

Online Workshop on New WIPO ADR Options for Life Sciences

WIPO's COVID-19 Related Services and Support

Supported by:

European Industrial Research Management Association (EIRMA)

International Association for the Protection of Intellectual Property (AIPPI)

International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)

Licensing Executives Society International (LESI)

UNION of European Practitioners in Intellectual Property (UNION-IP)

October 19, 2021

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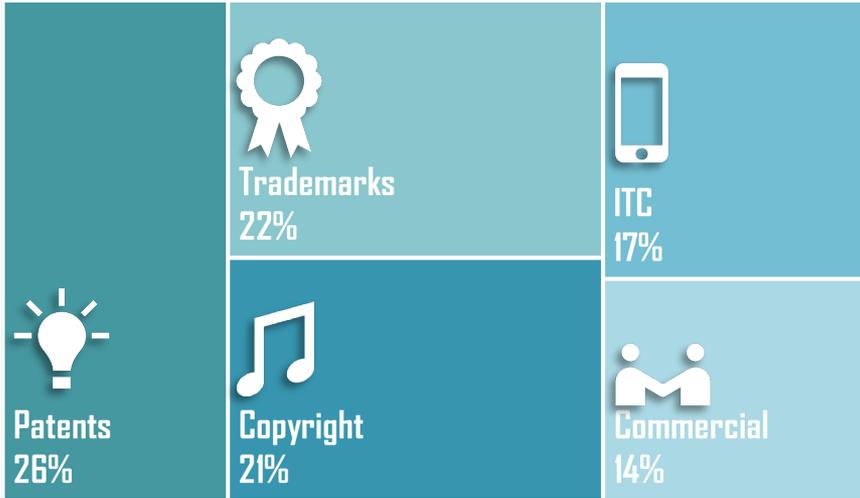
WIPO Arbitration and Mediation Center

- 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 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: Arbitration/Expedited Arbitration, Mediation, Expert Determination and Dispute Resolution Boards

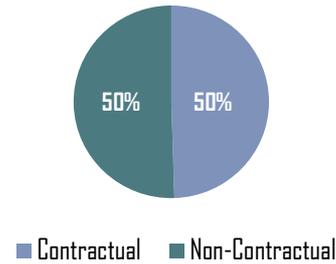


WIPO ADR Caseload

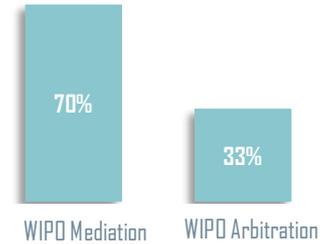
Legal Area



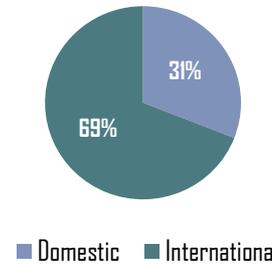
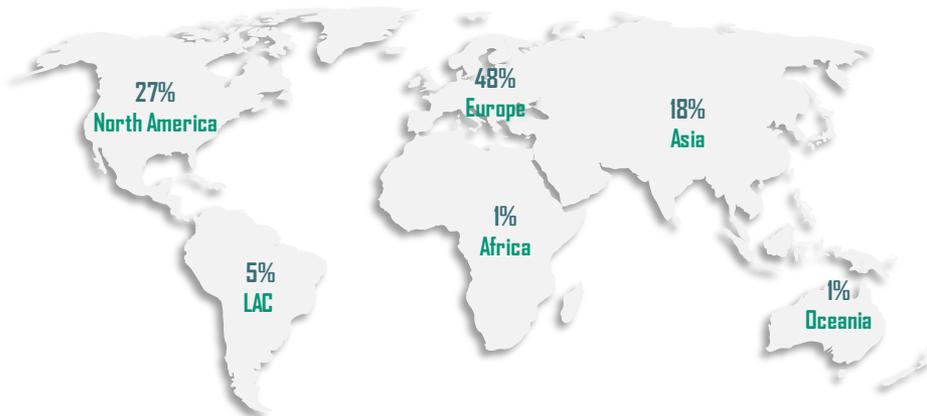
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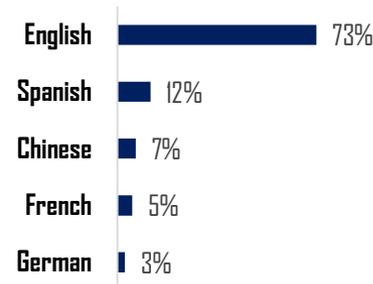
Settlement Rate



Party Location



Language



2020-2021

78% settlement rate in 2020 in WIPO Mediation
Increased use of **WIPO online case tools**

+24% in 2020

+30% in 2021

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

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
 - funding bodies

WIPO ADR Services for Life Sciences

- Tailored WIPO ADR Options developed in consultation with industry experts:
 - WIPO Mediation (including Unilateral Request under Article 4)
 - WIPO Dispute Resolution Boards (“DRB”)

- WIPO Arbitration/Expedited Arbitration

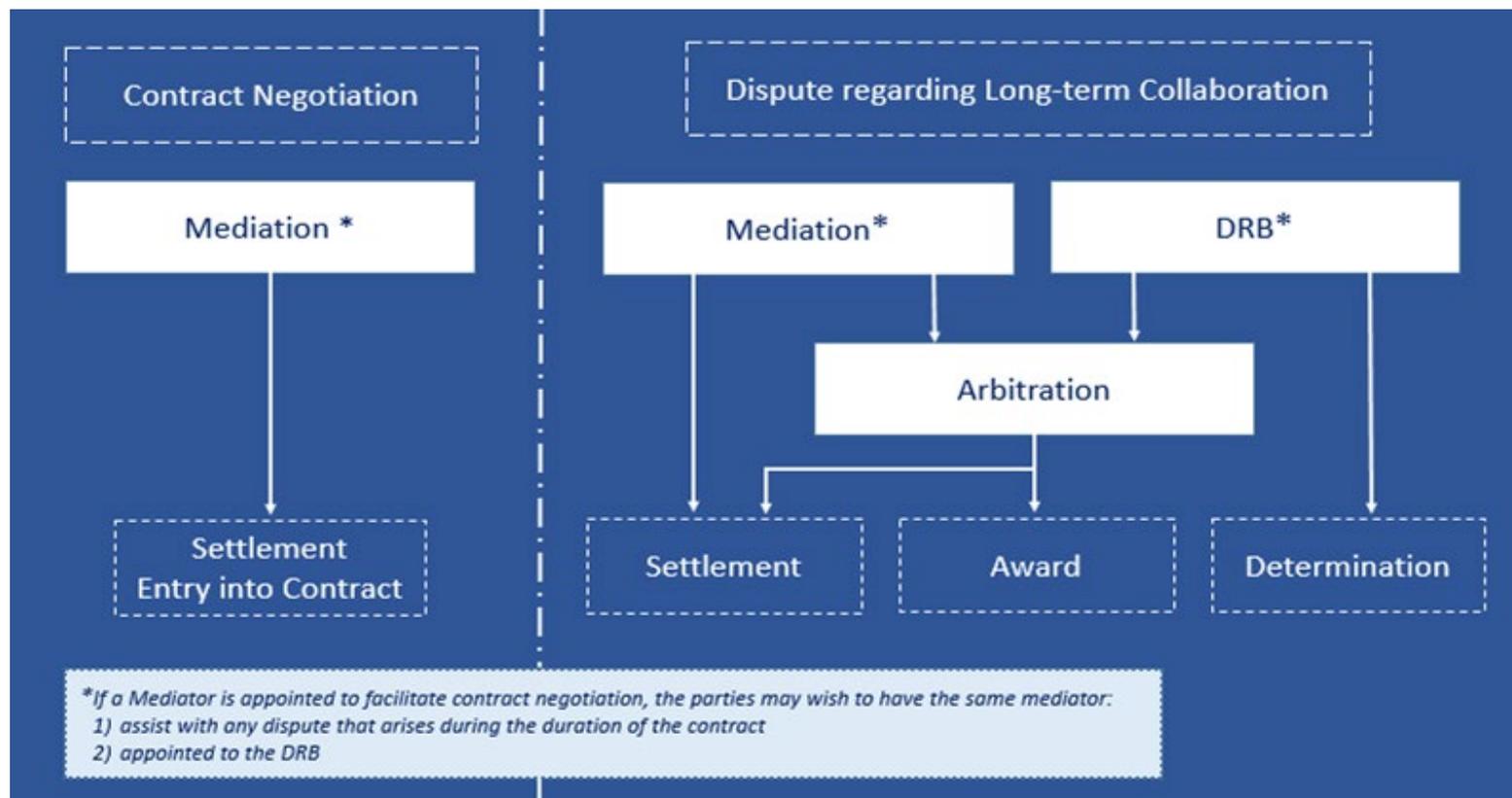
- WIPO Expert Determination

- Open-ended list of experts specialized in Life Sciences

WIPO Mediation Case Example

- A European university holding pharmaceutical patent applications in several countries negotiated a license option agreement with a European pharmaceutical company. The pharmaceutical company exercised the option and the parties started to negotiate a license agreement. After three years of negotiations the parties were unable to agree on the terms of the license. At that point the parties submitted a joint request for WIPO mediation.
- The one-day meeting session allowed the parties to identify the issues and deepen their understanding of the legal circumstances. On this basis, the parties continued direct negotiations amongst themselves and reached a settlement agreement.

WIPO ADR Services for Life Sciences



Contract Negotiation – WIPO Mediation Submission Agreement

1. We, the undersigned Parties, hereby agree to submit to mediation in accordance with the WIPO Mediation Rules the:

[following matter in relation to the ongoing negotiations relating to [brief description] [1]]
[following dispute [brief description of the dispute]

2. The appointment of the mediator shall take place in accordance with the procedure set out in Article 7(a) of the WIPO Mediation Rules. In proposing candidates to the Parties, the WIPO Arbitration and Mediation Center (WIPO Center) shall to the extent possible draw on its open-ended List of Experts Specialized in Life Sciences.

3. **[Optional: Standing Mediator [2]**

The mediator shall remain appointed as mediator for the duration of

[contract(s) concluded as a result of the mediation] OR [specify contract(s)]

to facilitate the resolution of any disputes or disagreements that may arise concerning the performance of such contracts. [3]]

4. The place of mediation shall be [specify place]. Mediation sessions may be held through video or audio conferencing platforms with agreement of all parties.[4] The language to be used in the mediation shall be [specify language].

Contract Negotiation – WIPO Mediation Submission Agreement

- Parties may submit contract negotiations to WIPO Mediation via the model Submission Agreement
- Particularly useful:
 - to bridge parties' respective experience
 - where parties wish to ensure protection of confidential info/know-how
- WIPO Mediator appointed from WIPO open-ended list of experts specialized in life sciences
- Standing Mediator: mediator may be retained to resolve disputes that may arise during the life of any contracts concluded as a result of mediation

Long-Term Collaborations – WIPO Mediation Clause

1. 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.

2. The appointment of the mediator shall take place in accordance with the procedure set out in Article 7(a) of the WIPO Mediation Rules. In proposing candidates to the Parties, the WIPO Arbitration and Mediation Center shall to the extent possible draw on its open-ended List of Experts Specialized in Life Sciences.

3. [Optional: Standing Mediator [1]]

The mediator shall remain appointed as mediator for the duration of [specify contract(s)] to facilitate the resolution of any disputes or disagreements that may arise concerning the performance of such contracts. [2]

The place of mediation shall be [specify place]. Mediation sessions may be held through video or audio conferencing platforms with agreement of all parties. [3] The language to be used in the mediation shall be [specify language]. [4].

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

Long-Term Collaborations – WIPO Mediation Clause

- WIPO Mediator appointed from WIPO open-ended list of experts specialized in life sciences
 - If a mediator was appointed to facilitate contract negotiation, the parties may wish to have the same mediator
- Standing Mediator: same mediator may be retained to resolve any potential future disputes between the parties
- May be used in conjunction with WIPO Arbitration/Expedited Arbitration

Long-Term Collaborations - WIPO Dispute Resolution Board (“DRB”) Clause

1. Referral of Disputes [1]

Any dispute or difference between the Parties arising under, out of or relating to this contract [and any related contracts [insert details]] and any subsequent amendments of this contract [and any related contracts [insert details]] shall be referred to a DRB by filing a Request[2] in accordance with the [WIPO Expert Determination Rules](#) as amended by this clause.

2. Definitions

In this clause:

“Rules” means the [WIPO Expert Determination Rules](#)

“DRB” means the Dispute Resolution Board appointed by the Parties under this contract

Words and expressions shall have the same meanings as are assigned to them in the Rules. The words “expert(s)” and “Dispute Resolution Board/DRB Member(s)” shall be used synonymously.

3. Composition of DRB [3]

[Option 1: The Parties agree to appoint the following to act as [sole DRB Member/ a panel of [3] DRB Members]:

[Name(s)]

[Option 2: The DRB shall consist of a [sole DRB Member/ panel of [3] DRB Members] appointed in accordance with Article 9 of the Rules. In making any appointment under Article 9 of the Rules, the Center shall to the extent possible draw on its open-ended List of Experts Specialized in Life Sciences.

WIPO DRB Clause (cont.)

4. Term of Appointment

(a) The DRB Member(s) shall serve as DRB Member(s) for [the duration of this contract] [the period starting from the date of this contract and ending on the date that is [six months] following the date of termination of this contract].

(b) The DRB Member(s) may terminate their appointment at any time by giving the Parties [three months] written notice.

(c) The Parties may agree to terminate the appointment of any DRB Member at any time with immediate effect.

(d) Where the appointment of a DRB Member is terminated in accordance with this clause, the Parties may agree to appoint a new DRB Member.

5. [Optional: Information Sharing]

The Parties shall provide the DRB Member(s) with [monthly/quarterly] updates on the performance of each Party's obligations under this contract and the DRB Member(s) shall review such updates and may request any further information the DRB Member(s) consider is necessary to enable the DRB Member(s) to remain informed on the performance of this contract.]

WIPO DRB Clause (cont.)

6. Determination [and Escalation to Arbitration]

(a) The determination made by the DRB shall be [binding/non-binding] upon the Parties, unless otherwise agreed by the Parties.

(b) [Within [30] days of the communication by the DRB of its determination to the Parties, a Party may refer the matter referred to the DRB to WIPO [Expedited] Arbitration by filing a Request for Arbitration to be finally determined in accordance with the WIPO [Expedited] Arbitration Rules. [The arbitral tribunal shall consist of [a sole arbitrator] [three arbitrators].] In making any default appointment under the WIPO [Expedited] Arbitration Rules, including proposing candidates to the Parties, the Center shall to the extent possible draw on its open-ended List of Experts Specialized in Life Sciences. The place of arbitration shall be [specify place].

7. Fees and Expenses

The fees of the DRB Member(s) shall be fixed after consultation with the DRB Member(s) and the Parties in accordance with Article 22 of the Rules.

[**Optional:** The Parties shall pay a [monthly/quarterly] fee of [] to the DRB Member(s) in consideration for remaining informed regarding the performance of this contract. [4]]

8. Communications

Any communication relating to the DRB proceedings shall be by email and/or through the use of WIPO eADR. [5]

9. Language

The language to be used in the DRB proceedings [and any arbitration pursuant to Section 6(b) of this clause] shall be [specify language].

WIPO DRB Clause

- DRB: standing board of members who are kept informed of the project development and whose role is to assist parties with managing minor and more significant disputes as they arise
- Key features and benefits:
 - Efficiency
 - Appointment:
 - at the start of the contractual relationship
 - by parties or by the WIPO Center
 - may include Standing Mediator
 - Parties may agree whether determinations are binding/non-binding
 - Optional information sharing with DRB
- DRBs may be used in conjunction with WIPO Arbitration/Expedited Arbitration

The Covid-19 Technology Transfer Environment and the Potential Uses of WIPO's New ADR Options

Frederick M. Abbott, Professor of Law, Florida State University; Member of the WHO Technical Advisory Group on the COVID-19 Technology Access Pool (C-TAP)

Technology Transfer and COVID-19

- The COVID-19 pandemic raised (again) the public profile of technology transfer questions
 - The subject of negotiation and dispute at highest levels of government
 - Corporate policies in the spotlight
 - History informed better-tuned corporate responses
 - WIPO's programs evolving to meet challenges
- Technology-intensive product areas have involved diagnostics, therapeutics, vaccines, medical devices and personal protective equipment (PPE), among others
- Actors include government funders of R&D, private sector pharmaceutical companies, universities and other public research entities, public-private partnerships, foundations, multilateral institutions (e.g., WHO C-TAP and technology hub), national drug regulatory authorities, contract research organizations, and others

A Complex Web

- There is a web of licensing relationships among the various parties, some of them “traditional” in the sense of ordinary commercial practice to address the development, manufacture and distribution of products. Others involve “social components” that attempt to account for differential requirements among countries and individuals that might otherwise fall outside the protection of robust health systems
- Analogy to long-time “access-oriented” IP policies and licenses (inward and outward) of DNDi, FIND and MPP
- Unique elements of the COVID-19 pandemic involve intensive focus on the speed of development and introduction into the market that may place time pressures on negotiators that might (or might not) heighten the risks of contracting errors, or agreement to terms outside those normally accepted
 - Allocation (place in line), regulatory, liability and financing issues

WIPO ADR as a Problem Solver

- A trusted mediator appointed through the WIPO Arbitration and Mediation Center may assist parties having difficulty reaching mutually agreeable terms including those involving demands not ordinarily placed on the actors
- Complex negotiating environments may involve governments and private sector entities. Hypothetically a government approaches a private sector pharmaceutical company with a request that the company set up a manufacturing facility within its territory. The government is prepared to offer incentives such as tax holiday, guaranteed offtake agreement and/or other financial incentives. Attractive from a business standpoint to the private sector company, but the government also wants to promote its internal technological capacity and insists that an investment agreement include commitments by the private sector company to transfer technology to a local partner as part of the project

WIPO ADR as a Problem Solver

- Hypothesize a high-income country pharmaceutical company wishing to enter into a product development agreement with a university laboratory that has promising early-stage research for a low-cost/accurate diagnostic test for COVID-19. The University researchers had envisaged making the diagnostics available to low-income countries at a very low price, while the pharmaceutical company sees a large and profitable market in the high-income countries. It is not uncommon for these types of parties to reach agreement on a development and marketing arrangement that envisages distribution rights for different classes of purchasers, including based on geography, public or private procurement, and/or income
- There is room for disagreement regarding where boundary lines should be drawn, how agreements are to be enforced, and on rights to develop and market improvements. Negotiating parties can and do disagree regarding where country income level cutoffs should be established in the transition from low- to middle- to upper-middle income

WIPO ADR as a Problem Solver

- We could even envisage a circumstance in which a country expresses intention to issue a compulsory license following failed efforts to reach voluntary agreement. A neutral mediator might provide a useful sounding board for the parties to explore a middle ground
- In many or most of the contexts just described the availability of a neutral arbitrator in the event of a dispute arising out of an agreed arrangement may facilitate the conclusion of an agreement *ab initio*
- Private sector companies may be wary of ultimately having license disputes adjudicated by national courts, particularly the courts of the country receiving technology or related products
- Recall that WTO dispute settlement is limited to WTO Members, that many developing countries are wary of ADR institutions that typically adjudicate commercial disputes, and a neutral forum within WIPO might be agreeable to all sides

The Future is Famously Difficult to Predict

- The COVID-19 pandemic has taught us to be wary of prediction, and whether there will be demand for mediation or dispute settlement services specifically in the context of licensing and technology transfer relating to the pandemic is difficult to assess
- We can hypothesize many possibilities and it may be useful to bear these in mind as each of us involved in addressing the pandemic and its aftermath interact with relevant actors
- That is reason enough for a meeting such as this one
- There is and will be a technology transfer environment beyond COVID-19, along with the new WIPO ADR Life Sciences Options (a cautious prediction)

Negotiation: Challenges in Negotiating Life Sciences Agreements

Sally Shorthose, Bird & Bird, London

Type of Issues in Life Sciences Agreements which may be resolved by mediation

- Non-disclosure agreements (including trade secrets i.e. know-how/show-how)
- Clinical Trial agreements
- R&D agreements
 - Research Collaboration Agreements
 - Commercial Development and Licence Agreements NB milestones
 - Material transfer agreements
- Product Manufacturing, Supply and distribution agreements
- Licence agreements
- Assignments/corporate transactions

Most likely cause of dispute

- Milestones
 - A watershed in payment and commitment and therefore a frequent source of dispute as so much at stake
- Differences in expectations
- Changes in business needs, direction and environment
 - Especially an issue in long term agreements
- Ownership and exploitation of foreground
- Certainty of drafting

Why would mediations in Life Sciences be challenging

- Pharmaceutical and medical devices industry is IP rich – IP is the crux of so much development and exploitation
- Large range of contracts, almost always with a significant IP element
- Generally relate to patent rights and 'know how'...
- ...but can also involve other IP rights (e.g. trademarks, copyright or even regulatory rights)
- Disputes are often international and may be contractual/non-contractual
- Confidentiality is often a major consideration and disputes are resolved in secrecy: e.g. by arbitration
- Therefore, the examples are anonymised
- It is said that the increased reliance on arbitration and mediation is reducing the body of case law

WIPO Mediation Case Example

- A European university holding pharmaceutical patent applications in several countries negotiated a license option agreement with a European pharmaceutical company. The pharmaceutical company exercised the option and the parties started to negotiate a license agreement. After three years of negotiations the parties were unable to agree on the terms of the license. At that point the parties submitted a joint request for WIPO mediation.
- The one-day meeting session allowed the parties to identify the issues and deepen their understanding of the legal circumstances. On this basis, the parties continued direct negotiations amongst themselves and reached a settlement agreement.

Example 2

- An international pharmaceutical company and a European biotech company enter into a Collaboration & Licence Agreement to develop tissue repair products
- The biotech company sued the pharmaceutical company for breach of terms of the Agreement
- Dispute only related to certain products under development, so there was an ongoing relationship between the parties for the remainder of the term of the Agreement
- Directions were given for a trial on an expedited basis but with provision for mediation

Looking back at the examples, how were these resolved?

- Example 1 – parties reached a settlement agreement following WIPO mediation
- Example 2 – mediation was conducted at WIPO following service of fact evidence, this resulted in the parties reaching a settlement agreement

Types of Disputes in Life Sciences Collaborations

Joachim Feldges, Allen & Overy, Munich

Types of disputes in life sciences collaboration

■ Long- term collaboration

- License agreements, with true technology transfer in contrast to the sole resolution of an IPR conflict
- Joint development and commercialization agreements
- Co- promotion and other commercialization agreements
- Manufacturing and supply agreements

■ Short term collaboration

- Confidential Disclosure Agreements
- Research Agreements

Types of disputes in life sciences collaboration

- **Disputes in life sciences collaboration may relate to many topics, including:**
 - Quality of technology transfer (on both sides)
 - Sufficient efforts to make the collaboration successful
 - Competitive activities
 - Quality of products or services
 - Quality, maintenance and enforcement of licensed IP
 - Disclosure or other leakage of know-how to third parties
 - Mutual trust
 - Disturbance or disruption of communication

Types of disputes in life sciences collaboration

- Dispute resolution in life sciences collaboration may differ between the various types and status of collaboration
 - Do the parties intend to continue the collaboration or is that terminated?
 - In case of terminated collaboration dispute resolution means wrapping up remaining issues
 - In case of continued collaboration dispute resolution means rebuilding it
 - Can the issues be separated and fixed individually?
 - Measures to ensure quality and/or to rebuild trust and communication
 - Definition and evaluation of the common interest and ground for collaboration
 - Personal and cultural issues

Mediation: Pros/Cons and Practical Experience

Russell E. Levine, P.C., Kirkland & Ellis LLP, Chicago

Mediation Is Common In Life Sciences IP Litigation

- In the U.S., the Alternative Dispute Resolution Act of 1998 requires federal district courts to authorize, by local rule, the use of at least one ADR process in all civil actions.
- As a result, U.S. district courts have adopted ADR rules.
- Most district courts also are requiring, or strongly encouraging, parties to engage in ADR or at least to have discussions about ADR.
 - Many Judges ask about the possibility of settlement at the initial scheduling conference.
- Outside the U.S., parties in disputes also are being encouraged to engage in ADR

Examples of U.S. Local Rules Regarding ADR

- The Northern District of California has a stand-alone set of “ADR Local Rules” <https://www.cand.uscourts.gov/localrules/ADR>
- The Eastern District of Texas has a Court Annexed Mediation Plan <http://www.txed.uscourts.gov?q=court-annexed-mediation-plan>
- The International Trade Commission’s rules permit Administrative Law Judges hearing Section 337 patent infringement investigations to direct the parties to discuss settlement.
- The Northern District of Georgia’s Local Civil Rules (as well as the local civil rules of many other district courts) include an ADR provision:

The district judge “may in his or her discretion refer any civil case to a non-binding ADR process,” or, with the parties’ consent, “may refer any civil case to binding arbitration, binding summary jury trial or bench trial, or other binding ADR process.”

There are Numerous Benefits of Mediating Life Sciences Disputes

- It's a non-binding, confidential process.
- When ordered by the Court, and/or included in a Scheduling Order, it provides an opportunity to discuss business resolution without one party appearing weak.
- These are cost savings from early resolution.
- Even if the case isn't resolved, the issues in dispute could be narrowed.
- A mediated resolution presents an opportunity for a business "Win-Win" versus litigation or arbitration "Win or Lose."

It's Important to Select the Right Mediator

- Determine the type of Mediator that is best for your case.
 - The WIPO Center can help in this regard.
 - WIPO evaluates the disputes and makes recommends the several mediators who are best for the particular dispute
- Conduct due diligence regarding potential or proposed mediators.
- Pick someone who the other party will listen to.
 - Again, the WIPO list of approved mediators are mediators that parties will listen to.

You Must Prepare, and Prepare the Client, for The Mediation

- Draft an effective mediation statement
 - make sure you know whether it will be ex parte or shared with the other side
- Explain the process & potential outcomes to our client
 - develop a plan for your proposals, counterproposals, etc.
 - insist that the person(s) with full authority to settle attend
- Instill realism: your client should hear things from you before hearing them from the Mediator
 - the merits of dispute
 - the legal fees and costs
 - the business disruption associated with discovery and/or trial

If a Deal Is Reached, You Must Document the Deal

- Enter into a written term sheet
- Include language that it's not binding unless signed by both parties
- Don't let the parties leave the mediation until the term sheet is signed
- Consider a clause that converts the term sheet into the final agreement if a more detailed agreement isn't entered into by a date certain
- Use the Mediator to help resolve disputes that arise when going from the term sheet to the detailed agreement

If a Deal Isn't Reached, Keep the Door Open

- Consider reconvening after an inflection point
 - close of fact discovery?
 - close of expert discovery?
 - completion of briefing on Summary Judgment?
- Brainstorm how to break the deadlock
 - neutral evaluation?
 - baseball arbitration on the issue creating the deadlock?
- Think outside the box

Further Information

- WIPO ADR for Life Sciences:
<https://www.wipo.int/amc/en/center/specific-sectors/lifesciences/>
- WIPO Life Sciences ADR Clauses
(also available in Chinese, French, Spanish):
<https://www.wipo.int/amc/en/center/specific-sectors/lifesciences/clauses/>
- WIPO procedures, neutrals and case examples:
<http://www.wipo.int/amc/en/>
- 2021 WIPO Rules:
<https://www.wipo.int/amc/en/rules/>
- Contact information, general queries and case filing:
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