

Intellectual Property, Contracts and Disputes in Life Sciences & Bird & Bird

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Intellectual Property, Contracts and Disputes in Life Sciences

1. Overview of contracts concluded by Life Sciences stakeholders
2. Overview of commercial and IP disputes that arise out of Life Sciences contracts

Section 1 – Overview of contracts concluded by Life Sciences stakeholders

Overview of contracts concluded by Life Sciences stakeholders

- 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)

Overview of contracts concluded by Life Sciences stakeholders

Examples of Life Sciences contracts

- Non-disclosure agreements
- Clinical Trial agreements
- Collaborative R&D agreements
 - Research Collaboration Agreements
 - Commercial Development and Licence Agreements
- Product Manufacturing and Supply agreements
- Licence agreements
- Assignments/corporate transactions

Overview of contracts concluded by Life Sciences stakeholders

Which Life Sciences contracts are most likely to lead to disputes?

- In 2013, the WIPO Centre conducted the International Survey on Dispute Resolution in Technology Transactions
- Survey based on replies by 393 respondents from 62 countries, with 20% operating in the Life Sciences/Pharmaceutical/Biotechnology sector
- Overall, for all sectors, patent issues arose nearly twice as often as copyright or know-how. (n.b. this is not a forum for discussing 'pure' patent or copyright litigation)
- Over a quarter of all disputes related to licences:

	Non-disclosure Agreements	R&D Agreements	Licenses	Settlement Agreements	M&A Agreements	Assignments
Life Sciences	15%	20%	27%	15%	11%	12%
Pharmaceuticals/ Biotechnology	15%	20%	26%	13%	13%	13%

Source: WIPO Arbitration and Mediation Center, International Survey on Dispute Resolution in Technology Transactions

Section 2 – Overview of commercial and IP disputes that arise out of Life Sciences contracts

Overview of commercial and IP disputes that arise out of Life Sciences contracts

What is the most likely cause of disputes?

- 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

Overview of commercial and IP disputes that arise out of Life Sciences contracts

Examples of disputes in Life Sciences contracts

- 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

Overview of commercial and IP disputes that arise out of Life Sciences contracts

Example 1

- European university held pharmaceutical patent applications in several countries
- European pharmaceutical company held a licence option
- Pharmaceutical company chooses to exercise the option
- Parties negotiated for three years but were unable to agree terms for a licence

Overview of commercial and IP disputes that arise out of Life Sciences contracts

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

Overview of commercial and IP disputes that arise out of Life Sciences contracts

Example 3

- An international life sciences company granted a biotech company a licence to use its technology to bring the licensed products to market.
- Following a change of control of the life sciences company, it sued for breach of the licence agreement for failing to use reasonable endeavours to maximise the sales of licensed product within the terms of the agreement

Merck KGaA v Merck Sharp & Dohme / Merck & Co Inc

Example 4

National IP rights vs borderless internet

- History and co-existence



- Internet uses complained of: domain names, websites, social media, metatags, email address

Merck KGaA v Merck Sharp & Dohme / Merck & Co Inc

- Claimant successful. Being appealed.
- Targeting of "info/promotional" websites towards territories
 - Mere accessibility vs directing activity
 - UK specific elements, site architecture, visitor numbers, terms of use
- Geo-targeting/geo-blocking
 - Claimant's approach
 - Social media
 - Remedies
- Domain names and email addresses
 - Use in relation to goods/services?

Option for resolving disputes and points to consider

i. Litigation

- Which jurisdiction?
- Formal and complex procedure – lack of flexibility
- Adversarial nature
- Advantage to wealthy litigants
- Public proceedings
- Expensive

Option for resolving disputes and points to consider

ii. Arbitration

- Which seat of arbitration? Choice of language ? Choice of law?
- Will be compulsory
- Protect time bar
- No power to grant orders over third parties
- Private (beware foreign law appeals)
- "with prejudice"
- Costly
- Adversarial
- Risky?
- Costs recoverable and follow the event (generally)
- Appeal on point of law
- Final award enforceable as judgment

Option for resolving disputes and points to consider

iii. Mediation

- Private and confidential
- Without prejudice
- Quick
- Cheap
- Collaborative
- Reduces risk
- Costs shared 50/50
- Creates no precedent
- Final agreement readily enforceable
- WIPO expert determination?
- Renegotiation / settlement

Option for resolving disputes and points to consider

iv. WIPO expert determination?

- Suitable where there are technical, scientific or related business matters to be resolved
- e.g. valuation of IP
- Establishment of royalty rates
- Interpretation of patent claims
- Extent of rights covered by a patent
- Collaborative and done with parties' agreement
- Maybe binding or not
- Renegotiation / settlement

Option for resolving disputes and points to consider

1. Expert determination
 - WIPO expert determination?
2. Renegotiation / settlement

Overview of commercial and IP disputes that arise out of Life Sciences contracts

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
- Example 3 – the parties negotiated a settlement before trial, which altered the terms of the licence
- Example 4 – a long and expensive court case!

Thank you & Bird & Bird

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