This document has been developed by the WIPO Arbitration and Mediation Center (WIPO Center), as part of WIPO’s COVID-19 support package for member states. It takes into account input from WIPO Arbitrators and Mediators specialized in life sciences.

This document is for general guidance only and is not intended to provide legal advice.
# Table of contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>II. ROUTES TO LIFE SCIENCES ADR</td>
<td>4</td>
</tr>
<tr>
<td>A. Standard WIPO ADR Procedures for Life Sciences Disputes</td>
<td>4</td>
</tr>
<tr>
<td>Mediation</td>
<td>4</td>
</tr>
<tr>
<td>Arbitration</td>
<td>4</td>
</tr>
<tr>
<td>B. New Tailored WIPO ADR Procedures for Life Sciences</td>
<td>5</td>
</tr>
<tr>
<td>1. Mediation for Contract Negotiation and Dispute Management</td>
<td>5</td>
</tr>
<tr>
<td>2. Dispute Resolution Boards (DRB)</td>
<td>6</td>
</tr>
<tr>
<td>3. Expert Determination for IP Valuation</td>
<td>7</td>
</tr>
<tr>
<td>III. ADDITIONAL PROCEDURAL OPTIONS</td>
<td>8</td>
</tr>
<tr>
<td>A. Applicable law, place, and language of the proceedings</td>
<td>8</td>
</tr>
<tr>
<td>B. Scope of the proceedings</td>
<td>8</td>
</tr>
<tr>
<td>C. Appointment procedure and qualifications of the mediators,</td>
<td>9</td>
</tr>
<tr>
<td>arbitrators, and experts</td>
<td></td>
</tr>
<tr>
<td>D. Procedural schedule and evidentiary issues</td>
<td>10</td>
</tr>
<tr>
<td>E. Confidentiality</td>
<td>11</td>
</tr>
<tr>
<td>F. Remedies and claims</td>
<td>12</td>
</tr>
<tr>
<td>G. Interim and emergency relief</td>
<td>12</td>
</tr>
<tr>
<td>H. Appeal</td>
<td>13</td>
</tr>
<tr>
<td>I. Online case administration tools</td>
<td>13</td>
</tr>
<tr>
<td>ANNEX I: WIPO Model Mediation Submission Agreement to Facilitate</td>
<td>17</td>
</tr>
<tr>
<td>Contract Negotiation or the Resolution of Life Sciences Disputes</td>
<td></td>
</tr>
<tr>
<td>ANNEX II: WIPO Model Mediation Clause for the Resolution of Life Sciences Disputes</td>
<td>19</td>
</tr>
<tr>
<td>ANNEX III: WIPO Model Dispute Resolution Board (DRB) Clause for the</td>
<td>21</td>
</tr>
<tr>
<td>Resolution of Life Sciences Dispute</td>
<td></td>
</tr>
<tr>
<td>ANNEX IV: WIPO Model Expert Determination for IP Valuation Submission</td>
<td>23</td>
</tr>
<tr>
<td>Agreement</td>
<td></td>
</tr>
<tr>
<td>ANNEX V: Sample Mediation Confidentiality Undertaking for Life Sciences Disputes</td>
<td>25</td>
</tr>
<tr>
<td>ANNEX VI: Sample Arbitration Procedural Order for Life Sciences Disputes</td>
<td>27</td>
</tr>
</tbody>
</table>
I. INTRODUCTION

(1) The global life sciences sector including pharmaceuticals and medical devices was valued at USD 1,250 billion in 2021,¹ and plays a significant role in the functioning of healthcare systems globally. The sector has always deployed a wide range of deal strategies and creative partnerships in the form of mergers and acquisitions (M&A), patent licensing, technology transfers, and research and development collaborations (R&D), to balance opportunities and risks in pursuing innovation and expanding product portfolios across global markets.

(2) Since the advent of the COVID-19 pandemic, there has been a remarkable growth in medical innovation and collaborations across regions and different types of entities, with research institutions and universities playing a role of paramount importance.² The number and value of life sciences transactions has increased by 32 percent in 2020 and 65 percent in 2021.³ The growth has been particularly dramatic for transactions using deal structures such as R&D collaborations which witnessed an increase of 50 percent, while asset licensing deals increased by approximately 39 percent in 2020.⁴

(3) While the COVID-19 pandemic has created opportunities for the life sciences sector, it has also placed significant operational, financial, legal, and political strains on existing and new collaborations, which continue to disrupt the sector, and in turn access to global health. Facilitation of contract negotiation and dispute resolution may be particularly useful during this period given the entry of new actors in the sector, and the conflicts that are likely to arise out of such collaborations.

(4) The WIPO Arbitration and Mediation Center (WIPO Center) has recently developed new tailored WIPO Alternative Dispute Resolution (ADR) options to facilitate contract negotiation and dispute resolution specifically in the context of life sciences disputes.⁵ Such options are intended to assist parties in the licensing, manufacture, supply and distribution of critical medical products such as vaccines, tests and therapies.

(5) Fifteen percent of arbitration and mediation cases filed with the WIPO Center relate to life sciences.⁶ Parties include a wide range of stakeholders, including generic and originator pharmaceuticals, diagnostics and biotech companies, industry associations, funding bodies, government agencies, insurance companies, research institutions, and universities. Such disputes often arise from technology transfers, product designs, financing, R&D agreements, licensing and cross-licensing agreements, settlement agreements, marketing, supply chain or distribution agreements, and related Non-Disclosure Agreements (NDA) negotiated or concluded by parties.

(6) Such life sciences disputes may be contractual or non-contractual in nature. As indicated in the diagram below, they may arise before the conclusion of the contract, during contract negotiations, or during the performance of the contract, and may relate to a wide range of intellectual property (IP) and general commercial matters.
(7) ADR mechanisms, understood here to include mediation, arbitration, expert determination, and dispute resolution boards (DRB), are time- and cost-effective alternatives to court litigation for stakeholders to facilitate the resolution of commercial disputes in the field of life sciences. These options offer parties the opportunity to adopt practical and satisfactory solutions, with a view to limit disruption in long-standing business relationships and in the development, marketing, and distribution of medical products.

(8) Given the complexity of technical subject matter involved in life sciences disputes, ADR mechanisms allow parties to choose specialized neutrals as mediators, arbitrators or experts knowledgeable in the specific legal field, life sciences sector, IP, and dispute resolution. ADR options also allow parties to consolidate multiple cross-jurisdictional disputes in a single neutral forum, through a procedure that takes into account parties’ business, research and other strategic goals.

(9) Another core advantage of ADR, particularly relevant for life sciences, is the private nature of the proceedings, where parties may agree to keep confidential all or specific elements of the dispute at hand. The international enforceability of settlement agreements and arbitral awards, and the autonomy provided to parties to structure proceedings are among other benefits of ADR in resolving life sciences disputes. These benefits have recently been recognized by several pharmaceuticals and life sciences stakeholders, who have incorporated ADR procedures in their licensing agreements concerning COVID-19 treatments.

(10) Bearing in mind the high settlement rates in WIPO Mediation and Arbitration, it is understood that referral to ADR procedures may stimulate positive opportunities for party settlement while serving as a catalyst in the facilitation of life sciences contract negotiations. Mediation, expert determination or DRB can additionally benefit contractual negotiations for technical determinations such as royalty rates, royalty terms, as well as commercially reasonable efforts and milestones clauses.
(11) While parties themselves can handle ADR proceedings directly with the neutral(s) and without administration by an ADR institution, such ad hoc procedures require considerable ADR experience and practical cooperation between all parties to avoid delays and unnecessary costs.\textsuperscript{11} In WIPO ADR proceedings, the WIPO Center provides a tested framework for initiating and conducting the procedure, case management services, and access to qualified mediators, arbitrators and experts with experience in life sciences, IP and commercial contracting.\textsuperscript{12}

(12) The purpose of this document is to help parties and neutrals understand and utilize procedural ADR options available to them at different stages of life sciences collaborations or transactions.

(13) To that effect, Section II of the document summarizes ways of submitting life sciences matters to standard WIPO ADR procedures, notably mediation, arbitration, and expert determination. In addition, three new tailored WIPO ADR options for life sciences disputes are introduced, namely mediation to facilitate contract negotiation and dispute management, DRB, and IP valuation under the WIPO Expert Determination Rules. Annexes I-IV include model clauses and submission agreements for these new tailored ADR procedures.

(14) Section III identifies some additional procedural options that parties may wish to consider in shaping their ADR proceedings, notably in light of the anticipated claims or a specific dispute at hand, to contain time and costs of the proceedings. Such procedural options are illustrated in Annexes V-VI.
II. ROUTES TO LIFE SCIENCES ADR

(15) Referral to ADR is usually consensual and requires mutual agreement between the parties. Parties may have agreed to submit life sciences disputes to ADR in dispute resolution clauses of pre-existing contracts. If no contractual agreement exists between the parties, they may decide to submit their dispute or specific aspects of it to ADR through a submission agreement, during or after the contract negotiation phase, and even after the commencement of court litigation. Depending on the jurisdiction, courts may support, suggest or mandate the use of ADR proceedings, especially mediation.

(16) Selection of the type of ADR method primarily depends on the circumstances of the case and parties’ needs and expectations. Each type of ADR has features that, if well managed, can translate into substantial time and cost savings, making them more affordable and accessible avenues for resolving life sciences disputes. WIPO offers the following types of ADR procedures:

A. Standard WIPO ADR Procedures for Life Sciences Disputes

Mediation

(17) Mediation is an informal consensual process in which a neutral intermediary, the mediator, assists the parties in reaching a settlement based on the parties’ interests. While the mediator cannot impose a settlement, any settlement agreement has the force of a contract. Mediation does not preclude the use of a subsequent court or other ADR options. In practice, parties often choose mediation as a first step in an escalation process, with DRB, arbitration, or court litigation as a subsequent step.

(18) Where one party wishes to submit a dispute to mediation, but no mediation agreement has been concluded, under the WIPO Mediation Rules a party may submit a unilateral Request for Mediation to the WIPO Center. The WIPO Center may then assist the parties in considering the Request or, upon request, appoint an external neutral to provide such assistance. If the other party agrees to submit the dispute to WIPO Mediation, the WIPO Center proceeds with the appointment of a mediator; otherwise, the mediation is terminated. This process is frequently used in WIPO cases and may be of interest for parties that wish to formalize their willingness to submit a life sciences dispute to mediation where there is no prior mediation agreement between the parties.

Arbitration

(19) Arbitration is a consensual procedure in which the parties submit their dispute to one or more arbitrators of their choice for a binding and final decision (an “award”) based on the respective rights and obligations of the parties and enforceable under arbitral law.

(20) The WIPO Center also offers expedited arbitration, another form of arbitration conducted in a shortened time frame and at reduced costs for parties. Expedited arbitration may be suitable for less complex life sciences disputes with a well-defined scope.
Expert Determination

(21) **Expert determination** is an evaluative ADR option used to determine issues of scientific or technical nature in which the parties submit their dispute to one or more experts with the relevant expertise of their choice. The expert’s determination is binding unless the parties agree otherwise. Expert determination is flexible and can be structured to be more informal than the arbitration process. It can be used on a stand-alone basis, in the context of a broader dispute, or during contract negotiation. When used in connection with a broader dispute or negotiation, expert determination can be used to determine a specific issue, as per parties’ agreement.

(22) A party may file a unilateral Request for Expert Determination to the WIPO Center, and share a copy of such Request with the other party. The WIPO Center may then assist the parties in considering the Request.

B. New Tailored WIPO ADR Procedures for Life Sciences

(23) In addition to the above-stated options, the WIPO Center has launched three new ADR options tailored to life sciences disputes, summarized below, that may be used separately or in conjunction with other options.

New Tailored WIPO ADR Procedures for Life Sciences

1. Mediation for Contract Negotiation and Dispute Management

(24) The first option is the use of WIPO Mediation to facilitate contract negotiation and dispute management. This option includes the appointment of an experienced mediator by the WIPO Center in consultation with the parties from the WIPO Open-Ended List of Experts Specialized in Life Sciences and can be exercised in the following ways:

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(a) **Contract Negotiation**: Parties may agree to appoint a mediator even before the main contract is negotiated, or before a NDA is concluded. The mediator helps parties in concluding a memorandum of understanding or a term sheet, stating reasons for the collaboration, and an assessment of their interests and expectations in the commercial venture, in a strictly confidential manner. Further, the mediator may assist parties in determining the scope and use of confidential information revealed during negotiations. Finally, the appointed mediator facilitates negotiations between the parties for concluding a formal contract.

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**Case Example: WIPO Mediation to Facilitate Contract Negotiation**

A European university holding pharmaceutical patent applications in several countries negotiated a license option agreement with a pharmaceutical company. The pharmaceutical company exercised the option and the parties began negotiating to conclude a license agreement. The parties failed to agree on the terms of the license. After three continuous years of failed negotiations, they submitted a joint request for WIPO Mediation. A single session with the mediator allowed the parties to identify relevant issues and underlying mutual interests, and gain better understanding of the legalities surrounding their agreement. This allowed parties to engage in direct negotiations amongst themselves and reach a settlement agreement.

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(b) **Dispute Management**: Once the contract is concluded, the mediator remains available to assist parties with disputes that may arise during the collaboration (Standing Mediator). The Standing Mediator may guide the parties in reaching an amicable settlement in case of discrepancies that may arise between the parties. This option may be particularly useful in long-term collaborations to help bridging parties’ expectations or protecting proprietary, confidential information and know-how without the risk of adverse publicity.17

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2. **Dispute Resolution Boards (DRB)**

(25) Second, the DRB is a new ADR procedure offered under a tailored WIPO Expert Determination framework, particularly designed to manage long-term collaborations. This option can be used subsequently, or as an alternative to mediation. DRB procedures allow parties to request the establishment of a WIPO DRB, which may comprise of expert neutrals or the mediator who facilitated contract negotiations and reviewed confidential information in the pre-contract stage, or members of a Joint Steering Committee, or any similar committee, appointed by the parties.18

(26) Parties may agree that the DRB remains informed of certain key developments in the course of the collaboration. The DRB’s role is to assist parties in managing minor or more significant disputes as and when required, without the interference of a party stranger to the process. Moreover, having lived through the journey of the parties’ collaboration, the DRB facilitates a speedy dispute resolution by drastically reducing the time to familiarize themselves with the issues at hand while also preserving confidentiality.19 Parties may choose as to the binding or non-binding nature of the DRB determinations.20
3. **Expert Determination for IP Valuation**

(27) Third, the WIPO Center offers an IP valuation service under the WIPO Expert Determination Rules. Here, parties may appoint a neutral having strong expertise in IP asset valuation to determine the monetary value of the IP assets forming the subject matter of a contract or dispute. IP assets in the context of life sciences may include trademarks, patents, know-how/show-how, clinical trial data, and other forms of data sold, transferred, or licensed under different types of contracts between life sciences stakeholders.

(28) Valuation of such assets may be important in the context of licensing, including royalty determination, IP infringement, mergers and acquisitions, IP-backed financing, and financial reporting. It may include assessing fair transfer prices of IP assets, calculating damages in infringement cases, and liquidation amount in case of defaults. The IP valuation option can be used before the finalization of a commercial transaction between the parties, during contract negotiations, or in the course of mediation, arbitration, or court proceedings, where the subject matter of the dispute includes the economic value of the IP involved in the transaction.

(29) The above WIPO ADR options are available to parties through a Model Mediation Submission Agreement, a Model Mediation Clause, a Model DRB Clause (including an escalation clause to refer unsettled matters to arbitration), and a Model Expert Determination for IP Valuation Submission Agreement, as set out in Annexes I-IV. The WIPO Center is available to assist parties that wish to commence a WIPO ADR procedure through its complimentary Good Offices services.21
III. ADDITIONAL PROCEDURAL OPTIONS

(30) Based on the WIPO Center’s life sciences case experience, the WIPO Center has identified a range of procedural options that parties may wish to consider to effectively resolve life sciences disputes and to preserve business relationships, particularly in case of long-term collaborations. Parties and their lawyers can contact the WIPO Center if they have any queries when drafting ADR clauses.

(31) Generally, the content and level of detail that parties may address will depend on the procedural stage. When negotiating contract clauses for future disputes, parties typically do not know details of the dispute that may arise much later in the collaboration and will often include standard WIPO contract clauses. For an existing dispute, including where litigation has already commenced, parties have a good understanding of the issues at stake and will seek to shape the ADR process in the submission agreement in line with their needs.

(32) In the course of the ADR proceedings, parties can further tailor the ADR process in consultation with the mediator, arbitral tribunal, expert, or DRB. In arbitrations, any procedural issues agreed by the parties are generally reflected in a procedural order issued by the arbitral tribunal following consultation with the parties. The WIPO Model Procedural Order, included in Annex VI, summarizes some options observed in life sciences arbitrations. This section identifies some matters that parties may wish to consider when tailoring a life sciences ADR process to their needs.

A. Applicable law, place, and language of the proceedings

(33) To facilitate efficient conduct of the mediation or arbitration proceedings, parties are strongly encouraged to agree on the law that will govern the merits of the dispute, the place of mediation or arbitration, and the language of the proceedings as core elements of mediation or arbitration clauses or submission agreements. Under the WIPO Rules, all these elements can be freely chosen by the parties.

B. Scope of the proceedings

(34) Parties have complete flexibility to define the scope of the proceedings in line with their needs. In view of the complexity and variety of life sciences disputes, especially in case of long-term collaborations, a clear definition of the scope of the subject matter referred to ADR may be crucial to contain time and cost of the proceedings. While in standard WIPO Mediation and Arbitration clauses parties give wide power to the mediator or arbitral tribunal (including contractual and non-contractual claims), in some circumstances it may be appropriate to limit the scope of the proceedings. The following examples may be considered:

(a) Limitation of claims and defenses: In the interest of time and cost-efficiency, parties may agree to limit proceedings to specific claims, including for example interpretation and application of licensing agreements, patent ownership or co-ownership, enforceability, or infringement issues. Parties may also agree in arbitration that certain arguments, such as patent validity, are excluded from the scope of the proceedings, or that they may be considered, but the tribunal may take no binding decision regarding such arguments.
Case Example: Limitation of Scope in a WIPO Arbitration

In a WIPO life sciences arbitration relating to a cancer treatment product, parties agreed in their submission agreement to limit the scope of the proceedings to two main areas, which covered financial elements of the contract such as the royalty rates, and the patent ownership status of three selected patents.

(b) Geographical scope: Parties may agree to submit a global dispute in its entirety, or may limit the proceedings to select markets or specific jurisdictions, for example by selecting one or several national patents.

(c) In patent-related arbitrations, concerning for example medical devices, where several patents may be involved, a selection of patents (“patent sampling”), a preliminary claim construction process, or the conduct of the proceedings in several stages may be agreed at the start or in the course of the proceedings. Such case management discussions are usually conducted by the tribunal at the preparatory conference.27

Case Example: Procedural Stages in a WIPO Arbitration

In a WIPO Arbitration concerning the determination of royalty rates, parties agreed in their submission agreement that specific issues would be submitted to the tribunal in a first stage, whereas other topics would be subject to further negotiations between the parties. If such negotiations were not successful within a specified period, then those issues would be referred to the tribunal's determination in a second stage.

C. Appointment procedure and qualifications of the mediators, arbitrators, and experts

(35) Specialized neutrals with expertise in IP and commercial life sciences disputes are fundamental for achieving high-quality outcomes while limiting the time and cost of the proceedings. The appointment procedure is usually governed by the applicable institutional rules unless otherwise agreed by the parties.

(36) Under the WIPO Mediation Rules, parties are free to choose a mediator of their choice or provide the WIPO Center with their preferences regarding the qualifications of mediator candidates, best suited to the nature of their dispute.28 In the absence of an agreement between parties as to the person of the mediator, the WIPO Center will share a list of candidates from the WIPO Open-Ended List of Experts Specialized in Life Sciences, along with a copy of their qualifications with the parties (list procedure).29 The parties will be invited to number the candidates according to their preference and return the list to the WIPO Center. Finally, the WIPO Center will appoint a mediator after considering the preferences and objections raised by all parties in their respective lists.

(37) A similar list procedure applies to ensure candidates' expertise for appointment as sole or presiding arbitrators in life sciences-related WIPO Arbitration and Expedited Arbitration proceedings.
In WIPO Arbitration, the arbitral tribunal may consist of a sole arbitrator or three arbitrators, depending on the agreement between the parties, and the facts and circumstances of the dispute. In case of an arbitral tribunal consisting of three arbitrators, under the WIPO Arbitration Rules, each party will be requested to appoint one arbitrator. The two arbitrators thus appointed will then appoint the presiding arbitrator. In WIPO Expedited Arbitration, the tribunal consists of a sole arbitrator.

In making any default appointment including proposing candidates to the parties in accordance with Article 19(b) of the WIPO Arbitration Rules and Article 14(b) of the WIPO Expedited Arbitration Rules, the WIPO Center will, to the extent possible, draw on the WIPO Open-Ended List of Experts Specialized in Life Sciences.

In expert determination proceedings, (including when related to IP valuation) and DRB, where the parties have not agreed on the expert(s) or on the procedure for appointing the expert(s), the WIPO Center will appoint the expert(s) from its WIPO Open-Ended List of Experts Specialized in Life Sciences after consultation with the parties and taking into account the specifics of the collaboration or dispute.

Prior to any appointment under the WIPO Rules, the mediator, arbitrator, or expert confirms its impartiality and independence and, by accepting appointment under the WIPO Rules, undertakes to make available sufficient time for the expeditious conduct of the proceedings.

D. Procedural schedule and evidentiary issues

In their WIPO ADR clause or submission agreement, parties may establish a procedural schedule to facilitate the efficient conduct of meetings or proceedings. If parties have not agreed on such a schedule, it may also be developed by the mediator or the arbitral tribunal, once appointed, in consultation with the parties.

In WIPO Mediations, parties are free to agree on the duration of each mediation meeting and the length of the proceedings. In the WIPO Center’s case experience, the conclusion of a mediation typically may vary from a few weeks to a couple of months from the date of commencement of the mediation, depending on the nature, facts and circumstances of the dispute.

Arbitral schedules usually envisage that a final award shall be issued within 6-8 months in a WIPO Expedited Arbitration, and 14-16 months in a WIPO Arbitration. Specific timelines may be reduced or extended in the course of the proceedings by the parties, the tribunal, or the WIPO Center under the WIPO Arbitration and Expedited Arbitration Rules. A Sample Arbitration Procedural Order as set out in Annex VI proposes a detailed procedural schedule and flexibilities for the proceedings, guided by WIPO Arbitration case experience in the life sciences sector.

Parties may also agree on specific evidence procedures, including the scope of discovery, if any, tribunal- or party-appointed technical experts, and testimonies of witnesses of fact and expert witnesses. Subject to a determination on admissibility, relevance, materiality, and weight of the evidence by the tribunal, parties are permitted to produce technical evidence such as reports of experiments, inspections, testing, or sampling conducted to
support their case. The WIPO Model Arbitration Procedural Order proposes some options for parties to that effect.

E. Confidentiality

(46) Given the potential for adverse publicity or disclosure of sensitive and commercially valuable information in life sciences disputes, the WIPO Rules provide that unless otherwise agreed by the parties or required by law, the existence of the proceedings, input on disclosures made during ADR proceedings, as well as the final outcome of the dispute in the form of settlements, determinations, or awards shall be confidential.

(47) At the onset of a WIPO Mediation, as a step towards establishing trust between the parties and subject to parties’ requests, the mediator may guide the parties in concluding a separate confidentiality undertaking. Annex V provides an illustration of a Sample Confidentiality Undertaking entered between parties in a WIPO Mediation. In addition, any views expressed, suggestions or admissions made by the parties or any settlement agreement(s) entered between the parties, carry a high-level of protection and cannot be used as evidence in any subsequent arbitral or judicial proceedings. A mediation settlement agreement may only be introduced in such proceedings to the extent that is necessary for the enforcement of such agreement or as otherwise required by law. Further, the mediator cannot act in any capacity in any pending or future proceedings concerning the subject matter of the mediation, except when authorized by the parties in writing or required by a court.

(48) The WIPO Arbitration and Expedited Arbitration Rules give the arbitral tribunal the power to issue protective orders as may be appropriate during the proceedings. For example, documents concerning know-how or comparable licenses which are requested to be produced in the arbitration may contain confidential information. The WIPO Arbitration and Expedited Arbitration Rules provide mechanisms for addressing such issues, by including, where appropriate, special measures of protection such as protective orders, an “attorneys’ eyes only” designation or the appointment of a confidentiality advisor. Broadly, parties may assign different levels of confidentiality to different categories of documents to ensure they have appropriate levels of control over sensitive information.

**Case Example: Protective Orders in WIPO Arbitration**

Requests for protective orders are common in WIPO Arbitration proceedings. For example, in a WIPO Arbitration where parties contested the admissibility of a third-party contract, the tribunal rejected a party’s request to obtain redacted excerpts of such contract, as it considered it confidential and irrelevant to the dispute at hand.

(49) Parties’ agreement concerning disclosure of certain information can be reached at any stage of WIPO ADR proceedings, if parties so wish. In any event, to the extent necessary to comply with a legal requirement imposed on a party, or in connection with a court action relating to the award or as otherwise required by the law, the parties, the tribunal, and the WIPO Center can disclose the award under the WIPO Arbitration and Expedited Arbitration Rules.
F. Remedies and Claims

(50) In WIPO Mediation, parties are free to raise any remedies they deem appropriate in light of the facts and circumstances of their dispute. In the WIPO Center’s life sciences case experience, claims are often contractual in nature and relate to the interpretation or enforcement of contractual obligations such as outstanding payments, specific performance, and terminating or modifying an existing contract. Such claims also relate to the unauthorized use of intellectual property, breach of confidentiality, and exclusivity provisions.

(51) Typical remedies sought by parties in WIPO life sciences arbitration proceedings include requests for contract termination, specific performance, determination of royalty rates, the duration of royalty payments, the fulfilment of conditions for milestone payments, damages for failure to comply with a contractual obligation or for a breach of contract, the determination whether an innovation or a product falls under the agreement. Other remedies requested have included declarations of patent infringement and compensatory damages.

(52) The amount or valuation of damages is typically left to the arbitral tribunal or expert(s) appointed by the tribunal or the parties. In infringement cases, damages may take the form of royalties payable in a lump sum or based on a specific rate, as determined by the arbitral tribunal or expert(s). The arbitral tribunal may stage the proceedings by deciding first on the obligation to pay damages and then in a second phase decide on the amount (quantum).

G. Interim and Emergency Relief

(53) The WIPO Arbitration and Expedited Arbitration Rules provide for emergency relief proceedings for parties seeking urgent interim relief before the establishment of the tribunal.45

(54) In addition, under the WIPO Arbitration and Expedited Arbitration Rules, the arbitral tribunal may issue any provisional order deemed necessary.46 Interim measures may be relevant in life sciences disputes where the rights of multiple parties are at stake, or for preserving the status quo in exclusivity claims. Such measures may include entering into an escrow agreement to facilitate the deposit of funds, pending a final resolution of the dispute by the tribunal.

**Case Example: Escrow Account in a WIPO Arbitration**

In a WIPO Arbitration involving three parties, as an interim order, the tribunal advised the parties to enter an escrow agreement and deposit funds in the escrow account, and granted a temporary stay on arbitral proceedings until a connected matter pending adjudication before a national court was concluded.

(55) Furthermore, the WIPO Arbitration and Expedited Arbitration Rules do not prevent a party to seek interim measures from national courts at any stage.47 Such flexibility may be especially relevant in life sciences cases concerning trade secrets, clinical data, or patent infringement.
H. Appeal

(56) By agreeing to arbitration under the WIPO Arbitration and Expedited Arbitration Rules, the parties waive their right to any form of appeal (subject to the law at the seat of the arbitration). An award under the WIPO Rules is binding on the parties and enforceable internationally.

(57) Exceptionally, parties may agree that the award issued by the arbitral tribunal be subject to review by an appellate arbitral tribunal under certain conditions, such as limiting the scope of an appeal to specific issues. While such appeal clause is extremely rare in WIPO Arbitration case experience, such option may provide parties with a second chance at presenting their case, which may be of interest in complex and high-value patent infringement claims in the life sciences area.

Case Example: Appeal Option in a WIPO Arbitration

In a WIPO Arbitration relating to medical devices, the dispute resolution clause included an option to file an appeal to an appellate tribunal to conduct de-novo proceedings of the case. Parties did not make use of the appeal option.

I. Online case administration tools

(58) As one of the consequences of the COVID-19 pandemic, parties have increasingly used online case administration tools provided by the WIPO Center. WIPO eADR, an online case administration platform that the WIPO Center makes available to parties at no additional cost, allows parties and all other actors in a case under the WIPO Rules to submit communications electronically into a secure online docket. In addition to facilitating secure online transmission and storage, WIPO eADR also provides a summary of case information, an overview of timelines, the contact information of all parties, and the finance status of the case.

(59) As reflected in the WIPO Rules, the WIPO Center also supports the online conduct of ADR proceedings, including by facilitating online meetings and hearings. Parties may refer to the WIPO Checklist for the Online Conduct of Mediation and Arbitration Proceedings. Parties have control over the online conduct and are free to select an online platform of their choice or list their preference with respect to the video conferencing facilities provided by the WIPO Center.
NOTES


2. Research institutions and universities filed nearly as many patent applications as private corporations for COVID-19 related products such as therapeutics and vaccines. See New COVID-19 Research: Universities and Research Organizations Highly Active in Vaccine Patenting During Pandemic's Early Days; China, U.S.-based Applicants Lead in Vaccine and Therapeutics Innovation.


4. See Biopharmaceutical deal trends.

5. See WIPO COVID-19 Related Services and Support – New ADR Options Tailored to the Life Sciences Sector.

6. For more information on WIPO Center’s case experience in life sciences, please refer to WIPO Alternative Dispute Resolution (ADR) for Life Sciences.


9. See for example, “Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries”; See also “Afrigen signs grant agreement with MPP to establish a technology transfer hub for COVID-19 mRNA vaccines”; See also “35 generic manufacturers sign agreements with MPP to produce low-cost generic versions of Pfizer's oral COVID-19 treatment”.

10. To date, the settlement rate of WIPO mediations is 75 percent, and 33 percent of arbitration disputes have been settled before the issuance of a final award; see WIPO ADR Highlights January 25, 2021. The WIPO Arbitration Rules explicitly state that the arbitral tribunal may suggest that the parties explore settlement, including by commencing mediation. See Article 67(a) WIPO Arbitration Rules / Article 60(a) WIPO Expedited Arbitration Rules.

11. In the Queen Mary University/Pinsent Masons 2016 International Dispute Resolution Survey, 94 percent of respondents stated that the choice of institution is part of their organization's dispute resolution policy.

12. The WIPO Center maintains a special list of mediators, arbitrators and experts in life sciences. The WIPO Center proposes candidates for appointment from that list to parties involved in WIPO ADR proceedings relating to life sciences disputes.

13. For guidance on how to submit a Unilateral Request for Mediation, please refer to the WIPO Mediation Case Filing Guidelines.

14. For guidance on how to submit a Unilateral Request for Expert Determination, please refer to the WIPO Expert Determination Case Filing Guidelines. See Articles 5-6 WIPO Expert Determination Rules.
For guidance on how to submit a Request for WIPO Expert Determination, please refer to the WIPO Expert Determination Case Filing Guidelines.

See WIPO Neutrals.

Parties may utilize other options to facilitate contract negotiations, including (1) Depository of Know-how/Confidential Information/Data: parties may deposit confidential information with an independent WIPO-appointed expert. Such an expert could assess the know-how that is to be transferred and/or identify whether there are any gaps in information provided; (2) Escrow: parties may agree to deposit a sum of money in escrow to demonstrate their willingness to conclude an agreement. If contract negotiations are not concluded successfully, such funds would be returned to the parties.

The fees of the DRB members are fixed by the WIPO Center in consultation with the parties and the DRB members. In addition, parties may choose to pay the DRB members a monthly retainer to remain informed of the project's development phases and retain their impartiality throughout the duration of the project.

See Dispute Boards: A Novel Dispute-Resolution Technique for Life Sciences Companies Fighting COVID-19 (dechert.com).

Escalation Clause: Mediation for contract negotiation and DRB procedures may be used in conjunction with WIPO Arbitration or Expedited Arbitration where parties cannot reach a full settlement agreement or wish to enforce or challenge a DRB determination. The parties might be able to use their WIPO Mediation or WIPO DRB to narrow the scope of the dispute referred to arbitration. Parties may choose arbitration to commence within a specified period of the DRB issuing its determination, or at the termination of the contract. WIPO Arbitrators may be appointed from the WIPO Open-Ended List of Experts Specializing in Life Sciences. See Annex III, Sub-clause 6, WIPO DRB Clause.

The WIPO Center can be contacted at arbiter.mail@wipo.int. See also WIPO Good Offices.


The WIPO Center can be contacted at arbiter.mail@wipo.int.

See Recommended WIPO Contract Clauses and Submission Agreements.

See Annexes I-V.

See WIPO ADR Rules.

Article 40 WIPO Arbitration Rules; Article 34 WIPO Expedited Arbitration Rules.

Article 7 WIPO Mediation Rules.

Article 7 WIPO Mediation Rules; See also WIPO Neutrals.

Article 14 WIPO Arbitration Rules.

Articles 17-18 WIPO Arbitration Rules.

Parties also benefit from fixed arbitrator's fees in WIPO Expedited Arbitration. For more details, please refer to the WIPO Schedule of Fees and Costs.

See WIPO Neutrals.

Article 9 WIPO Expert Determination Rules.

Article 23(a) WIPO Arbitration Rules; Article 18(a) WIPO Expedited Arbitration Rules; Article 7(c) WIPO Mediation Rules; Article 10 WIPO Expert Determination Rules.

Articles 4(f), (g) and 37(c) WIPO Arbitration Rules; Articles 4(f)-(h) and 31(c) WIPO Expedited Arbitration Rules; See also Paragraph 15.

Articles 50-53 WIPO Arbitration Rules.
Articles 15-18 WIPO Mediation Rules; Articles 75-78 WIPO Arbitration Rules; Articles 68-71 WIPO Expedited Arbitration Rules; Article 16 WIPO Expert Determination Rules.

See Article 16 WIPO Mediation Rules; See also WIPO Model Confidentiality Undertaking under Annex V.

Article 18 WIPO Mediation Rules.

Article 18(v) WIPO Mediation Rules.

Article 21 WIPO Mediation Rules.

Articles 54 and 57 WIPO Arbitration Rules; Articles 48 and 51 WIPO Expedited Arbitration Rules.

Articles 77-78 WIPO Arbitration Rules; Articles 70-71 WIPO Expedited Arbitration Rules.

Article 49 WIPO Arbitration Rules; Article 43 WIPO Expedited Arbitration Rules.

Article 48 WIPO Arbitration Rules; Article 42 WIPO Expedited Arbitration Rules.

Article 48(d) WIPO Arbitration Rules; Article 42(d) WIPO Expedited Arbitration Rules. The availability and enforcement of such interim measures may depend on the law(s) of the place(s) where the request for interim relief is made or enforced.

Article 66 WIPO Arbitration Rules; Article 59 WIPO Expedited Arbitration Rules.

See model appeal clause in the WIPO Clause Generator: “The award pursuant to Article 64 of the WIPO Arbitration Rules shall only be subject to review through an appeal to an Appellate Panel consisting of [three arbitrators] appointed pursuant to Article 17 of the WIPO Arbitration Rules. No arbitrator in the arbitral tribunal may be an arbitrator on the Appellate Panel. Such an appeal must be initiated within [30 days] of the arbitral tribunal award or otherwise the award shall become a final award pursuant to the WIPO Arbitration Rules. [If an appeal is sought, the Appellate Panel shall conduct a de novo review of the legal determinations of the arbitral tribunal and shall determine whether there is reasonable basis for all factual determinations.]; for more details, please refer to the WIPO Clause Generator for WIPO Arbitration Submission Agreement.

See WIPO eADR.

See Article 10 WIPO Mediation Rules; Article 14 (f) Expert Determination Rules; Articles 40, 45, 49(g), and 55 WIPO Arbitration Rules; and Articles 34, 39, 43(g); and 49 WIPO Expedited Arbitration Rules.

In 2021, there was a marked increase in the use of WIPO Online Case Administration Tools, including the WIPO Center’s eADR online case management platform and videoconferencing facilities, by parties to facilitate their mediation and arbitration procedures. See WIPO ADR Highlights 2021.
ANNEX I: WIPO Model Mediation Submission Agreement to Facilitate Contract Negotiation or the Resolution of Life Sciences Disputes

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 Mediator²]
   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 conducted in the manner agreed by the parties, including meetings by telephone, videoconference or using online tools.⁴ The language to be used in the mediation shall be [specify language].

¹ Parties may utilize other options to facilitate contract negotiations such as: (1) Depository of Confidential Information: Parties may deposit confidential information with an independent WIPO-appointed expert. Such an expert could assess the know-how that is to be transferred and/or identify whether there are any gaps in information provided. The mediator may also assist parties with concluding a confidentiality undertaking in relation to such information; (2) Escrow: Parties may agree to deposit a sum of money in escrow with an agreed escrow agent to demonstrate their willingness to conclude an agreement. If contract negotiations are not concluded successfully, such funds would be returned to the parties.

² Parties may use a standing mediator as an alternative to a DRB. Alternatively, a DRB may be used if a settlement is not reached through the mediation.

³ Parties may choose to provide regular updates on the performance of the contract to the mediator, and pay a retainer to the mediator in consideration for remaining informed regarding the contract performance: “The Parties shall provide the mediator with [monthly/quarterly] updates on the performance of each Party’s obligations under such contracts. The Parties shall pay a [monthly/quarterly] fee of [ ] to the mediator in consideration for remaining appointed as mediator for the duration of such contracts and remaining up to date with the performance of such contracts.”

⁴ See Article 10 WIPO Mediation Rules and the WIPO Checklist for the Online Conduct of Mediation and Arbitration Proceedings.
ANNEX II: WIPO Model Mediation Clause for the Resolution of Life Sciences Disputes

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 (WIPO Center) shall to the extent possible draw on its open-ended List of Experts Specialized in Life Sciences.

3. [Optional: Standing Mediator]

   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.

4. The place of mediation shall be [specify place]. Mediation sessions may be conducted in the manner agreed by the parties, including meetings by telephone, videoconference or using online tools. The language to be used in the mediation shall be [specify language].

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1 Parties may use a standing mediator as an alternative to a DRB. Alternatively, a DRB may be used if a settlement is not reached through the mediation.

2 Parties may choose to provide regular updates on the performance of the contract to the mediator, and pay a retainer to the mediator in consideration for remaining informed regarding the contract performance: “The Parties shall provide the mediator with [monthly/quarterly] updates on the performance of each Party’s obligations under such contracts. The Parties shall pay a [monthly/quarterly] fee of [ ] to the mediator in consideration for remaining appointed as mediator for the duration of such contracts and remaining up to date with the performance of such contracts”.

3 See Article 10 WIPO Mediation Rules and the WIPO Checklist for the Online Conduct of Mediation and Arbitration Proceedings.

4 If the parties wish to combine WIPO Mediation with WIPO DRB, they may use the WIPO Mediation followed, in the absence of settlement, by a DRB clause.
ANNEX III: WIPO Model Dispute Resolution Board (DRB) Clause for the Resolution of Life Sciences Dispute

1. **Referral of Disputes**

   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\(^1\) 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\(^2\)**

   [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 WIPO Center shall to the extent possible draw on its open-ended List of Experts Specialized in Life Sciences.]

4. **Term of Appointment**

   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].

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

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

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\(^1\) The information that needs to be included in a Request is set out in Article 5 WIPO Expert Determination Rules.

\(^2\) If a WIPO Mediator was appointed by the parties to facilitate the negotiation of the contract, and the parties consider that it would be useful to retain the mediator’s services, the same WIPO Mediator may be appointed to be a DRB Member. In addition, where parties have created a Joint Steering Committee, or similar committee, to oversee the performance of the contract, the parties may appoint members of such committee to act as DRB Members.
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.]

6. **Determination [and Escalation to Arbitration]**
   
   The determination made by the DRB shall be [binding/non-binding] upon the Parties, unless otherwise agreed by the Parties.

   [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 WIPO 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.]

8. **Communications**
   
   Any communication relating to the DRB proceedings shall be by email and/or through the use of WIPO eADR.⁴

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].

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³ This may be relevant if the DRB members receive information under optional clause 5 on “Information Sharing”.

⁴ See WIPO eADR.
ANNEX IV: WIPO Model Expert Determination for IP Valuation Submission Agreement

We, the undersigned parties, hereby agree to submit to expert determination in accordance with the WIPO Expert Determination Rules the following matter:

[brief description of the IP or technology to be valued]

The determination made by the expert shall [not] be binding upon the parties.

The place of the determination shall be [specify place]. If the expert considers it necessary, or if agreed between the parties, the expert may hold any meetings between the expert and the parties by telephone, videoconference or using online tools, or in any suitable format.

The language to be used in the expert determination shall be [specify language].

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1 For example, in the context of IP licensing including royalty determination, IP infringement, mergers and acquisitions; IP backed financing; damages calculation; and financial reporting.
ANNEX V: Sample Mediation Confidentiality Undertaking for Life Sciences Disputes

As an attendee participating in the mediation meetings between [Party 1] and [Party 2], I undertake to comply with the confidentiality provisions stipulated in Articles 15-18 of the WIPO Mediation Rules, and in particular the following obligations:

1. I will not make or procure others to make recordings of any kind of any mediation meetings.

2. I promise to respect the confidentiality of the mediation and may not, unless otherwise agreed by both parties and the mediator, use or disclose to any outside party any information concerning, or obtained in the course of, the mediation.

3. On the termination of the mediation, I undertake to return, to the party providing it, any brief, document, or other materials supplied by a party, without retaining any copy thereof. I also undertake to destroy any notes taken concerning the meetings of the parties with the mediator on the termination of the mediation.

4. Unless otherwise agreed by the parties, I shall not introduce as evidence or in any manner whatsoever in any judicial or arbitration proceeding:
   (a) any views expressed or suggestions made by a party with respect to a possible settlement of the dispute;
   (b) any admissions made by a party in the course of the mediation;
   (c) any proposals made or views expressed by the mediator;
   (d) the fact that a party had or had not indicated willingness to accept any proposal for settlement made by the mediator or by the other party;
   (e) any settlement agreement between the parties, except to the extent necessary in connection with an action for enforcement of such agreement or as otherwise required by law.

5. Any disclosure made to group corporate officers, employees, and/or external counsel of the party should be limited to a need-to-know basis for the purpose of the mediation. I shall ensure that the person to whom I disclose the information understands and agrees to be bound by the same confidential obligations stipulated herein prior to making such disclosure.

I acknowledge and agree to be bound by the undertaking.

Date:

Name:

Signature:
ANNEX VI: Sample Arbitration Procedural Order for Life Sciences Disputes

In view of the parties’ submissions and positions, and issues raised during the preparatory conference conducted pursuant to Article 40 of the WIPO Arbitration Rules (“the WIPO Rules”) which took place on [date], the arbitral tribunal hereby makes the following order:

1. Article […] of the Agreement will govern the form and conduct of the arbitral proceedings. In accordance with this provision,

   “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 referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of three arbitrators. 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 shall be decided in accordance with the law of [specify jurisdiction].”

2. Following the submissions filed by the parties, the parties have agreed that the dispute concerns [specify scope],

3. Pursuant to its powers under Article 37 of the WIPO Rules, the arbitral tribunal hereby sets the following schedule as agreed by the parties:

   Statement of Claim  
   (Article 41 WIPO Rules)  
   30 days after Procedural Order [No. X]

   Statement of Defense  
   (Article 42 WIPO Rules)  
   30 days after Statement of Claim

   Claimant Reply  
   15 days after Statement of Defense

   Respondent Sur-Reply  
   15 days after Claimant Reply

   All Document Production Completed  
   (Article 50 WIPO Rules)  
   30 days after Sur-Reply

   Fact Witness Statements  
   (Article 56 WIPO Rules)  
   30 days after Document Production

   Expert Witness Statements  
   (Articles 56, 57 WIPO Rules)  
   30 days after Fact Witness Depositions

   Hearing (Article 55 WIPO Rules)  
   30 days after Expert Witness Depositions

   Claimant Post-Hearing Submission  
   30 days after Hearing

   Respondent Post-Hearing Submission  
   30 days after Claimant Post-Hearing Submission
Claimant Reply 15 days after Respondent Post-Hearing Submission

Respondent Sur-Reply 15 days after Claimant Reply

All submissions shall be made on the specified due date via the WIPO eADR.

4. Pursuant to Articles 41 and 42 of the WIPO Rules, the parties shall, to the extent possible, submit the documents and other evidence upon which they seek to rely concurrently with the Statement of Claim and the Statement of Defense. Supplemental documents and other evidence may be submitted concurrently with the Reply to the Statement of Defense and the Sur-Reply.

5. In accordance with Article 48(b) of the WIPO Rules, the arbitral tribunal may order that a party provide security for the claim or counter-claim in an escrow account.

6. The arbitral tribunal expects the parties to try to informally resolve requests for production of documents and other evidence. The parties may bring requests for disclosure under Article 50(b) of the WIPO Rules only if they reach an impasse on the production of documents or other evidence.

7. In accordance with Article 56 of the WIPO Rules, on [date], the parties shall simultaneously submit sworn witness statements for each witness of fact on whom they propose to rely at the Hearing pursuant to Article 55 of the WIPO Rules. Such a statement should be sufficiently detailed so as to stand as that witness’ direct testimony.

8. Further to Article 56 of the WIPO Rules and in accordance with the schedule set forth above, the parties shall submit sworn expert witness statements for each expert witness on whom they propose to rely at the Hearing pursuant to Article 55 of the WIPO Rules. Such statements should be sufficiently detailed so as to stand as that witness’ direct testimony.

9. [The parties are permitted to depose witnesses expected to testify at the Hearing pursuant to Article 55 of the WIPO Rules in accordance with the schedule set forth above.]

10. The Hearing pursuant to Article 55 of the WIPO Rules will begin on [date]. As agreed by the parties, the Hearing will be held [online] for not more than five days [at [venue of arbitration hearing], located at [address]].\(^1\) The arbitral tribunal expects the parties to arrange transcription services and other administrative details in due course.

11. The parties may file wholly or partially dispositive motions as they wish. Once filed, the arbitral tribunal shall determine if a briefing schedule is appropriate or if the motion should be stayed. The filing of any motion will not necessarily suspend or postpone the agreed schedule.

12. The arbitral tribunal and the parties acknowledge and accept that the processing of personal and sensitive data may be necessary for the purpose of the arbitral proceedings. The arbitral tribunal and the parties agree to comply with the provisions of the [relevant data protection laws and regulations] when processing any personal data of any person residing within [jurisdiction(s)] in connection with the arbitral proceedings.\(^2\)

On behalf of the arbitral tribunal

[date]

\(^1\) Parties may choose to conduct hearings by videoconference, using online tools or in-person.

\(^2\) For further information on how the WIPO Center manages personal data, please refer to the WIPO Arbitration Case Filing Guidelines.