



Life Sciences Disputes: the Role of Arbitration and Mediation

Life Sciences Symposium: Intellectual Property and Life
Sciences Regulation - November 16, 2007

Ignacio de Castro

WIPO Arbitration and Mediation Center





WIPO Arbitration and Mediation Center

- Established 1994
- Statistics
 - ▶ Over 26,000 domain name procedures
 - ▶ 67 mediations
 - ▶ 88 arbitrations
- Subject Matter
 - ▶ Contractual: Patent licenses, distribution agreements, R&D, joint ventures, software/IT, trademark coexistence agreements, etc.
 - ▶ Court proceedings between parties
 - ▶ Pharma, biotech, medical devices

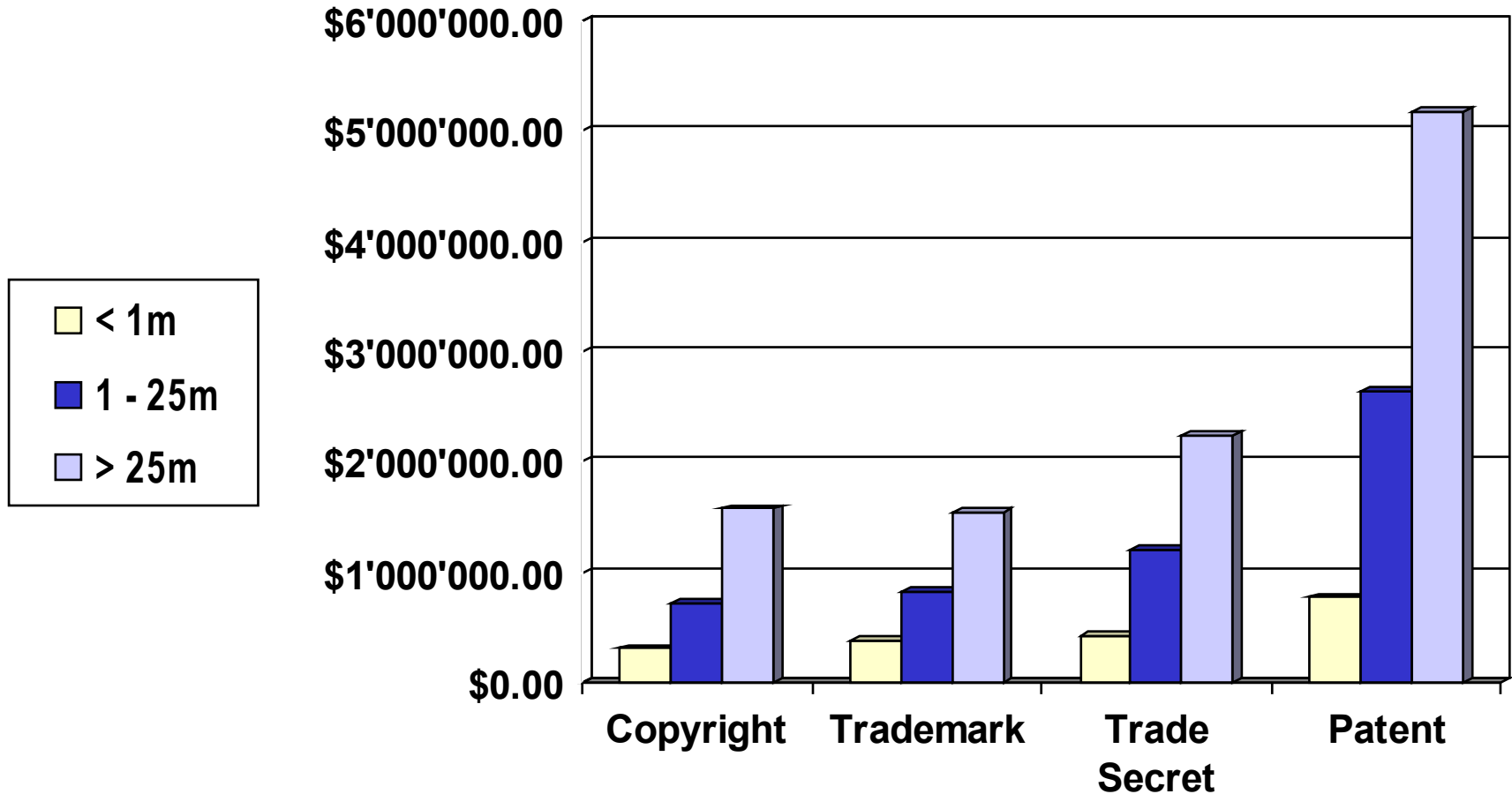


Dispute Resolution

- Globalization: IP international registration and licensing
- Enforcement IP country by country

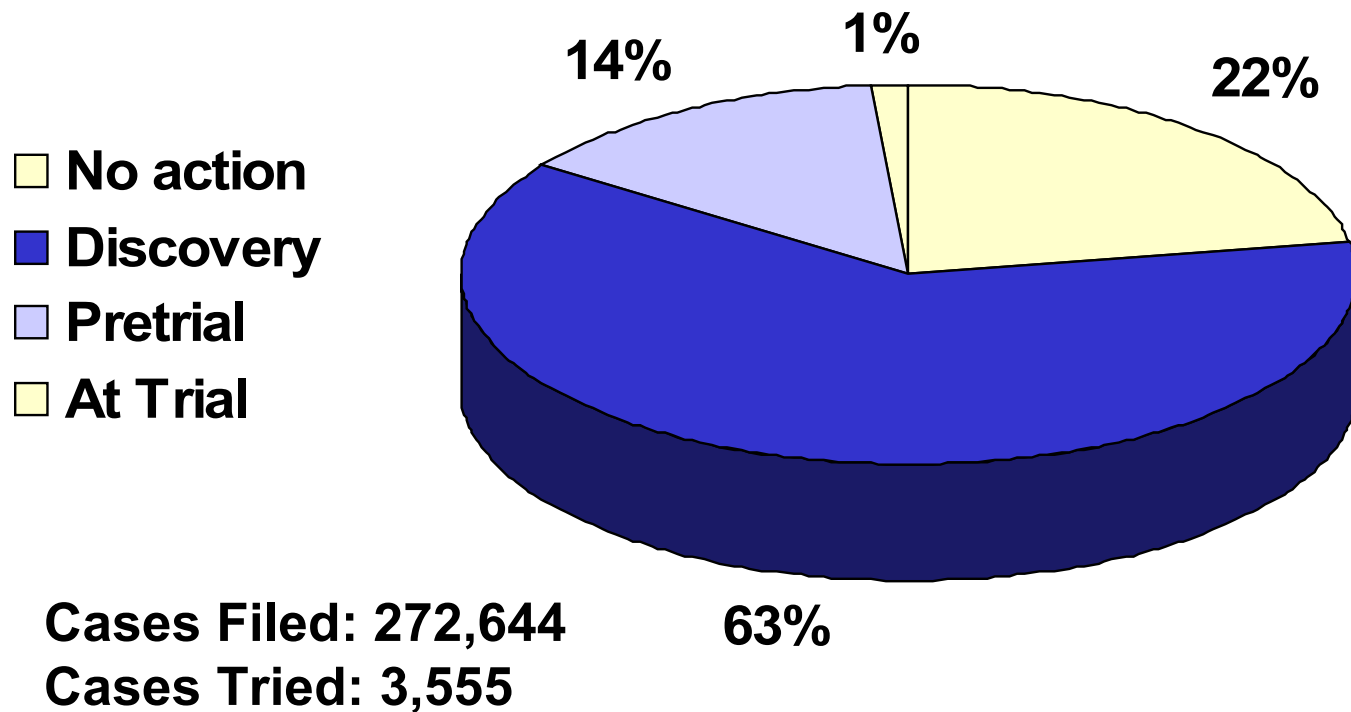
Country	Characteristic of Legal System	Average Length	Average Cost
France	<ul style="list-style-type: none"> - Civil Law - Unified Litigation - No specialized courts 	First Instance: 18-24 months Appeal: 18-24 months	€80,000-150,000 (1 st Inst.)
Germany	<ul style="list-style-type: none"> - Civil Law - Bifurcated Litigation - Specialized court for invalidity 	First Instance: 12 months Appeal: 15-18 months	€50,000 (1 st Inst.) €70,000 (App.)
Italy	<ul style="list-style-type: none"> - Civil Law - Unified Litigation - Specialized courts 	First Instance: few months – 24 months Appeal: 18-24 months	€50,000-150,000 (1 st Inst.) €30,000-70,000 (App.)
Spain	<ul style="list-style-type: none"> - Civil Law - Unified Litigation - Commercial Courts 	First Instance: 12 months Appeal: 12-18 months	€100,000 (1 st Inst.) €50,000 (2 nd Inst.)
UK	<ul style="list-style-type: none"> - Common Law - Unified Litigation - Specialized courts - Mediation promoted 	First Instance: 12 months Court of Appeal: 12 months House of Lords: 24 months	€750,000-1,500,000 (1 st Inst.) €150,000-1,500,000 (App.) €150,000-1,500,000 (House of Lords)
China	<ul style="list-style-type: none"> - Civil Law - Bifurcated Litigation - Specialized courts 	First Instance: 6 months (in law) Appeal: 3 months, no limit when foreigners litigate	Not Available
Japan	<ul style="list-style-type: none"> - Civil Law - Bifurcated Litigation - Specialized courts 	First Instance: 14 months Appeal: 9 months	Not Available
USA	<ul style="list-style-type: none"> - Common Law - Unified Litigation - Specialized court of appeals (CAFC) - Jury trial available - Mediation promoted 	First Instance: up to 24 months Appeal: 12 + months	Up to \$4,000,000 (1 st Inst.) \$150,000-250,000 (App.)

U.S. Litigation Expense



AIPLA Economic Survey 2005

U.S. Federal Court Resolution

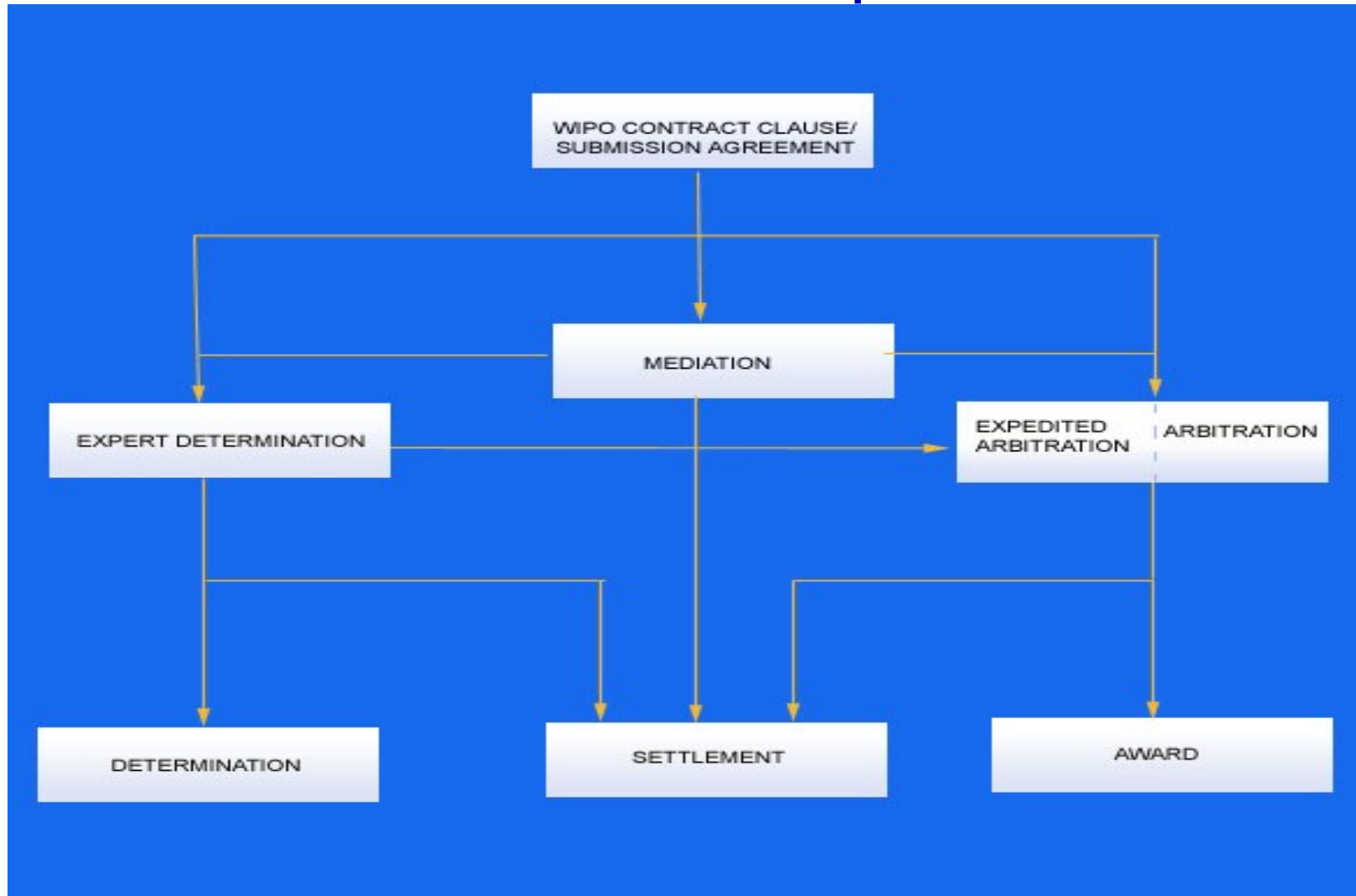


Federal Judicial Center, September 30, 2006 (MP)

Dispute Resolution

- National Courts:
 - Different legal systems
 - Expensive
 - Risk contradictory results
- Possible Solutions:
 - Brussels Convention
 - EPLA
 - Consolidation court procedures: Voda v Cordis (CAFC, February 2007)

WIPO Center: Options





Routes to ADR

- Voluntary decision of the parties
- Court annexed
- ADR clauses

Mediation followed by Arbitration

- Try mediation before arbitration, at least until
 - lapse of time period
 - termination
- Combining the benefits
 - arbitration well-prepared

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



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



WIPO Mediation

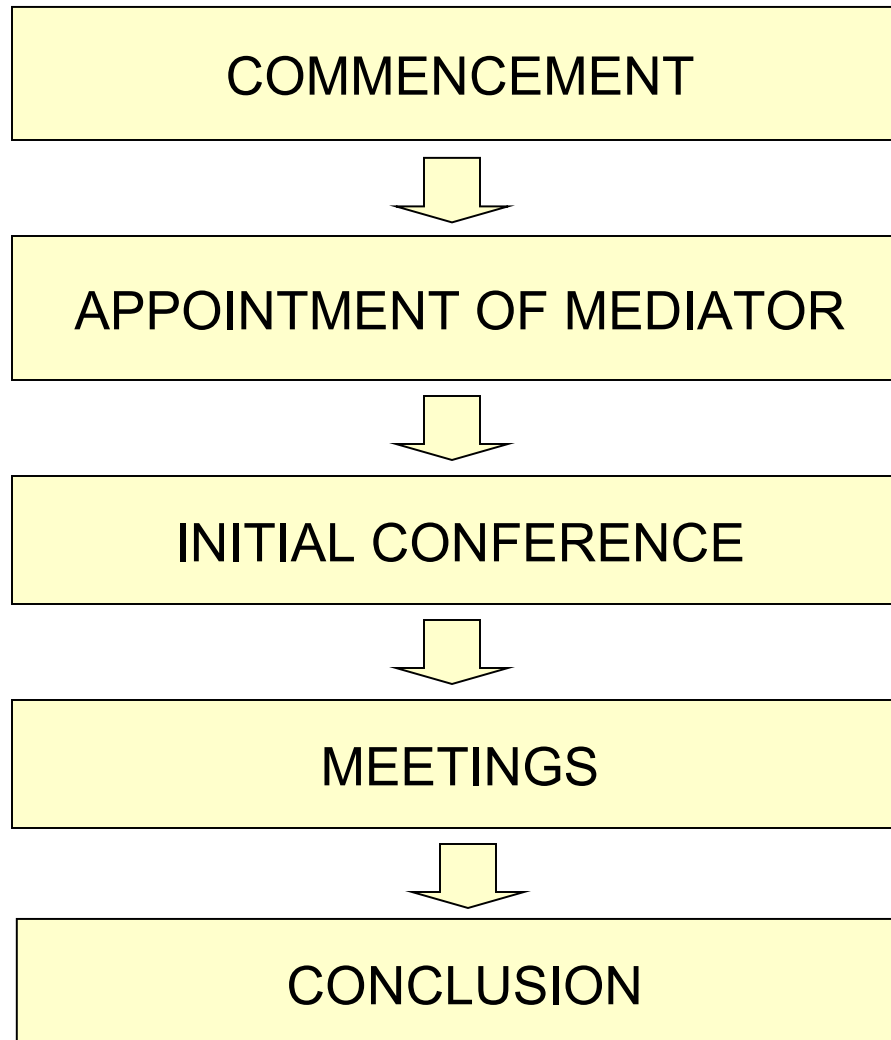
Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be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



Mediation

- Consensual
- Non-binding
- Confidential
- Limited risk
- Cost-effective
- 70% settlement

Mediation Process





WIPO Arbitration

Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules.

The arbitral tribunal shall consist of [a sole arbitrator]. The place of arbitration shall be [London]. The language to be used in the arbitral proceedings shall be [English]. The dispute, controversy or claim shall be decided in accordance with [English] law.

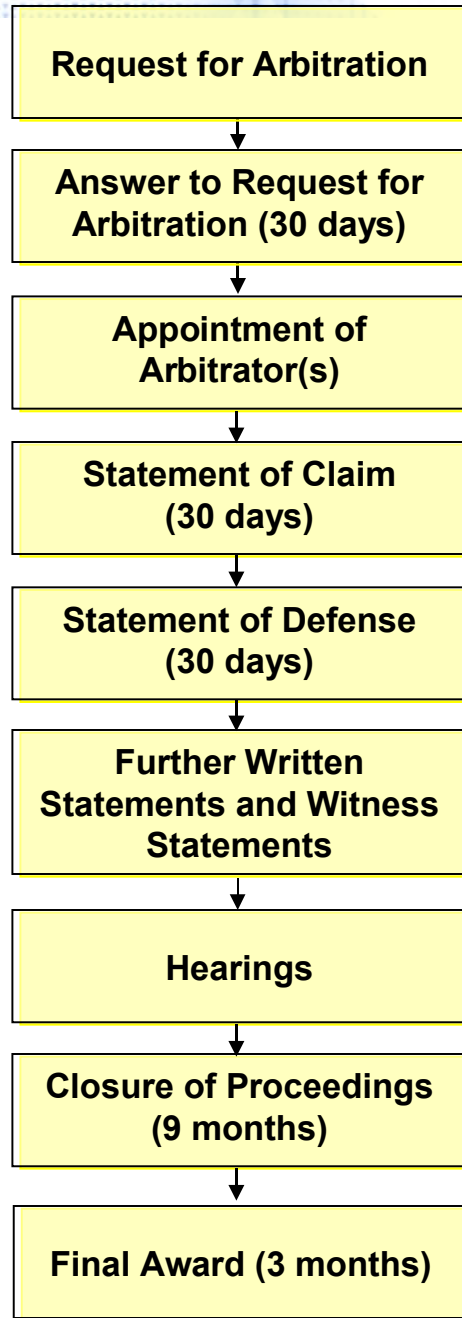


Arbitration

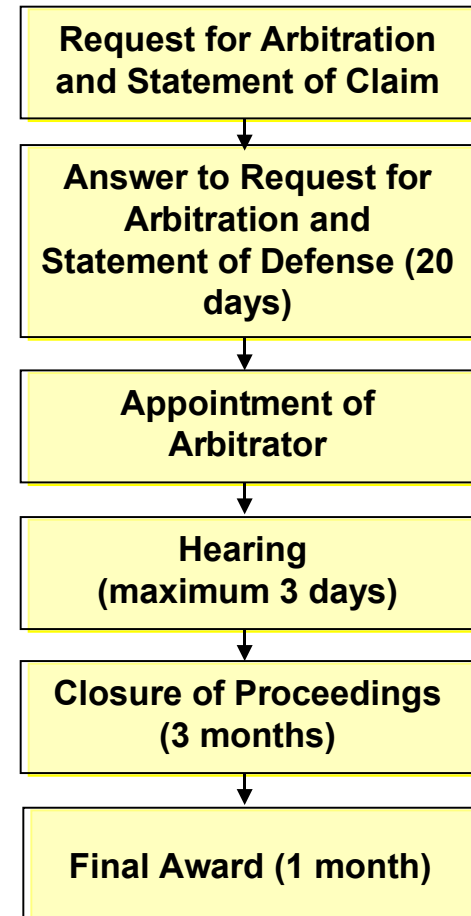
- Consensual
- Binding
- No Appeal
- New York Convention 1958



WIPO ARBITRATION



WIPO EXPEDITED ARBITRATION



- One exchange of pleadings
- Shorter time limits
- Sole arbitrator
- Shorter hearings
- Fixed fees

Biotech/Pharma Arbitration

- In 2000 Patent License and R&D Agreement between European biotech start-up and European pharma company
- WIPO Arbitration clause, sole arbitrator
- Alleged delays in testing and regulatory approval
- In 2005 biotech company files Request for arbitration
- Appointment of sole arbitrator
- Evidence including expert reports
- Hearing
- Settlement

Pharma Arbitration: Access to Test Data

- European pharma company holds patents in US, Europe and Asia and markets pharma product in Europe
- In 1998 European company licenses its patents to US pharma company
- US company to obtain regulatory approval with US Food and Drug Agency and market pharma product in US
- European company requests US company to deliver test data to apply for regulatory approval in Europe
- In 2006 European company files Request for arbitration

WIPO Electronic Case Facility (ECAF)

<http://www.wipo.int/amc/en/ecaf/index.html>

- Web-based electronic docket
 - For WIPO arbitration and mediation cases
 - Facilitates online communication and storage
 - Submission in most common formats (word, pdf,..)
 - Searchable by author, date, subject title
 - Email alerts
- Security
 - Authentication + Encryption + Firewall



WIPO ECAF Docket

The screenshot shows a web browser window displaying the ECAF Home page for case 2004A1. The page title is "2004A1 Licensing Ltd. v. AB Technics Inc.". A navigation menu includes "Case Overview", "Contact Information", "Time Tracking", "Docket Listing", "Finance Overview", and "Message Board". The "Docket Listing" section is active, showing a list of documents. A note states: "Only documents to be recorded as part of the casefile should be submitted in the Docket." Below the note are links for "Search Docket" and "Submit New File". A table lists the docket items with columns for Item No, Submitted By, Date, and Subject.

<u>Item No</u>	<u>Submitted By</u>	<u>Date</u>	<u>Subject</u>
7	John Doe Claimant Representative	14/02/05 14:52:51	<u>Claimant's Reply to Response</u>
6	Sophie Cloakville Respondent Representative	23/11/04 17:10:02	<u>Comments re: Confidentiality Advisor</u>
5	John Doe Claimant Representative	22/11/04 14:52:24	<u>Proposals re: Confidentiality Advisor</u>
4	John Doe Claimant Representative	14/05/04 17:18:48	<u>Mark Smith</u>
3	Sophie Cloakville Respondent Representative	14/05/04 17:13:50	<u>Answer to Request for Arbitration</u>
2	Tom Jones Case Manager	14/05/04 17:09:58	<u>Acknowledgment of Receipt of Request</u>
1	John Doe Claimant Representative	14/05/04 16:59:10	<u>Request for Arbitration</u>



Information

- <http://www.wipo.int>
- arbiter.mail@wipo.int