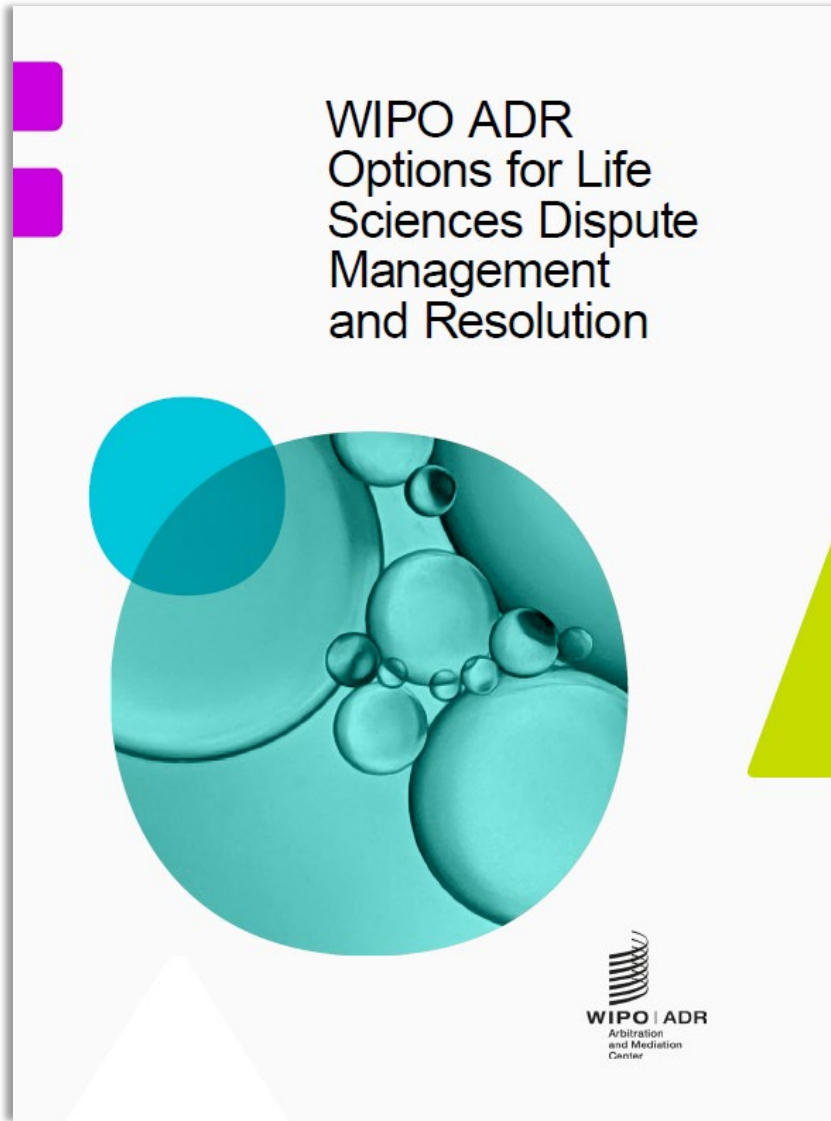


¹If a Mediator is appointed to facilitate contract negotiation, the parties may wish to have the same mediator:

a) assist with any dispute that arises during the duration of the contract

b) appointed to the DRB

²Parties may avail the WIPO IP Valuation option under the WIPO Expert Determination Rules.



- New WIPO publication, developed as part of the WIPO COVID-19 Response Package
- Proposes new tailored WIPO ADR procedures for life sciences disputes, in particular WIPO Deal Mediation
- Published in November 2022, available in Arabic, Chinese, English, French, Russian and Spanish
- Annexes include model clauses and submission agreements



https://www.wipo.int/export/sites/www/amc/en/docs/2022/lifesciences_adroptions.pdf

Routes to WIPO ADR

- ADR contract clause electing WIPO Rules
 - WIPO Mediation, and/or
 - WIPO Arbitration / Expedited Arbitration, and/or
 - WIPO Expert Determination
 - Model clauses: www.wipo.int/amc/en/clauses
 - Parties can shape the process via the clause (e.g., location, language, law)
- ADR submission agreement electing WIPO Rules, e.g., in existing non-contractual disputes
- Unilateral request for WIPO Mediation by one party (Art. 4 WIPO Mediation Rules)
- Court referrals
- Any request can be submitted online (email/WIPO IP Portal)
- WIPO Good Offices: Procedural guidance to parties to facilitate submission of a dispute to WIPO ADR

WIPO Model Clause Example: Mediation followed by Expedited Arbitration

"**Any dispute**, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, **shall be submitted to mediation in accordance with the WIPO Mediation Rules**. The place of mediation shall be [**specify place**]. The language to be used in the mediation shall be [**specify language**]"

If, and to the extent that, **any such dispute**, controversy or claim **has not been settled pursuant to the mediation within [60][90] days of the commencement of the mediation**, it shall, **upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules**. Alternatively, if, before the expiration of the said period of [60][90] days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. The place of arbitration shall be [**specify place**]. The language to be used in the arbitral proceedings shall be [**specify language**]. The dispute, controversy or claim referred to arbitration shall be decided in accordance with [**specify jurisdiction**] law."


<https://www.wipo.int/amc/en/center/specific-sectors/lifesciences/clauses>

Examples of WIPO ADR Clauses in Licensing Agreements

- Increasing use of WIPO ADR clauses in cross-border agreements involving patent pools, and product development partnerships (PDPs), including, Medicine Patent Pool (MPP) and FIND, the global alliance for diagnostics.
- For example, licensing agreement between MPP and Novartis for cancer drug Nilotinib, available at:
<https://medicinespatentpool.org/licence-post/nilotinib>

Unilateral Request for WIPO Mediation

- Request for WIPO Mediation by one party in the absence of a mediation clause (Art. 4 WIPO Mediation Rules)



Request for WIPO Mediation
(Article 4 of the WIPO Mediation Rules)

Note: The requesting party shall complete sections 1 and 2(a). The other party shall complete section 2(b).

1. Parties

Please provide the following contact information:

Requesting Party	Other Party
Name:	Name:
Country of domicile:	Country of domicile:
Tel:	Tel:
E-mail:	E-mail:
Address:	Address:
Represented by:	Represented by:
Tel:	Tel:
E-mail:	E-mail:
Address:	Address:

2. Dispute

Please provide a brief description of the dispute:

a) The requesting party agrees to submit the above-described dispute to mediation in accordance with the WIPO Mediation Rules.

Please sign this form and submit it to arbitrator.mail@wipo.int and to the other party.

Place and Date: _____

Signature: _____

b) The other party agrees to submit the above-described dispute to mediation in accordance with the WIPO Mediation Rules.

Please sign this form and submit it to arbitrator.mail@wipo.int and to the requesting party.

Place and Date: _____

Signature: _____

WIPO Mediation relating to Biotech/Agricultural Services

- Parties* European biotech/agricultural company and a European university
- Contract* Consortium agreement between multiple parties relating to stacking of ecosystem services such as crop protection, pollination enhancement, and productivity.
- Dispute* Dispute concerning both commercial and IP issues: Exclusion of a party from the Consortium Agreement, and unauthorized use of research publications.
- Basis* Dispute resolution clause in the Consortium Agreement providing for WIPO Mediation followed by, in the absence of a settlement agreement, court litigation.
- Process* WIPO Center proposed a list of a mediator candidates having experience in the management of biotech-related research projects between universities and SMEs, including familiarity with research policies in the EU and IP; parties agreed on one of the mediators from the proposed list.
- Result* Two-day session with the mediator allowed the parties to enter a MoU and continue direct negotiations to reach a settlement agreement.

WIPO Mediation concerning License and Supply Agreements

- Parties* Two European pharmaceutical companies
- Contract* Parties entered supply and license agreements to market pharma products in some European countries
- Dispute* Agreements terminated due to an alleged breach of contract by the responding party
- Basis* Dispute resolution clause referring the dispute to WIPO Mediation followed, and in the absence of a settlement, by court litigation
- Process* The WIPO Center appointed a mediator with demonstrated experience in commercial agreements within the field of medical supplies based on the preferences indicated by the parties.
- Result* After a virtual preparatory conference, and a single in-person session with the mediator, the parties entered a term sheet, and eventually settled the dispute by amending some terms in the existing agreements.

WIPO Arbitration relating to a Pharma Patent License Agreement

- Parties* Two European pharmaceutical companies
- Contract* Joint Development Agreement to develop a cancer treatment & License Option Agreement
- Dispute* One of the parties sub-licensed an alleged jointly-owned product to a third-party.
- Basis* Parties eventually entered a MoU to settle the contractual dispute, and agreed to submit the issue concerning the assignment of rights relating to the disputed patents to arbitration.
- Process* Parties entered a Submission Agreement to submit dispute to WIPO Arbitration and jointly agreed to limit the scope of issues two main areas:
(a) Determination of royalty rates
(b) Patent ownership status of some patents
- Result* Award rendered on patent ownership status and royalty rates. The tribunal also ruled on other procedural aspects such as admissibility of expert witness reports, and scope of discovery.

Further Information

- Contact: arbiter.mail@wipo.int
- WIPO ADR for Life Sciences:
www.wipo.int/amc/en/center/specific-sectors/lifesciences
- WIPO Publication on WIPO ADR for Life Sciences: (available in six UN languages)
https://www.wipo.int/export/sites/www/amc/en/docs/2022/lifesciences_adroptions.pdf
- Clauses: www.wipo.int/amc/en/clauses
- Rules: www.wipo.int/amc/en/rules
- Neutrals and Case Examples:
www.wipo.int/amc



Swiss Biotech Association / WIPO

Alternative Dispute Resolution for Life Sciences Disputes



Philipp Groz

Zurich, 21 June 2023

Some Key Characteristics of Contract Disputes in Life Sciences

- Parties often from different jurisdictions
- Technical subject matter
- Knowledge of industry and regulatory framework required
- Intellectual property (IP) issues are relevant
- Efficient and definitive resolution is key
- Confidentiality concerns
- Preserving business relationships

Potential Benefits of Arbitration for Life Sciences Disputes

- **Parties often from different jurisdictions**
 - No “home court advantage” / flexibility / choice of language for proceedings / choice of law and procedural rules / enforceability of award
- **Technical subject matter / Knowledge of industry and regulatory framework required**
 - Selection of qualified decision-makers / use of party-appointed experts / technical primers, demonstrative evidence and site visits
- **IP issues are relevant**
 - Potential to resolve IP issues in a single arbitration and to avoid multi-jurisdictional IP litigation

Potential Benefits of Arbitration for Life Sciences Disputes

– **Efficient and definitive resolution is key**

- Parties may opt for expedited arbitration or other ways to streamline proceedings / no contradictory decisions from different courts / paperless proceedings and remote hearings are common / usually limited appeal options against arbitral award (if any)

– **Confidentiality concerns**

- Parties may agree on confidentiality / hearings not open to the public / awards not published (at least if a party objects)

– **Preserving business relationships**

- Arbitration may be less adversarial than state court litigation

Potential Procedural Pitfalls

Escalation clauses (multi-tier dispute resolution clauses)

- Example: Negotiation followed by mediation followed by arbitration
- May be useful, especially in long-term collaborations, to resolve disputes efficiently and more business-oriented

But:

- Clarify which ADR steps are mandatory and when they become exhausted or terminable
- Do not include too many or too extensive mandatory steps prior to arbitration (or litigation) and align with dispute resolution mechanism applicable to Joint Steering Committee (if any)
- Consider statute of limitations periods
- Ensure access to interim relief

Potential Procedural Pitfalls

Agreeing on arbitrator qualifications

- Qualifications may turn out to be irrelevant to dispute that ultimately arises
- At least the presiding arbitrator or sole arbitrator should be experienced in managing an arbitration
- In any case, avoid unclear and/or overly restrictive criteria, such as:

«All three arbitrators shall have significant experience in the biotechnology industry and expertise in U.S. patent law»

Potential Procedural Pitfalls

Be careful when carving-out issues from dispute resolution clause

- To ensure a single forum, usually preferable to agree on arbitration clause with a broad objective scope, including IP and related non-contractual issues
- Arbitrability of IP disputes should be considered, but is rarely an obstacle in practice
- Be careful with vague carve-outs, such as:

*«any dispute shall be settled by arbitration,
except to the extent it involves or relates to
a patent claim, question or controversy»*

Potential Procedural Pitfalls

Avoid conflicting dispute mechanisms in different phases of collaboration

- Example:
 - NDA: “Litigation in Basel“
 - Term Sheet: “ICC Arbitration seated in Frankfurt”
 - License and Development Agreement: “WIPO Arbitration seated in Geneva”
- If necessary, clarify relationship between different dispute resolution clauses

Case Example: Global Patent License

- Dispute arising from international patent license agreement
- Parties: Pharma companies from different jurisdictions
- Applicable law
 - Agreement: Swiss law
 - But alleged invalidity/non-infringement of a U.S. patent
- Arbitration Clause: WIPO Arbitration seated in Switzerland

Initiation of WIPO Arbitration

- Claimant sought (in WIPO arbitration):
 - Declaration of invalidity/non-infringement of licensed U.S. patent
 - Declaration that Claimant owes no further royalty payment
 - Reimbursement of royalty payments previously made
- Strategic considerations in arbitrator selection?

Procedural Issues in the Arbitration

- Procedural issues included:
 - Presentation of evidence by various party-appointed experts and sophisticated demonstrative exhibits (animations, etc.)
 - Confidentiality issues (cf. Art. 75 WIPO Arbitration Rules)
 - Taking of evidence both inside and outside of the arbitration: parties filed 28 U.S. Code § 1782 evidence gathering requests to U.S. courts

Substantive Issues in the Arbitration

- Issues in dispute included:
- Is the licensed U.S. patent invalid?
 - applicable law: U.S. law (*lex loci protectionis*)
- What are the consequences of patent invalidity?
 - applicable law: Swiss law (*lex contractus*)
 - For the future:
 - Will the licensee have future obligation to pay royalties once the Tribunal declares patent invalid? When does obligation exactly end?
 - For the past:
 - Is licensee entitled to recover past royalty payments under the Agreement? Did licensee not get what it bargained for (i.e. de facto protection from competitors based on apparent existence of patent)?

Termination of Arbitration

- 8-day hearing in Zurich scheduled for:
 - Examination of party appointed experts
 - Examination of witness
- Parties settled on the first day of the hearing
- Arbitral Tribunal issued termination order

Thank you.

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