

Success Factors in Licensing in the Pharmaceutical Industry

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RESUME

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Education

Ph.D., Dental Regenerative Biotechnology, Seoul National University

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Publications & Presentations

Review of interpretation of patent claim scope (2001)

The Patentability of Human Embryonic Stem Cells Derived from Somatic Cell Nuclear Transfer (2006)

Strategic Patent Management (in field of Chemistry and Biotechnology) (2009)

Business Development utilizing Antibody-binding peptide (2012)

Affiliations

Korea Biotechnology Industry Organization

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Minister Prize from the Ministry of Environment (2011)

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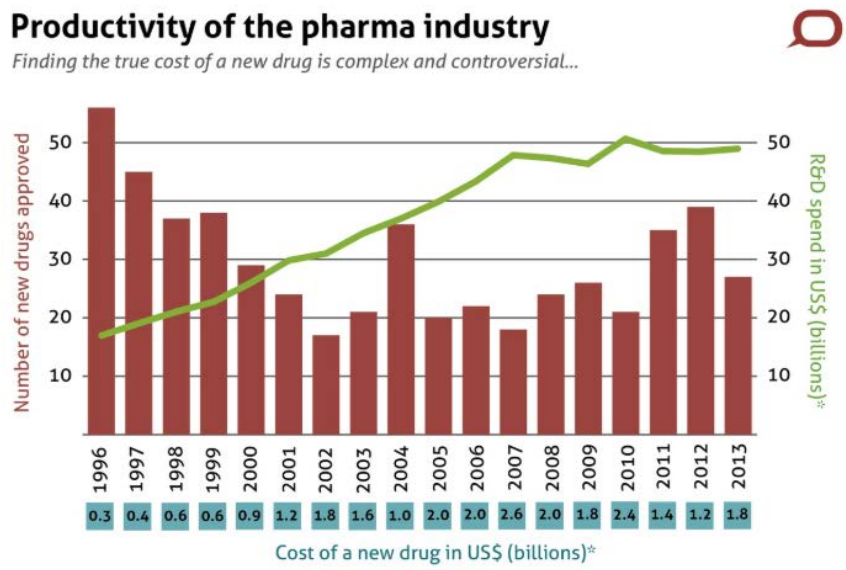
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1. INTRODUCTION

- The pharmaceutical industry has in the recent decade struggled with its financial performance and maintaining its former stellar R&D productivity

- An analysis of the 15 largest pharmaceutical companies showed that the companies lost around \$850 billion in shareholder value, from 2000 until 2008, and that the average share price fell from 32 to 13 times earnings (Garnier, 2008).



Data: USFDA, PhRMA
Akshat Rathi | theconversation.com * New drug cost and R&D spend could be 30% higher if non-PhRMA members are included

1. INTRODUCTION

- Several challenges have had an impact on the industry's financial performance, e.g. patent expiration of several blockbuster drugs shorter exclusivity periods, declining R&D productivity, higher cost of commercialization and increasing payer influence (Garnier, 2008).



- The patent expiration of drugs between 2010 and 2014 has estimated to have put around **209 billion US dollar in drugs sales** at risk (Evaluate Pharma Alpha World Preview 2014, Evaluate pharma Report 2009).



1. INTRODUCTION

- Several scholars argue that the traditional business model in the pharmaceutical industry needs to evolve to solve the grand problem of a declining R&D productivity (Booth, et al., 2004; Paul, et al., 2010)
- Traditionally mergers and acquisitions (M&A) have been the usual response as an effort to fuel the internal R&D pipeline.

- However, the results of M&A activities have not been able to increase the R&D productivity. On the contrary, a review of Ornaghi (2009) showed that companies that are very active with M&As actually perform worse.

Pharma and Biotech M&A Transactions Announced Each Quarter

Source: EvaluatePharma* January 2017



1. INTRODUCTION

- Chesbrough (2003) introduced the concept **open innovation** as a new paradigm where a firm can and should use both external and internal knowledge and ideas to accelerate internal innovation.
- It is safe to say that drug development has transformed into an open innovation ecosystem where small biotech companies are the innovators and where the large pharmaceutical companies act as their commercialization partner.

The Future of Pharma R&D

How external innovation changes pharma R&D

Research and Development (R&D) is crucial for the growth and future success of research-based pharma companies. To maintain their R&D organisations efficient, pharmaceutical companies started to hedge the potential of open innovation to cut R&D costs and to access external knowledge. These new strategies could be divided into several categories: open source, innovation centres, crowd sourcing and virtual R&D.

Alexander Schuhmacher, Professor, Reutlingen University
Michael Kuss, Partner, PeC's Governance, Risk & Compliance (GRC) Practice



R&D has traditionally been and will continue to be (probably even more) crucial for the growth and future success of research-based pharma companies. Given the industry's traditional R&D strategy, that was built on internal innovation, and the rising regulatory hurdles, pharma companies continuously increased their financial input into R&D related work with the hope to produce a higher nominal R&D output. Today the total worldwide R&D spend of pharmaceutical and biotechnology companies amounts to US\$150 billion, the global average R&D rate (R&D as per cent of sales) of pharma and biotech companies is 10.6 per cent (for the big players up to 20 per cent) and 15 companies in the top 50 R&D investors worldwide based on their R&D rate are pharma companies [1]. Two simple comparisons with the automotive and the chemical sectors illustrate the importance of R&D in the pharma industry:

1. INTRODUCTION

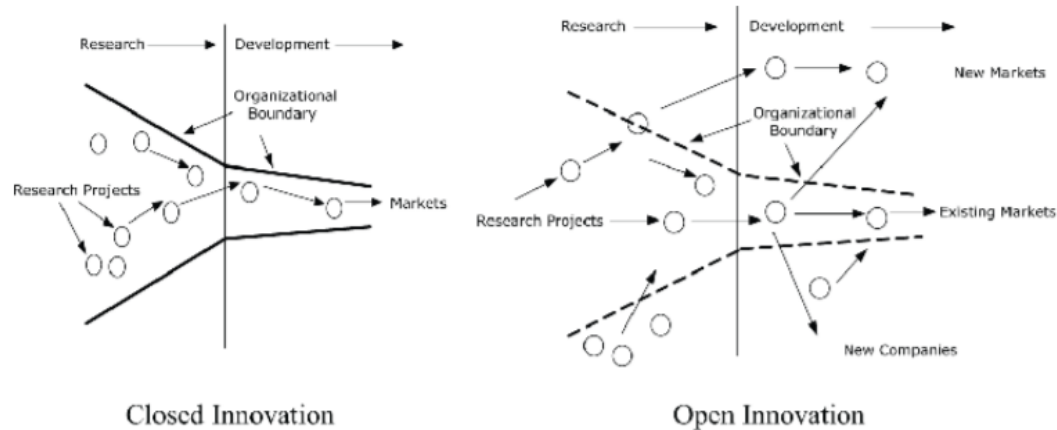


Figure 1. Comparing closed innovation and Open innovation. The closed innovation model with its organizational boundaries can be observed on the left, where all the generation of innovation occurs within the firm. The concept of open innovation can be observed on the right side with an influx and out-flux of knowledge crossing organizational boundaries. Source: Chesbrough 2006.

- In the open innovation model, companies fill the gap of their internal product portfolio through licensing and acquisition of drug candidates.
- In-licensing compound from a biotech company or a university allows the pharmaceutical companies to avoid the full cost of development, decrease the early risk and selectively choose products that fit the firm's business model.

2. Licensing in the Pharmaceutical Industry

- The complex activity of out-licensing is the sum of several sub-activities which include as follows (Reepmeyer, 2006).
 - strategic planning,
 - preparation of supporting material,
 - targeting of potential opportunities,
 - evaluation of the product and partner,
 - contact with potential partners,
 - due diligence,
 - negotiation and
 - the maintaining and management of the deal once it is set in place

2. Licensing in the Pharmaceutical Industry



General out-licensing process in the pharmaceutical industry adapted from Reepmeyer (et al., 2006)

1 The first action of an out-licensing process is **the decision of which product to potentially license out.**

- the intellectual property status,
- potential commercial positioning and
- unique characteristics of the product.

2 The data gathered during this phase is what **makes up the prospectus**, a document that is reviewed internally to access and evaluate the opportunity (Reepmeyer, 2006).

2. Licensing in the Pharmaceutical Industry

3 After the prospectus document has been set up, **the identification of the optimal partner profile** is constructed.

- Smaller biotech companies do not have access to all the necessary skills and organizational capabilities to commercialize the product.
- Drug development is changing rapidly, the sources of knowledge are dispersed across many companies, requires regulatory savviness and is financially demanding.
- Biotech firms will have strong incentives to enter into an array of alliances (Powell et al., 1996).

4 Once the characteristics of the optimal partner has been constructed, it is up the business development and licensing department to **set a list of potential partners**.

General out-licensing process in the pharmaceutical industry adapted from Reepmeyer (et al., 2006)

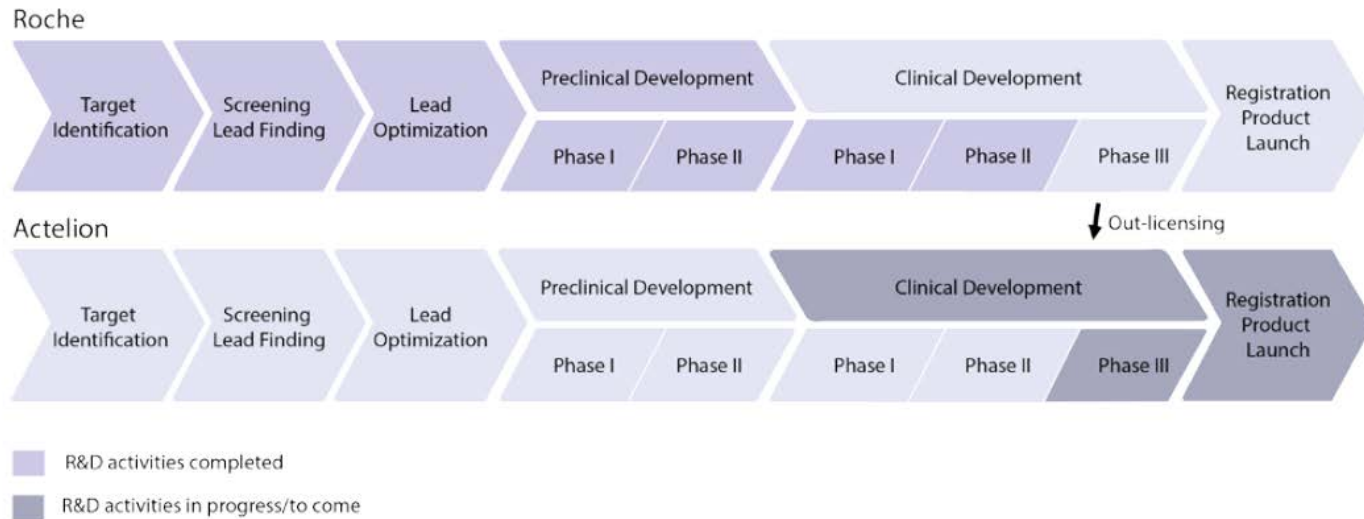
2. Licensing in the Pharmaceutical Industry

- 5 Once the interest of partner firm has peaked and a **non-disclosure agreement**
- 6 has been signed, the biotech company can choose to **share additional sensitive and confidential material**. This is the initiation of the **due diligence process**
- 7 and this often includes close communication and the exchange of critical information and knowledge between the firms. Not unusual in this phase is providing the product for test trials at the partner's own research locations enabled by a **material-transfer agreement** and site visits as an effort to convince the partner to acquire the license.
- 8 Once the due diligence process has been completed, the two actors need to define the contractual detail and **negotiate the deal terms and structure**. Term sheets are exchanged in the start of negotiations as a suggestion of deal structure, scope and financial terms of the deal.
- 9 Once an agreement has been reached and **a licensing agreement has been signed** the deal is **completed**. What remains is to **maintain and support the partner** during the remainder of the agreement (Powell, 1996).

industry adapted from Reepmeyer (et al., 2006)

2. Licensing in the Pharmaceutical Industry

- Example of a licensing deal- *Licensing deal between Roche and Actelion.*



- A timeline of the licensing deal between Roche and Actelion in relation to the **drug development process** is presented.
- In this case Roche decided that the development of the asset was best suited for out-licensing. Actelion in-licensed the phase II asset and was thereafter responsible for further development and commercialization of the asset.

3. Success Factors for licensing deal

Theoretical Framework of Financial Value Drivers by Arnold

- A key insight from the work performed by **Arnold** and her group is that various financial valuation methods do not explain the valuation of many licensing deals. Thus suggesting that the total value of a deal cannot be defined by only looking at a financial valuation.
- The framework is built on an analysis where 16 biotechnology leaders were tasked, through a survey, to rank which factors influence the deal value and assess the importance of certain value drivers.

Ranking	Factor
1	Phase of molecule
2	Therapeutic area
3	Type of agreement
4	Scope of agreement
5	Type and reputation of partner
6	Type of molecule

3. Success Factors for licensing deal

Perception about the Importance of value drivers

[Factors mentioned most times as a value driver]

Ranking	Factor
1	Market: including market size, market potential and patient population
2	Stage: phase or stage in development, e.g. phase I-III
3	Strategy: the strategic fit with the company's pipeline and potential synergies
4	Competition: competition from other companies on the same target or other substitute products
5	Reputation of the licensee or licensor: including management or scientific talent
6	Investments: the financial need to develop the product
7	Intellectual property: access to key patents or other IP
8	Novelty: the inventiveness level of the product
9	Control of development and commercialization
10	Comparable deal values: similar target or technology
11	Reimbursement: willingness of payer to pay for the treatment

3. Success Factors for licensing deal

Theoretical Framework of Financial Value Drivers by Arnold

- The most interesting results from Arnold's (et al., 2002) analysis is that 46-68 % of the deal value cannot be accounted for by defined **quantitative** parameters. Meaning that **qualitative factors such as negotiation skills** most likely play an important role and constitutes the remaining 32-54 % of deal values.
- It is logical to assume that the perceived value drivers in the above table will also have an impact on the likelihood of getting a licensing deal in place. Therefore, a part of the focus in this thesis will be to investigate, test and further expand on the factors in the above table.

3. Success Factors for licensing deal

Theory about Strategic Fit

- **The concept of strategic fit** is nothing new in business research and several different aspects and themes of strategic fit have been debated and researched extensively (Venkatraman, et al, 1984). According to A Dictionary of Business and Management from Oxford University Press (Law, J., 2016) **strategic fit is defined as:**
 - “The extent to which diversification into another field fits with the future scope of a firm. To evaluate whether or not the proposed action would fit strategically with a firm’s plans requires the strategic logic to be examined in detail and the extent to which integration could be achieved to be evaluated.”
 - Most of the research regarding strategic fit in the interplay between biotech companies and large pharmaceutical companies focuses on how their business models, both the biotech and pharmaceutical companies, should be adapted to fit with a changing environment e.g. in research done by Carsrud (et al., 2008).
 - Hess (et al, 2011) researched strategic fit in relation to the value chain in the pharmaceutical industry and defines a fit or that an asset is complementary as when upstream (discovery research) and downstream (marketing) process are matched.

3. Success Factors for licensing deal

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3. Success Factors for licensing deal

In-depth Interviews with Industry Professional

- Three in-depth interviews were conducted and the results have been divided into four topics: **Success Factors, Strategic Fit, Deal-breakers and Value Drivers and Likelihood of Completion**. These topics were chosen based on the result of both the literature review and the interviews.

Success Factors

- As an entry point into the discussion of success factors, the interviewees were given open ended and exploratory questions regarding their perceived success factors in licensing activities.
- From these discussion, several categories of success factors were brought up and discussed in further detail. These factors have been categorized into broader categories below.

3. Success Factors for licensing deal

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3. Success Factors for licensing deal

- Success Factors**
- *Scientific Attractiveness and Quality of Data Package*
 - *Relationship*
 - *Differentiation from Competition*
 - *Strategic Fit*
 - *Timing and Momentum*
 - *Commercial Attractiveness*
 - *Internal Project Champions*
 - *Competition or the Perception of Competition*
 - *The Lack of Mention of IP and the Non-necessity of Freedom to Operate*

3. Success Factors for licensing deal

① Scientific Attractiveness and Quality of Data Package

- The first factor mentioned by all the industry professionals as the main critical success factor was **scientific attractiveness**. As one of the interviewees put it: **“It’s the science that drives the deal”**.
- According to the industry professionals, scientific attractiveness is determined by the quality of the data package. The data package needs to be convincing and as stated by the interviewees it is key that it represents the stage of the asset.
- For example, a phase II asset should have a data package that represents that stage and supports further clinical development without having to build up data that already should have been gathered since this will negatively affect timelines, labeling possibilities and increase risk.
- An aspect that was mentioned as an important factor in relation to the scientific attractiveness and data package was a transparent communication about what data you have and what data you lack and how and when you will generate it.

3. Success Factors for licensing deal

① Scientific Attractiveness and Quality of Data Package

- The data set is also highly linked to the concept of best-in-class and first-in-class.
- For **a potential first-in-class asset**, a less comprehensive data set can be offset with the opportunity to be first to market with a new mechanism of action (MoA). On the contrary, for **a best-in-class asset** more data needs to be shown to prove that the asset is superior to what already is or will be on the market.

3. Success Factors for licensing deal

- ② **Strategic Fit**
- During the conversations the topic of strategic fit was raised and the factor was deemed significant during all aspect of the deal making process.
 - Specific components of strategic fit that were mentioned by the interviewees were e.g. **established sales force within the indication, complementing to existing product portfolio** and **aligned with overall strategy.**
 - Essential factors mentioned were focusing on **the characteristics of the partner and aspects of scientific and business synergy.**

3. Success Factors for licensing deal

3 Commercial Attractiveness

- All the industry professionals mentioned **commercial attractiveness** as an important factor.
- The commercial attractiveness goes hand in hand with **an unmet medical need and a clearly defined patient population.**
- When it comes to valuation of the asset a rNPV (risk-adjusted net present value) model is standard in the industry when it comes to clinical stage assets.
- The rNPV model of the asset is however rarely shared. What was regarded as important, is to be transparent with assumptions in relation to the commercial case.

3. Success Factors for licensing deal

4 Differentiation from Competition

- A success factor that was mentioned by all of the biotech experts and is highly linked to both scientific and commercial attractiveness is **differentiation**.
- If you have an asset that is not differentiated from competition, then the scientific attractiveness is likely lower and the commercial case not as good.
- In a sense the concept of differentiation overlaps with competition. However, differentiation can also include a novelty aspect which in itself can be regarded as a success factors, as one of the interviewees brought up.

3. Success Factors for licensing deal

5 Timing and Momentum

- **Timing** was mentioned as a success factor.
- An interesting aspect of timing is that the professionals talked about it as an “**element of luck**” or “**serendipity**”.
- If you have good timing and starting to gain traction within the partner organization, keeping the momentum up is a key according to the interviewees. As one of the interviewees put it: “*There are thousands of reasons not to do a deal, so move fast when you have reached a term sheet*”
- A factor with strong ties to both timing and momentum is the effect of market trends or an increased interest in a specific indication or MoA at the time.
- As an example **immuno-oncology** and **CRISPR/Cas9** are two “**hot fields**” at the moment where a lot of investments are made. A “**hot indication**” comes with increased likelihood of more licensing deals being made but it also increases the amount of competition.

3. Success Factors for licensing deal

6 Competition or the Perception of Competition

- The perception of competing actors interested in the product was mentioned as an important factor of product licensing and particularly relevant to the likelihood of deal completion and as an important value driver.
- The factor was deemed particularly important as it incentivizes the potential actors to advance more quickly in the deal process.

3. Success Factors for licensing deal

- 6 Relationship**
- A success factor that was mentioned by all of the experts was **relationships** and especially what entry point you have into the potential partner's organization.
 - As an example one of the interviewees talked about **how personal relationships between the executive management** at both companies can prioritize the review of an opportunity.
 - This factor can further give an additional indication on what some of the qualitative factors are that Arnold (et al., 2002) has shown make up for a lot of the value in a licensing deal.

3. Success Factors for licensing deal

7 Internal Project Champions

- Individuals characterized as **internal project champions** within the potential partner's organization was identified by all interviewees as a highly influential success factor.
- The interviewees differentiate between scientific and business connected champions but were not unanimous in their differentiation. The importance of an internal champion was increased if the evaluation process at the partner company is rigorous and takes a long time.
- The product licensing deal might in an initial process be declined but remain in the potential deal making sphere thanks to the persistence of a project champion and eventually find a better footing in the conversation and results in a deal completion.

3. Success Factors for licensing deal

8 The Lack of Mention of IP and the Non-necessity of Freedom to Operate

- From a knowledge based economy perspective intellectual property rights are key to profit financially from a valuable asset (Petrusson, et al. 2009).
- The value of one single patent, a composition of matter patent, in the pharmaceutical industry **has a very high value** in comparison to what **a single patent** in many other industries e.g. information and communications technology (ICT) has. In the ICT industry the value of **a patent portfolio** is more relevant than the value of **a single patent**.
- IP was not mentioned as a success factor in the interviews initially. However, when the subject was brought up it was a consensus among the professionals that it is important to have IP protection and **that regulatory exclusivity is not enough** but that it is more of a requirement that is checked off and not something that has a large impact on a potential deal.

3. Success Factors for licensing deal

8 The Lack of Mention of IP and the Non-necessity of Freedom to Operate

- Interesting is **the question of freedom-to-operate (FTO)**. One of the experts stated that the industry in general has become more and more relaxed when it comes to IP and FTO and that companies are prepared to launch at risk despite the fact that there might be dominant IP out there.
- The interviewee brought up the ongoing patent dispute between Bristol-Myers Squibb/Ono Pharmaceuticals and Merck & Co regarding **PD-1 antibodies** arising in 2014 and another lawsuit from 2016 between Morphosys and Johnson & Johnson regarding **CD38 antibodies**.
- Yet **another good example** is the large investments made in and large IPOs by companies working on CRISPR/Cas9 **despite the fact that** the patent landscape is uncertain and is currently being battle out through an interference proceeding.
- As one of the biotech experts said during the interview, this can be due to the fact that there are so many things that can go wrong during drug development and to take the patent landscape into account for a preclinical asset, when the likelihood of even reaching the market already is low, does not make too much sense.

3. Success Factors for licensing deal

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- As one of the biotech experts said during the interview, this can be due to the fact that there are so many things that can go wrong during drug development and to take the patent landscape into account for a preclinical asset, when the likelihood of even reaching the market already is low, does not make too much sense.

3. Success Factors for licensing deal

Strategic Fit

- **The importance of a strong strategic fit** was strongly stressed by the interviewees and the literature research as critical success factors that heavily influences the deal outcome.
- **Several components of strategic fit** that were highlighted during conversations with the interviewees were;
 - existing salesforce or clinical program in the therapeutic area,
 - complementary to existing product portfolio,
 - complementary capabilities e.g. development, technology and regulatory expertise, executive management relationships and management credibility.
- However, strategic fit is not always something that is apparent to an external actor and therefore needs to be communicated.
- One interesting aspect and potential downside of having an existing salesforce or clinical program within the same therapeutic area is that it increases the risk of cannibalization of the partner's internal programs.

3. Success Factors for licensing deal

- Deal-breakers*
- Deal-breakers have been defined as factors that are an absolute requirement but do not necessarily increase the value or likelihood of the deal.
 - Several factors have been mentioned but response has not been as clear cut. However, one factor that stood out was **IP**. It is essential that the drug program is protected but in relation the strength of the IP is not as important and does not affect the deal to a larger extent.
 - Another factor that was mentioned throughout the interviews was **conflicting data and scientific reputation of the licensor**. This leads back to the fact that it is the scientific attractiveness that is the key success factor.

3. Success Factors for licensing deal

- Deal-breakers***
- An interesting aspect of deal-breakers are “**must-haves**”.
 - A must-have is an individual deal-breaker for one of the parties involved in the negotiation e.g. “we need to have a co-development structure for this asset”. When it comes to negotiations, a communicated must-have really needs to be an absolute requirement.
 - All interviewees said that you need to be prepared to be called on your must-have, in other words you need to be prepared to walk away from the deal. Otherwise you lose credibility and your bargaining position.

3. Success Factors for licensing deal

Value Drivers and Likelihood of Completion

- An interesting aspect of the success factors is how they relate to the **deal value and the likelihood of completing the deal**. Is the factor a value driver or does it increase the likelihood of deal completion? According to Arnold (et al., 2002) 46-68 % of the deal value cannot be accounted for by quantitative criteria such as market potential instead they argue that it comes from qualitative factors such as negotiation skills.
- The interviewees thought that **negotiation skills** would be beneficial in getting a desired deal (e.g. scope, structure and financial terms) in place but it will not enable getting a deal in place independent on the asset. In that sense they saw negotiation skills as a value driver.
- However, the most important value driver was **competition or the perception of competition** on an asset, meaning that several are interested in the same deal. This is an important aspect that Arnold's (et al., 2002) framework lack. According to the interviewees you can be more aggressive regarding timelines in negotiations and the deal structure and push up the value if you have competition.

3. Success Factors for licensing deal

Value Drivers and Likelihood of Completion

- Another interesting aspect of value drivers are **individual people's need**. As one of the interviewees said there might be a case where the organization has as a goal to make one certain type of deal and that the responsible person for the transaction has bonuses tied to reaching this goal. In this case they might overpay since the individuals at the partner company have a personal gain on getting the deal in place.
- Having **an internal champion** at a potential partner is the key success factor for increasing the likelihood of completing the deal according to the biotech professionals. At larger pharmaceutical companies there are a lot of processes and obstacles to overcome to successfully set up a licensing deal. One of the interviewees said that it is therefore key to have an internal champion who convinces the organization to buy in to your program.

3. Success Factors for licensing deal

Questionnaire with Industry Professionals

- In order to validate the results from the in-depth interviews, a questionnaire was constructed and sent out to industry professionals within the pharmaceutical industry.
- The participants in the questionnaire were selected to create a representative group of the industry as a whole. The distribution of market cap of the companies where the responders are employed and their years of experience within licensing can be seen in table 3 and 4. In total there were 19 responders to the questionnaire.

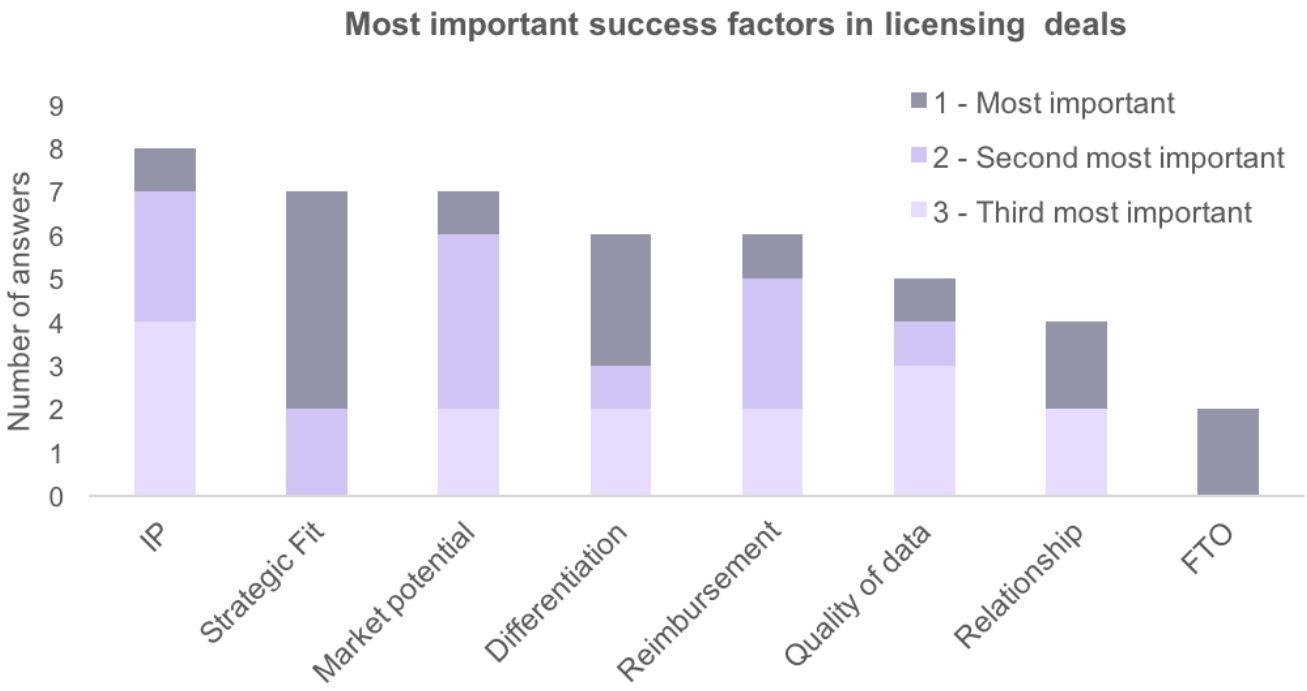
3. Success Factors for licensing deal

Success Factors ■ Top success factors mentioned by participants in the questionnaire.

Top Mentioned Success Factors	Percentage of participants mentioned it as part of top 5 most important factors
Strategic fit (including complementary with existing portfolio, overall strategy, need of technology access and partner capabilities)	69%
Internal alignment (including executive management support)	50%
Negotiations (including negotiation skills, aim for a win-win and negotiations preparations)	50%
Relationship (including personal relationships and respect and trust for partner)	44%
Commercial attractiveness	38%
Financials (including aligned financial deal-terms with value of asset, financial structure)	38%
Scientific attractiveness (including quality of data)	31%
Momentum and timing	19%
Preparations and Coordination	19%
Communication (transparency and honesty)	19%

3. Success Factors for licensing deal

Success Factors ■ When offered the choice to rank which success factors the participants considered as most important, they clearly favored **strategic fit** as the single most significant factor. Factors related to the commercial case of the product such as **market potential, differentiation and reimbursement system** did also perform well in the rankings..



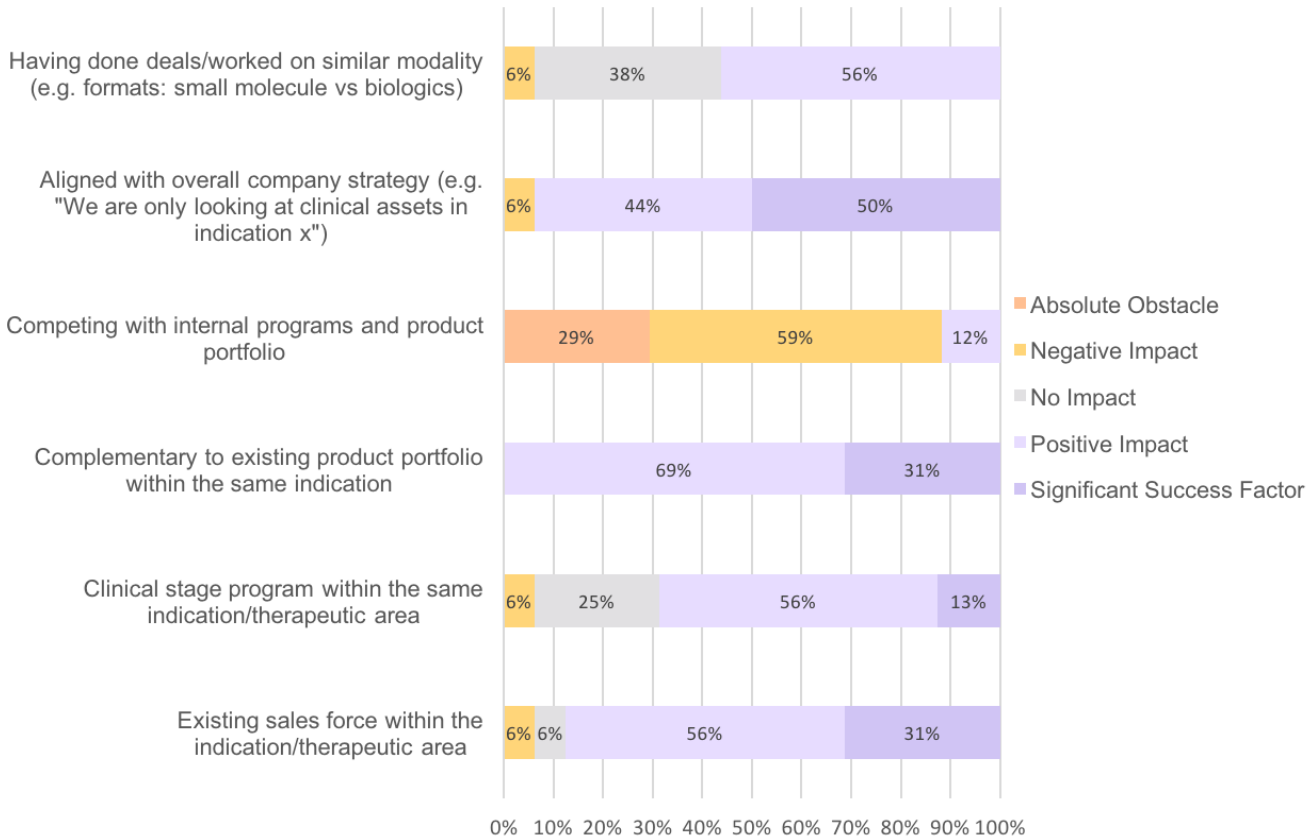
3. Success Factors for licensing deal

- Success Factors***
- It is clear from the results that **IP** is considered important by more industry professionals than **FTO**.
 - Interestingly IP and FTO are not one of the top mentioned success factors but when given the option to rank they are among the top factors.
 - **Qualitative or subjective factors** such as quality of data set and relationships were also ranked among the top factors.

3. Success Factors for licensing deal

Strategic Fit ■ Key components of Strategic fit

Key Components of Strategic Fit



3. Success Factors for licensing deal

Strategic Fit

- The results from the questionnaire point towards two key components of strategic fit:
 - 1) Aligned with overall company strategy (e.g. “We are only looking at clinical asset in indication X”) and 2) Complementary to existing product portfolio within the same indication.
 - The first factor **Aligned with overall company strategy** (e.g. “We are only looking at clinical asset in indication X”) has the highest percentage of “Significant Success Factor” as can be seen in the above figure.

- The results further indicate that approaching a partner that either has an **existing salesforce or a clinical stage program** within the same indication/therapeutic area as the asset to be licensed increases the chance of a good strategic fit. It is however skewed towards a “positive impact” and not “significant impact factor”. This is what could be defined as a “nice-to-have” but not a “must-have”.

3. Success Factors for licensing deal

Deal-breakers ■ Top success factors, in percent, mentioned as deal-breakers by the participants in the questionnaire. Thank you for listening.

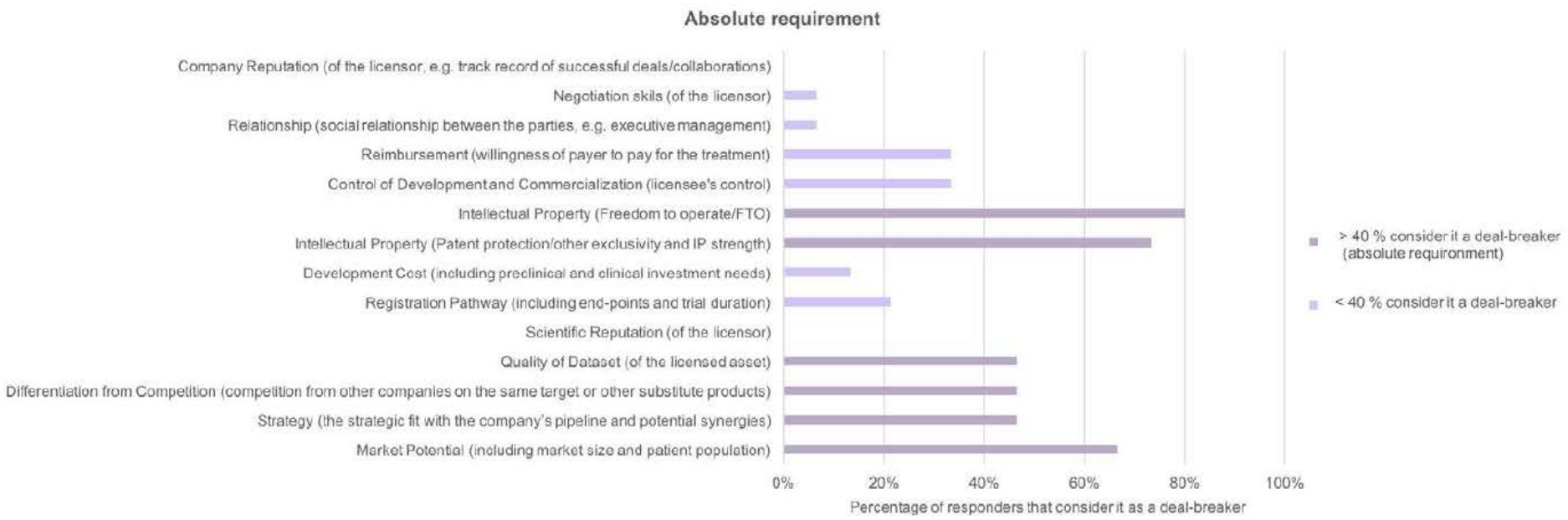
Top Mentioned Deal-breakers	Percentage of participants mentioned it as part of top 3 deal-breaks
Intellectual property (IP protection and FTO)	56%
Financial terms (Unreasonable price compared to value of asset)	31%
Scientific attractiveness (Quality of data)	31%
Available Rights (Including sub-licenses, scope, exclusivity etc.)	31%
Commercial case (including differentiation, change in competition)	25%
Negotiation (including unwillingness to negotiate and change in key terms)	19%
Strategic fit (including cannibalization of internal pipeline, overall company strategy)	19%
Relationship (including trust, respect and executive management relationship)	19%

3. Success Factors for licensing deal

- Deal-breakers***
- The above table shows a summary of the top eight deal-breakers that the participants in the questionnaire highlighted.
 - The participants were asked what they consider to be the top three deal-breakers.
 - The results show that intellectual property including **both IP protection and FTO** is considered to be a deal-breaker by more than half of the participants.
 - **Financial terms**, in relation to unreasonable price compared to the value of the asset, is also considered a deal-breaker by around one third of the participants.
 - At the same percentage as financial terms the participants also considered **available rights** (including sub-licenses, scope and exclusivity) and **scientific attractiveness** (quality of data) to be deal-breakers. Other factors mentioned were: commercial case, negotiation, strategic fit and relationship.

3. Success Factors for licensing deal

Deal-breakers



- Absolute requirement. Graph showing the percentage of responders in the questionnaire considering specific success factors as deal-breakers. The color scheme indicates for each factors if more or less than 40 % of the responders considered the specific success factors as a deal-breaker.

3. Success Factors for licensing deal

- Deal-breakers***
- When the participants were asked to define if they consider a specific factor **an absolute requirement for a deal**, the results align with the results in the table to a large extent.
 - **IP and FTO** are the factors that are considered an absolute requirement by most of the participants.
 - When asked about **the market potential**, which relates to the commercial attractiveness, the majority considered it to be an absolute requirement.
 - Only IP and FTO surpassed **commercial attractiveness** as an absolute. This is however not the case in table 6 where only 25 % mention it as a deal-breaker.
 - However, contractual aspects such as **scope of license (rights)** and **financial terms** were not taken into consideration in figure 5. Differentiation, Strategic fit, and Quality of data are also considered an absolute requirement by more than 40 % of the participants.

3. Success Factors for licensing deal

Value Drivers and Likelihood of Completion

- The results from the questionnaire show that factors related to the **commercial attractiveness** had the largest impact on additional financial value, as can be seen in figure.
- **Market potential, differentiation and reimbursement** are the main aspects of the commercial case and these are the factors that have the highest response rate for adding moderate or significant additional financial value.
- Qualitative factors such as **scientific and company reputation, relationship and negotiation skills** do not seem to add additional financial value to a deal.

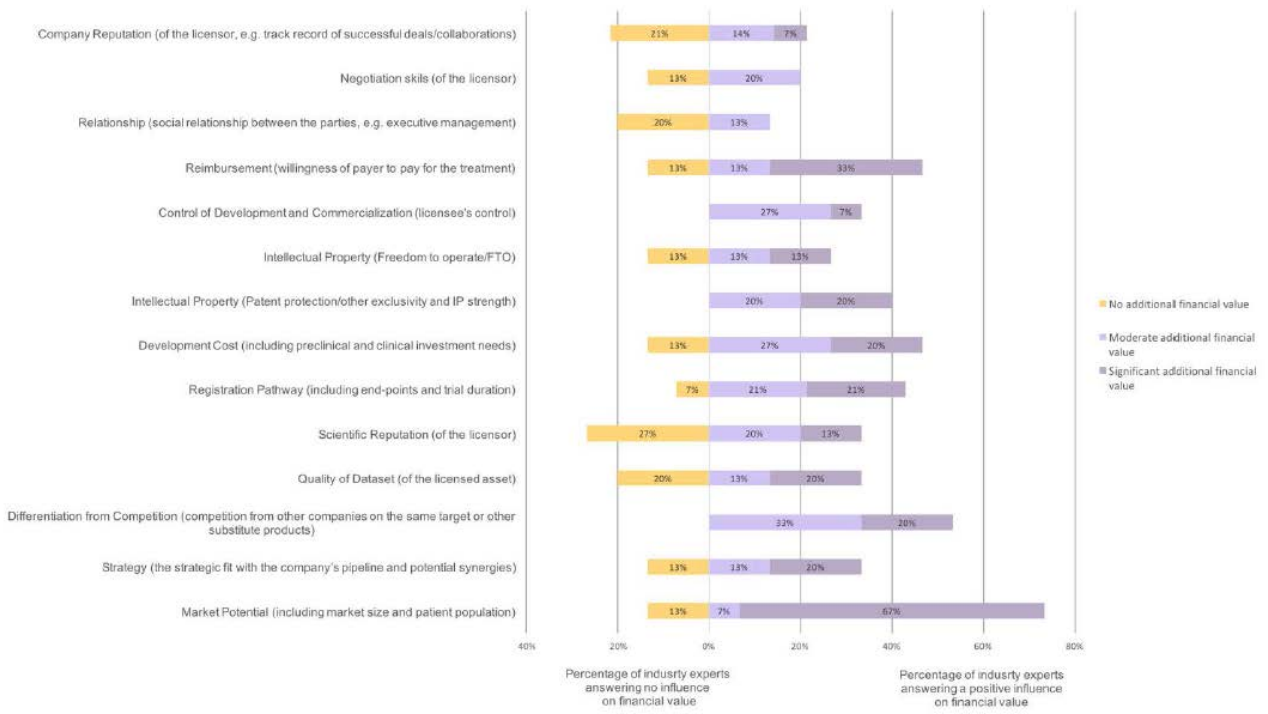
3. Success Factors for licensing deal

Value Drivers and Likelihood of Completion

- When observing the data, it becomes clear that **strategic fit** is once again an important component of the deal process and particularly in this case of deal likelihood.
- Additionally, **relationship** arises as an important aspect of increasing deal likelihood, contrasting its lack of relevance as a value driver.
- Another interesting aspect comes in the form of a clear registration pathway, which adds twice as much impact on increasing deal likelihood compared to increasing the financial value.
- Aspects of **reputation** are contested and opinions differ on its influence. IP apparently does not influence the financial value nor does it increase the likelihood but is a requirement, for a deal process, which would potentially indicate a binary requirement i.e. a deal-breaker.

3. Success Factors for licensing deal

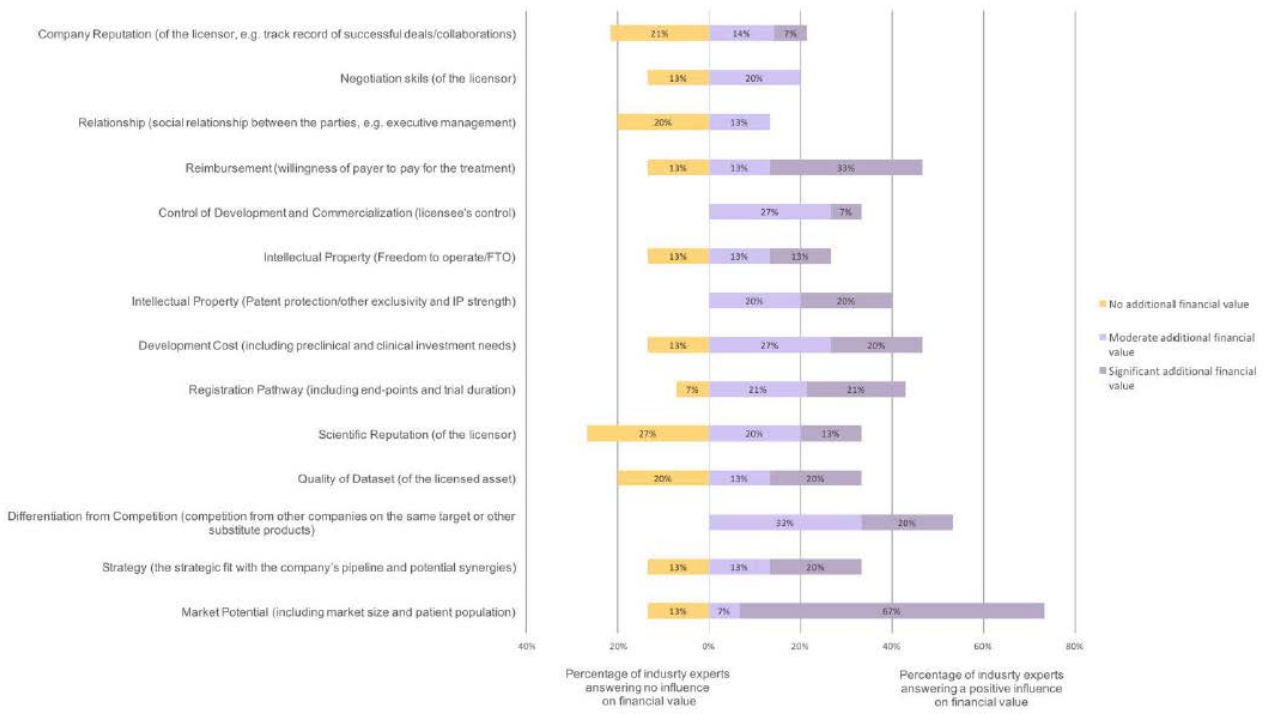
Value Drivers and Likelihood of Completion



- Financial value. Graph of responder's **perception of additional financial value** added by different success factors. No additional financial value and moderate/significant additional financial value responses are stacked in opposite directions.

3. Success Factors for licensing deal

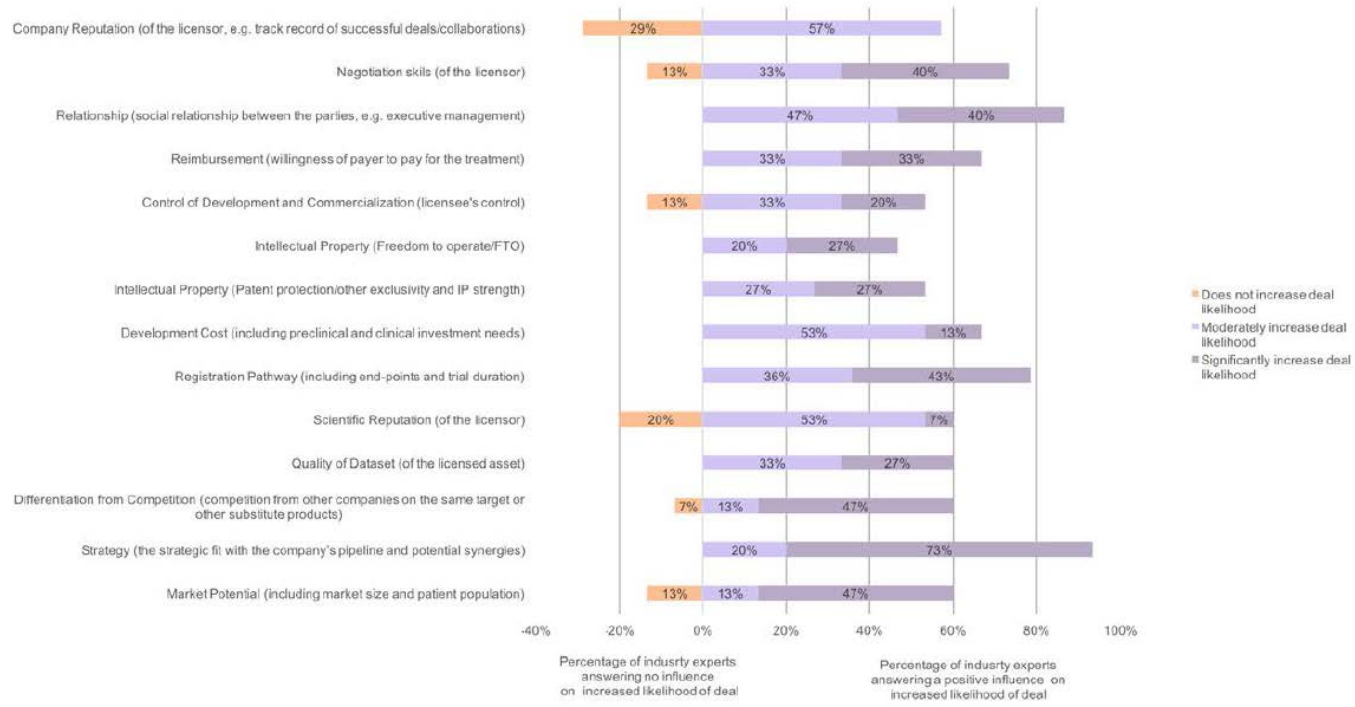
Value Drivers and Likelihood of Completion



- Financial value.** Graph of responder's perception of additional financial value added by different success factors. No additional financial value and moderate/significant additional financial value responses are stacked in opposite directions.

3. Success Factors for licensing deal

Value Drivers and Likelihood of Completion



- Likelihood of a deal.** Graph of responder's perception of success factors impact on **the likelihood of a deal**. No increases in deal likelihood is stacked in the opposite direction of moderate/significantly increasing likelihood.

4. Conclusion

Licensing in the biotech and pharmaceutical industry is a complex activity.

- Our results show that there is a range of success factors that influence the outcome. In general, there are a few success factors that stand out as more important than others.
- From the results it is apparent that **strategic fit** is a crucial success factor from both the biotech and large pharmaceutical perspective.
- For a biotech company, to succeed, it is key to **facilitate internal alignment** within the potential large pharmaceutical partner. **Relationship and scientific attractiveness** are the main success factors involved in creating internal alignment.

4. Conclusion

- strategic fit*** ■ In the pharmaceutical industry the concept of strategic fit is, based on our findings, defined and used differently compared to business research in general.
- According to our findings strategic fit is defined as “the extent to which diversification into the same field fits with the future scope of a firm”. **Strategic fit** involves a few key components based on our research:
 - 1) **complementary to existing product portfolio,**
 - 2) **aligned with overall strategy and**
 - 3) **existing salesforce or late-stage clinical asset within the same indication.**
 - These results give an idea of **which characteristics a biotech company should look for in a potential partner.**

4. Conclusion

Different types of success factors influence different aspect of a licensing deal.

- **Qualitative factors** such as strategic fit and relationship have a large impact on **the likelihood of a deal**.
- In comparison, **quantitative factors** that make up the commercial attractiveness have the largest influence on **increasing the financial value**, e.g. market potential, reimbursement and differentiation.
- Collecting data from both the biotech and the large pharmaceutical actors. One key question of financial value drivers is what drives a premium value, a higher value than the result of a valuation, e.g. DCF or rNPV.
- Based on our results, the factor **competition** for the asset to be licensed stands out as the main success factors that has an impact on the premium value.

4. Conclusion

- Intellectual property***
- **Intellectual property** in the form of intellectual property rights or rather the lack of, stands out in our result as the most significant deal-breaker.
 - Intellectual property does not increase the likelihood of the deal not does it influence the financial value **but it needs to be present for a deal to be possible**.
 - Interestingly, FTO as a deal-breaker is more contested.

References

1. Success Factors in Product Licensing in the Pharmaceuticals Industry, Identification and evaluation of factors influencing likelihood and financial value of a licensing deal, JIMMIE HOFMAN, ADAM NIKLASSON, Department of Technology Management and Economics, Division of Entrepreneurship and Strategy, CHALMERS UNIVERSITY OF TECHNOLOGY, Gothenburg, Sweden 2016.

Thank you for listening!!

Q&A

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