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LEXOLOGY Webinar

Resolving contract disputes in life sciences

Philipp Groz / Dr. Lorenza Ferrari Hofer

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Overview

- Some Key Characteristics of Contract Disputes in Life Sciences
- Potential Benefits of Arbitration for Life Sciences Disputes
- Potential Procedural Pitfalls
- Take Aways from Recent Cases: Substantive Issues
- Discussion / Q&A



Part I – Procedural Issues

Philipp Groz

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Practice Areas

- Intellectual Property
- Life Sciences
- International Arbitration
- Dispute Resolution

Languages

German
English

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Philipp Groz is a Partner in Schellenberg Wittmer's Dispute Resolution Group and heads the IP and Life Sciences Groups. He represents clients in domestic and international litigation and arbitration, particularly in the fields of intellectual property, unfair competition, licensing and distribution. He also sits as an arbitrator.

Philipp is a member of several professional associations, including the Swiss Arbitration Association, the Licensing Executives Society (board member of LES Switzerland), the International Trademark Association (member of ADR committee) and the International Association for the Protection of Intellectual Property (member of standing committee on ADR).

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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 / 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

Be careful when 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 pharmaceutical matters 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

Plan ahead for multi-party / multi-contract scenarios

- Example: Disruption due to alleged force majeure along supply chain



- For CMO:
 - Risk of parallel proceedings, duplicated costs, contradicting decisions
 - Can CMO join Sub-Supplier to arbitration against Customer (Joinder)? Can CMO request that two parallel arbitrations be consolidated (Consolidation)?
 - Are arbitration clauses compatible? Requirements under the chosen arbitration rules for joinder and consolidation? Confidentiality aspects?

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: “ICC Arbitration seated in Basel”
- If necessary, clarify relationship between different dispute resolution clauses



Part II – Substantive Issues

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Practice Areas

- Intellectual Property
- Life Sciences
- ICT
- Corporate & Commercial
- Dispute Resolution

Languages

German
English
French
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Lorenza Ferrari Hofer is a Partner in our IP and Life Sciences Groups in Zurich. She specializes in intellectual property, unfair competition, data law and contract law. She has profound knowledge of the development, licensing, trade and distribution of technology, therapeutic, health and food products, as well as product liability matters.

Lorenza has a long-term experience in structuring and negotiating intellectual property rights-related agreements, including R&D, transfer and licensing, and distribution agreements. Her life sciences practice also includes regulatory and compliance matters, as well as product liability defense.

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Take Aways from Recent Cases

(1) Flexible allocation of manufacture and supply activities

- Continual managing and supervising of manufacturing and distribution capacity is essential
- Subcontracting of manufacture and supply activities needs to be coordinated, also with regard to contractual termination and termination consequences
- Consider second lines of production, several warehousing possibilities and provide for quality controls
- Ensure regular and transparent information about the manufacture and distribution chain so that upon termination of the contract all details of the product logistics are available and allow a proper transition to new contractual partners
- Specifically address post-termination duties and rights, return of stocks, transfer of technology, know-how and materials

Take Aways from Recent Cases

(2) Clear attribution of regulatory responsibilities and liabilities

- Set clear regulatory responsibilities and adverse case reporting (incl. costs)
- Ensure regulatory compliance and quality management along the contractual relationship (steering committees, quality agreements and audits)
- Provide for process to address changes of regulatory framework
- Upon issuing/receiving termination of a distribution agreement, provide for automatic transfer of marketing authorizations and conformity assessments and immediate information of the regulatory authorities
- Specifically address post-termination issues, such as responsibility for market vigilance, product liability procedures and contact with regulatory authorities

Take Aways from Recent Cases

(3) Confidentiality

- Always provide for strict contractual confidentiality clauses
- Ensure confidential treatment of any (proprietary) information developed, created or composed by contractual parties
- Confidentiality obligations must include sub-contractors, consultants and employees
- Address confidentiality after contract termination
- If suitable, provide for penalties for breach of confidentiality

Take Aways from Recent Cases

(4) Leverage through termination and cancellation clauses

- Termination of long-term contracts is complex and is time and cost consuming
- Leverage termination with short notice periods and option for cancellation of orders
- Consider the subsequent impact of contract terminations on the entire supply and distribution chain (and right exclusivities)
- Address termination payments, e.g. clientele compensation and costs

Termination for convenience

- Termination with immediate effect, but with termination costs
- Address regulatory and post-termination issues

Force majeure and hardship clauses

- Termination for reasons not originated with contractual parties
- Limited field of application, so do not rely on it

Q&A / Discussion

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