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NETWORK INFLUENCE KNOWLEDGE LEARN

SESSION NUMBER 9

**IP COMMERCIALISATION, VALUATION AND
LICENSING**

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trading ideas

THE FUTURE OF IP IN ASIA PACIFIC

Licensing

- Licensing a very broad subject
- Focus on what is perhaps the most difficult part of a license to negotiate.
- Performance obligations
- More difficult to negotiate than royalties and financial terms.
- A licensee does not resist negotiating royalties and financial terms.
- It's a contentious part of a negotiation, but it is negotiated
- Performance obligations are more difficult to negotiate because
 - they are resisted
 - It is a contentious part of a license.

Outline

- What are performance obligations ?
- Why have them ?
- “Best endeavours” performance obligations
- Types of performance obligations
- Consequences of failing to comply with performance obligations

What are performance obligations

- Obligations that oblige a licensee to exploit a technology to a minimum extent
- Licensor seeks to
 - maximise its financial return on its technology
 - ensure that the licensee does not
 - underperform,
 - fail to perform
 - “shelve the IP”
- Performance obligations oblige a licensee to perform to a minimum extent
- With termination of the license / damages as the result if the licensee fails to do so

Are performance obligations necessary?

- Why would a licensee not perform?
- Has gone to the trouble of seeking and negotiating the license
- Not in the licensee's interests to be idle, nor to underperform

- In the licensee's interests to maximise the financial returns from the commercialisation of the technology

- Interests of the licensor and the licensee are aligned
- Both wish to maximise financial return
- That being so, are performance obligations really necessary ?

Are performance obligations necessary?

- Postulate:
- License granted of technology that is not fully developed
- Licensor licenses to partner with a licensee that has the capability to complete R&D, and to take to market
 - Engineering product at prototype stage
 - IT Product: patents & theoretical code but no application code
 - Biotech product in late pre-clinical stage, with years of clinical development still to go
- Licensee has finite resources
- Resources sufficient for top 3 projects – this one ranks fourth
- Licensee makes a prudent commercial decision to defer R&D
- The technology remains idle, perhaps forever
- Licensor obtains no financial returns

Are performance obligations necessary?

- Postulate:
- License is granted to an Australian licensee
- Australian licensee has no capability of servicing a global market
- Australian licensee must go out and secure global partners
 - To complete R&D
 - To travel regulatory / clinical pathway
 - To enter the global market place
- Australian licensee's global network uninterested
- Australian licensee fails to establish global partners
- Technology remains idle, perhaps forever
- Licensor obtains no financial returns

Are performance obligations necessary?

- Postulate:
- At the time of the license the licensee has best of intentions to commercialise to the maximum extent
- Afterwards
 - Licensee develops its own competing product
 - Licenses in a superior competing product
 - Licenses in an inferior but less expensive competing product
- Licensor's technology remains idle, perhaps forever
- Licensor obtains no financial returns

Are performance obligations necessary?

- In each case
 - Technology is idle
 - Licensor obtains no financial returns
 - Technology is trapped with the non performing licensee
- Licensor needs a mechanism to achieve:
 - Termination of license
 - Reversion of rights back to the licensor
 - Licensor free to go out and find another licensee that can perform and maximise the financial returns back to the Licensor

Are performance obligations necessary?

- Licensee to Licensor
- “But if any of that happens, I’ll give up my rights and you can have the technology back”
- May be said with the best of intentions
- But:
 - Will not be done if the Licensee has developed or licensed in a competing product
 - Will not be done if the Licensee is an Australian licensee with the prospect of capital gains tax being triggered by the surrender of the license

“Best endeavours” obligations

- Licensee to Licensor:
- “I’ll agree to use my best endeavours to commercialise”
- May once have been a sufficient obligation
- “Best endeavours” obligations were once onerous obligations:
- Required “leave no stone unturned”: *Sheffield District Railway Co v. Great Central Railway Co* (1911) 27 TLR 451
- “Best endeavours means what it says - it does not mean second best endeavours” *Sheffield District Railway Co v. Great Central Railway Co* (1911) 27 TLR 451

“Best endeavours” obligations

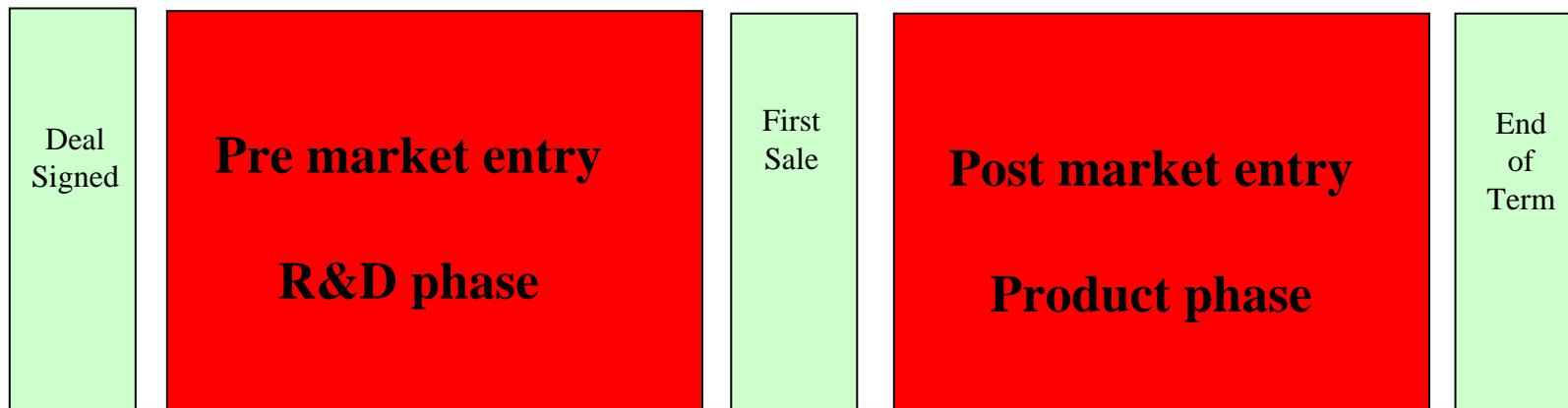
- But best endeavours obligations have been watered down
- It requires what “could reasonably be expected... having regard to the circumstances” *Transfield Pty Ltd v. Arlo International Ltd* (1980) 144 CLR 83
- commercial and financial considerations can be taken into account to weigh up the reasonableness of the obligation *Terrell v Mabie Todd & Co* [1952] 2 TLR 574
- These commercial considerations may operate to relieve a Licensee from the obligation to perform
- This is one of the issues in the current litigation between Biota Limited and GSK in relation to its license of Relenza to GSK

“Best endeavours” obligations

- Best endeavours obligations:
- Vague
- Uncertainty of whether the obligation would be found to be breached
- Not a basis upon which to terminate
 - It may take years to sort the issue out
 - In the meantime the technology
 - is not is not earning a financial return
 - may become superceded
- Not necessarily a basis to confidently seek damages
- Reasonable endeavours - a lower standard, and not a better option

Better approach to performance obligations

- A better approach to performance obligations is
 - to negotiate precise performance provisions
 - to provide for the consequences of non compliance
- Two phases to consider performance obligations:



Performance obligations - R&D phase

- Licensor wants to know that the Licensee
 - Will continue R & D (if applicable)
 - Will complete R & D (if applicable)
 - Will expeditiously start and travel the regulatory pathway (if applicable)
 - Not “shelve” the IP
- Commercialisation Milestones
 - Milestones that a Licensee must achieve along the R&D and regulatory pathway
 - Not achieve milestone – license is ultimately terminated

Performance obligations - R&D phase

- Commercialisation Milestones: engineering example:
 - If more research is needed to bring product to a market ready state, the completion of that research
 - Produce a prototype
 - Conduct a trial
 - Complete construction of pilot plant
 - Complete construction of production plant
 - Obtain any regulatory approval
 - Employ a person with particular expertise
 - Grant a sub license to a partner in key market
 - First sale anywhere in the world

Performance obligations - R&D phase

- Commercialisation Milestones: Biotech example:
 - If following completion of research, more research is needed to bring products to a market ready state, the completion of that research
 - Completion of animal studies
 - Completion of collection of data for lodging IND in USA
 - Commencement of Phase 1 Clinical Studies
 - Commencement of Phase 2 Clinical Studies
 - Commencement of Phase 3 Clinical Studies
 - Filing of NDA with FDA in USA
 - Approval of NDA with FDA in USA
 - First sale anywhere in the world

Performance obligations - R&D phase

- If these pre market entry milestones are not achieved
 - There may never be market entry and sales
 - Licensor may never receive royalties
- There needs to be mechanisms for
 - Termination
 - Reversion of rights to licensor
- So that
 - Licensor can find another licensee
 - Licensor can earn financial returns from a Licensee capable of achieving these pre market entry commercialisation milestones

Performance obligations - R&D phase

- Ultimately, failure to achieve these milestones must lead to termination and reversion
- But a sudden termination, given the uncertainties of traveling the R&D and regulatory path is draconian
- Many models that allow flexibility, but ultimately with termination
- For example:
 - Dates by which milestones must be achieved
 - Mechanisms for extension of time – discretionary and mandatory
 - Termination if not achieved in any extended time

Performance obligations - R&D phase

- Negotiating commercialisation milestones of this type with a licensee is perhaps the hardest part of a license negotiation
- In some respects harder than negotiating financial terms
- Licensee makes a speculative investment
- Does not wish that speculative investment at risk by the failure to comply with a timeline for the achievement of commercialisation milestones
- This is why there needs to be
 - flexibility in timeframes for the achievement of milestones
 - mechanisms for extensions of due dates

Performance obligations - R&D phase

- Particularly difficult to negotiate commercialisation milestones with
 - Multinationals
 - Pharmaceutical companies
- A Licensor may spend \$5m in developing a drug
- A Licensee will spend \$800m in completing the R&D and clinical phase to bring it to market
- The further away the technology is from market entry, the more difficult it is to negotiate
- The closer the technology is to market entry, the less difficult

Performance obligations – Product phase

- Performance obligations do not cease after market entry
- After first sale, Licensor wants to ensure that there is the maximum possible penetration of the market
- Achieved by minimum sales
- If minimum sales not achieved:
 - License may convert to non exclusive
 - Allowing licensor to find another non-exclusive licensee
 - License may be terminated
 - Rights revert to licensor
 - Again, allowing the licensor to find another licensee

Performance obligations – Product phase

Territory	Period	Target, in units
USA & Canada	Year 1	1.0m
	Year 2	1.25m
	Each following year	1.5m
European Union	Year 1	1.5m
	Year 2	1.75m
	Each following year	2.0m
China & South East Asia	Year 1	0.75m
	Year 2	1.0m
	Each following year	1.25m

Performance obligations – Product phase

- Might consider:
 - Broad geographical markets, region by region
 - Smaller geographical markets, country by country

 - Flat minimum sales in each period
 - Ramped up sales as marketing is ramped up, followed by flat minimum sales
 - Minimum targets holiday in initial period after market entry, followed by ramping up, and then flat sales

 - Reassessment of minimum sales if a competing product enters the marketplace

Conclusion

- All these performance obligations strategies aimed at
 - maximising the financials benefits back to the licensor
 - minimising the risk of a non performing or inadequately performing licensee
- Licensee's failure to perform may be reasonable
 - Resource issues
 - Capital issues
 - Marketing networks
- Not unreasonable for a licensee to inadequately perform
- But in that case, not unreasonable for a licensor to be able to
 - Terminate
 - Have IP revert back
 - Be able to find an alternative licensee