

International R&D and Technology Transfer Agreements

Negotiations and Conflict Management

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International R&D and Technology Transfer Agreements

Background

Innovative Healthcare Companies need numerous license agreements and collaborations in order to achieve/maintain a full product pipeline.



Immunological Testing



Blood Glucose Testing

Key to such R&D collaboration and technology transfer agreements and thus subjects of later disagreements and disputes are

- the scope of the collaboration
- the rights of the respective partners
- the field(s) of application
- the financials
- the opportunity of one party to compete

International R&D and Technology Transfer Agreements *Background*

In the pharmaceutical industry parties will typically go through an evaluation and allocation of tasks before development and clinical trials of product begin. Once successfully completed they lead to long-term manufacture or exploitation (marketing and sales) as long as patent protection exists. Regulatory requirements make swift changes difficult.

- Always long-term relationships
- Mostly of strategic importance
- Financial significance
- Complex multi-stage obligations of contract parties
- Amendments to agreed plans



Clinical Chemistry Testing

International R&D and Technology Transfer Agreements *Negotiation*

- Shared development activities need to be planned and set forth clearly.
 - *Deliverables, timelines, process for change decisions*
- Risky developments can lead to failure.
 - *Dispute clauses, steering committees*
- Milestones help to monitor progress.
 - *Risk allocation through milestone structure, compensation for work done*
- Exit provisions become more frequent.
 - *Transfer of work results, access to background technology*

International R&D and Technology Transfer Agreements *Negotiation*

- Universities conduct active IP exploitation.
 - *New approach in recent years*
- Negotiation of R&D Agreements is easier when the business models are understood (proprietary IP v. open IP).
 - *Agreement with competitor (same business model) can be easier than with university (different approach)*
- Universities should upgrade the quality of the IP/Licensing department and internal interfaces.
 - *Not a part-time position*
- Technology transfer should be encouraged as it is key for competitiveness.
 - *Filling the product pipeline is necessary and should result in a win-win situation*

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Dispute Resolution

Facts

In 2001 Roche and company X had entered into a co-development and supply agreement to develop an ISE Device for X's instrument. The product development yielded 6 prototypes and about 80 production instruments in 2002 and 2003, but X was not satisfied. Dispute over development steps and specifications arose and after many discussions the parties still had an insufficient development result. The unhappy contractual partner X sued Roche in a district court in Massachusetts.





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Dispute Resolution

Faced with the choice between a lengthy trial (estimated costs 1.5 Mio. USD) or mediation Roche took the initiative to propose mediation. The other side agreed to try mediation. Roche began preparations. These covered the contract history, financials, options, technology and opening briefs.

The mediation on the day was shuttle mediation where the mediator moved back and forth between the parties. It took almost 13 hours to come to a solution.

A payment to X was agreed and the dispute resolved.

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Dispute Resolution

Key Factors for Success in Dispute Resolution by Mediation

- Thorough preparation:
 - fact finding on overall relationship
 - fact finding on technical matters
 - legal and financial risk analysis
 - define goals
- Role of mediator
- Clear mandate for team at mediation
- Availability of back-up support



International R&D and Technology Transfer Agreements - Negotiations and Conflict Management *Summary*

- Collaboration, development, marketing or tech transfer agreements establish long-term relationships. Success depends on careful planning and follow through according to agreed R&D plan.
- If the parties anticipate problems during the negotiation or mediate their development difficulties early, the development can go on and the parties will most likely be successful.
- R&D contracts have to be specific and clear. Process for amendments needs to be defined.
- Any negotiated solution seems to be better than a one-time decision by an impartial third party. Template dispute resolution clauses encourage the use of mediation or alternative methods.

International R&D and Technology Transfer Agreements - Negotiations and Conflict Management *Summary*

- If the negotiated solution turns out to be lacking in some way, the parties are able to amend or to mediate a (new) solution.
- Disputes over R&D obligations or exploitation of license rights cannot linger on
4 – 6 years, which are sometimes necessary for a lawsuit.
- Mediation offers as expedited a solution as the parties require and a high degree of flexibility, e.g. mediation of one central question or mediation for a very limited time (with possibility to then find thereafter a solution without the mediator).



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