Biotech Licensing

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#784678

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July 1999

BIOTECH LICENSING

1 Prerequisite Activities

1.1 Assess strategic value based on business strategy and patent strategy

1.2 As owners of newly developed technology:

1.2.1 Does it represent a new direction for the company

1.2.2 Can company make more doing itself, choosing one partner, sharing with a partner, or allowing many partners

1.2.3 Is it complementary or distracting technology

1.2.4 Does it provide synergistic value with existing technology of company or with that of third parties

1.2.5 If licensing to one party, considerations to reflect upon:

1.2.5.1 How financially stable is the licensee? What will trigger return of rights?

1.2.5.2 Does the licensee have or have access to the resources necessary to develop, clinically test, manufacture, market the product/service? Where does the product fall in the licensee's priority of projects? Will it get the prominence it deserves?

1.3 As purchasers of new technology:

1.3.1 Assess whether the technology is ancillary or enabling

1.3.2 Determine the breadth of technology

1.3.2.1 Its criticality to a particular commercial endeavor and the lack of alternatives will be a large determinate of value

1.3.2.2 Is it feasible? How much development is required?

1.3.2.3 How is it protected: Patented? Patent pending? Trade Secret?

1.3.2.3.1 If subject to patent protection, what is the nature of the claims- Are they composition or method; have they been filed in countries of intended marketing activities or, where competitors are located?

1.3.3 Will the technology be solely implicated or is it one of several or many technologies required

1.3.3.1 Non-exclusivity may be more than adequate to deliver ultimate exclusivity if other parties will have difficulty accumulating all the necessary technologies → one exclusive link in a chain of non-

exclusive links could be sufficient to generate exclusivity while minimizing cost (and thus maximizing return)

1.3.4 Are others competing for the same rights; will securing such rights result in extreme competitive disadvantage for others, if so → exclusivity may be well worth the premium

1.3.5 Are there other barriers to entry?

1.3.5.1 Construction of a manufacturing plant

1.3.5.2 Orphan Drug Status - how meaningful? Will small changes to the therapeutic molecule be possible while still permitting it to retain biological effectiveness with an acceptable safety profile?

1.3.5.3 Limited availability of critical raw materials

1.4 If the technology is only patent pending - how likely is it that claims will issue? With meaningful breadth?

1.4.1 Consider how differing scope/timing of claims could affect the value and thus the consideration to be paid, now or in the future

1.4.1.1 milestone payments on patent issuance can be modified on the basis of claim scope such that broader scope is rewarded with higher payments

1.4.2 Build contingent relief provisions if claims become less valuable over time due to outside influences such as:

1.4.2.1 invalidity actions

1.4.2.2 development of other competitive technologies

1.4.2.3 unmitigated infringements, etc.

1.4.3 What is the timing of patent issuance and what subject matter will claims cover versus the activities to be undertaken - is a license actually necessary?

1.4.3.1 Conduct complete due diligence on the pending claims especially from §102 aspects (prior sale, publication, filing by others); Have proper assignments been filed? Maintenance fees paid?

1.4.3.2 Infringing activities may be concluded before issuance of the patent

1.4.3.3 Tool kit patents are especially prone to this and may not issue in time to be commercially relevant unless claims also issue to products resulting from the use of such claimed tools - compare to gene patents which are much more likely to retain relevance regardless of product or the timing of its development and commercialization [exception: gene used as part of screening assay for small molecule as part of combinatorial chemistry drug discovery program]

1.4.4 Who owns the patents or other IP to be licensed? Watch for this especially in the context of academic institutions which are notorious in their free-wheeling inter-institutional collaborations (generally without benefit of contractual guidance).

1.4.4.1 Have all owners consented to licensing? - not an issue in the US but necessary for foreign rights to be transferred

1.4.4.2 Also necessary if "exclusive" rights are to be transferred

1.4.4.3 Fixing it after the fact may be albeit impossible as the leverage of withholding signature is dissipated.

1.5 In Summary, where is the value and who is creating it?

1.5.1 The licensee should not be paying a premium for his work, efforts and risk in creating value added

1.5.2 The benefit of early access must be balanced against the additional risk presented due to that timing

2 Basic Terms of a License

2.1 Definitions

2.1.1 Effective Date - generally when both parties have attached authorized signatures to the effecting document

2.1.2 Licensed Patent Rights, Know-How - identifies applications, patents and defines unpatented technology, if any, to be transferred/licensed

2.1.2.1 are CIPs or other future filings included? Are there any broader umbrella IP positions held by the licensor that are not included but which could block subsequent commercialization of the technology? If not included, get at least a non-suit clause for protection.

2.1.3 Field: permitted areas of activities usually defined in terms of specific disease/application(s) but could also be negatively defined in terms of excluded areas of interest (which are generally retained by licensor for its use or for licensing to others)

2.1.3.1 Example: DNA vector construction for use in gene therapy treatment of Cystic Fibrosis

2.1.4 Territory: worldwide, specified continents, or identified country(ies)

2.1.5 Product/Service - defines for unambiguous clarity what the licensee has the right to sell but should not be so limiting so as to eliminate subsequent improved generational products or other products within the Field not yet contemplated at the date of signing -- want this clause to be inclusive, not exclusive in nature

2.1.6 Net Sales: sets forth the litany of acceptable deductible items such as transportation, insurance costs, bad debt, returned goods, etc.

2.1.6.1 In essence, the licensor should only get paid with respect to the value itself of the product/service sold, not the incidentals, and then only if the licensee gets paid

2.1.6.2 standard clauses also provide for combination products in the event the product is sold with other unrelated items under a single price - the licensor should not get a "piece" of an unrelated product [this is

of growing importance as products are bundled in the environment of managed health care]

2.1.7 First Commercial Sale - specify what comprises a sale and what is to be excluded, e.g. clinical trial material or material transferred at cost to a partner conducting the clinical trials?

2.1.8 Biological Materials - Sets forth the nature and identity of any material or related know-how to be transferred to licensee such as cell lines, vectors, Abs, genes, etc.

2.2 Grant of Rights

2.2.1 Exclusive, Sole, Semi-exclusive, Non-exclusive grants possible

2.2.1.1 Avoid a classic error: "...grants a sole and exclusive license..."

2.2.1.2 Include the rights to "make, have made, use, import, offer for sale and sell"

2.2.2 Must work in concert with the Territory, Field and Product/Service definitions

2.2.2.1 Watch for unintended limitations resulting from the combination of these definitions

2.2.3 Right to sublicense

2.2.3.1 generally not provided with non-exclusive licenses

2.2.3.2 may have additional limitations not present in the original grant, e.g., such rights themselves are without the right to grant further sublicenses

2.3 Payments - dependent upon facts and negotiation skills/leverage

2.3.1 Upfront fees range from $0 to astronomical amounts

2.3.2 Annual fees/minimum royalties as an advance against earned royalties - this is the most effective tool from licensor's perspective to ensure diligent development of the licensed technology - continues to cost the licensee money to maintain the license

2.3.2.1 If minimum annual royalties are demanded by licensor, as quid pro quo, licensee should specify that such payments are expressly in lieu of any "best efforts" obligations which would be imputed by a court in an exclusive license in the absence of any other specified standard of performance; use "commercially reasonable efforts" as a standard of performance

2.3.3 Milestone payments

2.3.3.1 Really is the only way a licensee can push off license costs which would otherwise be payable *ab initio* albeit subject to a NPV discount

2.3.3.2 Although often argued by licensors as a measure of diligence, milestones do not work this way since they create a disincentive to

advance development, e.g. every successful advance by licensee (at his cost) is 'penalized' by an additional payment to licensor which does nothing to advance development or strengthen licensee's ability to commercialize

2.3.3.2.1 If licensee is a small biotech company, siphoning away such funds (probably from a limited bank account) at a critical time in the product/service's development life cycle may not actually inure to the licensor's benefit

2.3.4 Royalties

2.3.4.1 Generally a % of Net Sales of Product/Service; may be stepped up or down with increasing sales; may also be reduced in the event of unlicensed competition (generally required to be material)

2.3.4.1.1 Alternatively royalties could be calculated on the basis of profits but obviously would then need to be a lower royalty (the psychology of a lower royalty number in the licensor's mind is, as a practical matter, generally prohibitive)

2.3.4.2 Commence with First Commercial Sale

2.3.4.3 Are Royalties payable on pending claims? If so, limit them for a reasonable time, if no patent issues, drop the royalties to zero or to a Know-How rate and then pick them up again upon issuance. (Licensee argument: no reason to pay for protection which doesn't exist – can't stop infringers; Licensor argument - still have benefit of *in terrorum* effect)

2.3.5 Share income generated from licensee's sublicensing endeavors with licensors

2.3.5.1 Many ways of handling sublicensee royalties - licensor wants pass through of royalties on sublicensee sales (may be impossible to get accurate information, e.g. Japan); licensee can offer a higher % on sublicensee royalty income

2.3.6 Reduction Factors

2.3.6.1 Royalty Stacking Provisions - generally acts to reduce royalties by some percentage of the royalties payable to third parties on the same Licensed Product/Service up to a maximum reduction percentage - all to be negotiated; protects licensee against excessive royalty burden if multiple royalties involved, spreads burden amongst all licensors (Licensee argument: smaller piece of something is much better than a bigger piece of nothing; Licensor argument: licensee controls choice/use of technologies and thus the royalty burden, not licensor)

2.3.6.2 Costs of patent procurement, defense, offense

2.3.7 Audit rights

2.3.7.1 Only by an internationally recognized CPA (e.g. one of the big 8, 6, 4 (or whatever!) firms), only once per year during normal business

hours and only as to unaudited records, subject to confidentiality provisions

2.3.7.2 Generally will be at licensor's expense unless large underpayment discrepancies found

2.3.7.3 Generally an under-utilized value generating provision, particularly with respect to multinational licensees whose primary interest is overall corporate revenue/tax issues, not following the royalty generating revenues of one product in numerous territories

2.3.7.3.1 Price-Waterhouse-Coopers IP Audit Group commented (Feb. 1997) that of the hundreds of audits they have done, only two did not result in corrections which exceeded the cost of the audit!

2.4 Diligence Requirements

2.4.1 Licensor should want to ensure diligent development - can incentivize this through a combination of annual maintenance fees and specified time lines for stages of development

2.4.1.1 Penalties can include loss of license or reduction of license from exclusive to non-exclusive or semi-exclusive status (generally less favorable to licensor however passage of time may have lowered salability of the technology and keeping one, albeit poorly performing licensee, may be better than having all rights and no licensees)

2.5 Ancillary Considerations

2.5.1 Joint Venture - an approach generally limited to circumstances involving two commercial entities and a technology in late stages of development or seeking a new application

2.5.1.1 due to the inherent complexities of such an arrangement, it is not favored if a simpler license/supported research (or other activity) agreement can be used to accomplish the same goals

2.5.1.2 figuring out whose personnel will run the JV, whose decisions govern, how the JV is financed (initially and then on an operating basis) and how the parties' ownership changes, all in the context of unpredictable scientific development can be an enormous headache and creates many issues to be negotiated, all of which detract from the realistic efforts of testing feasibility and commercial development

2.5.2 Shared Development Efforts - licensee may actually effectively buy in all but name the technology and contract back to licensor certain aspects of development, testing, or manufacturing

2.5.2.1 Provide for ownership of inventions arising out of such efforts along with license/field rights before the inventions are made and ownership/rights becomes an issue

2.5.3 Co-Marketing rights - often split by territory rather than application, [Does any scheme really work within the same Territory or is an "agreement" now

simply putting off the inevitable conflict till a time when there are even more dollars at stake and tempers are high?] - JVs can be a reasonable solution to these issues

2.6 Term

2.6.1 of the Grant - typically last to expire of the licensed patents but Know-How, particularly if successfully maintained as a trade secret, could be of unlimited duration

2.6.2 of the Royalty Obligations

2.6.2.1 Match to the patent term to absolutely avoid any antitrust/patent misuse concerns

2.6.2.2 Know-How vs. Patents, different rates necessary to avoid patent misuse, Know-How royalty could continue for whatever period of time the parties negotiate

2.7 Infringement Suits

2.7.1 Against licensee for infringement of third party's IP

2.7.1.1 Critical that licensee be permitted to stop sales immediately without incurring any penalty either in efforts obligations or minimum royalty obligations

2.7.1.2 If licensee continues to generate Net Sales, licensee should be permitted to apply at least a portion of the royalties against legal expenses since licensee is working to protect licensor's source of income

2.7.2 Against third parties for infringement of licensed IP

2.7.2.1 Licensee may wish to have the right, but should not have the obligation to bring suit; alternatively (and especially in non-exclusive licensing situations) licensee may want licensor to have the initial obligation to stop the infringement which, if not undertaken or unsuccessful, results in a reduction of the royalty rate so that licensee remains competitive against an unlicensed infringer (at least in the applicable geographic territory)

2.7.2.2 Numerous mechanisms for sharing of costs (although generally born solely by plaintiff party) and for sharing of any recoveries; equitably plaintiff should get the lion's share after expenses having undertaken the efforts and thus the risk that no recovery will be had and expenses not covered (licensor will counter argue that the suit is tantamount to sublicensing revenue generation and thus there should be a comparable contribution to the licensor)

2.8 Prosecution Efforts

2.8.1 Conflict of interest prevents in-house counsel from properly undertaking prosecution efforts however, close monitoring of outside counsel with active involvement (e.g. providing non-binding commentary on all communications) should be agreeable; choice of outside counsel should be subject to mutual agreement

2.8.2 When licensor is an academic institution, often there is a demand that licensee pay for the costs of prosecution, this is a point of negotiation but generally one with limited freedom on the university's part due to their fiscal restraints

2.8.2.1 Any payments should be directly deductible from any ensuing royalty obligations since but for such expenditure by the licensee, there would be no asset generating the royalty, e.g. the payment of prosecution costs is simply an interest free loan and as such further reduces the prospect of conflict

2.8.2.2 Limits on annual expenditures is however wise as is the avoidance of an obligation to pay for interferences or opposition defense (which can be subsequently waived as prudent)

2.9 Confidentiality provisions

2.9.1 Necessary (by both licensor and licensee) for the maintenance of Know-How as trade secrets; also want to prevent publication (before its time) of research results, particularly in a collaborative or supported research arrangement

2.9.2 Want to keep royalty information confidential, (would be valuable to competitors in marketing and pricing their product/service)

2.9.3 Licensee wishes to control/restrict dissemination of information concerning status and costs of technology, natural tension with SEC regulations regarding "materiality" which requires disclosure

2.10 Dispute Resolution - make it difficult, expensive and embarrassing to perpetuate disagreement to thereby incentivize the development of an informal solution

2.10.1 Litigation

2.10.1.1 Specify choice of forum, law; eliminate spurious jurisdictional issues

2.10.1.2 Perhaps penalize loser with costs as a disincentive to bringing/continuing frivolous actions

2.10.2 Alternative Dispute Resolution Mechanisms - "rent a judge" concepts abound

2.10.2.1 May be able to tailor the background and identity of the fact finder/decision maker to the circumstances

2.10.2.2 ADR mechanisms however often suffer many of the same disadvantages as conventional arbitration

2.10.3 Arbitration - there are pros and cons of a rapid process with limited discovery and discovery dispute redress, location, number of arbiters (e.g., is three effectively only one but at three times the price?); there are as many opinions of what is preferable as there are variations (which interestingly, also closely approximates the number of scriveners)

2.10.4 Hybrid Approach - create your own solution protocols, force CEO's to deal with the problem before formalizing process - use the power of

embarrassment, eliminate the layers between decision makers and those struggling with the real issues

2.11 Indemnity

2.11.1 Defend and settle - covers the cost of litigation but not any other damages or losses sustained by licensee

2.11.2 Indemnify and hold harmless - covers the cost of litigation (and attorneys fees if so specified) plus damages or losses such as costs of canceling contracts which can't be mitigated, lost profits, etc., except as limited

2.11.3 Limitations of liabilities - e.g. disclaimer of use warranties or consequential damages need to be in CAPS to highlight them (case law); need to consider how this interacts with the indemnity clauses.

2.12 Miscellaneous Clauses to Consider

212.1 Blocked Currency - provides for deposit of royalties into an account in Licensor's name in those countries which prohibit export of currency or in which there is no consistent currency conversion market

212.2 Currency Conversion - specify mechanism and date of currency conversion using readily accessible information sources (e.g. rates listed in Wall St. Journal on last business day of applicable quarter)

3 Summary Goals

3.1 Of a specific license → Eliminate threat of litigation from patent owner/licensee at a cost commensurate with the risk eliminated

3.2 Of a licensing program → obtain rights to all requisite technology at a reasonable cost and if possible, additionally provide a competitive edge also upon a rational cost basis

3.3 Remember - a patent does not give the right to practice the claimed invention, only the right to exclude others from practicing the invention; accordingly, licenses to several broader/umbrella patents may be required in order to legally practice a particular claimed invention and costs can skyrocket accordingly

4 Special Concerns

4.1 Hart-Scott-Rodino Notification Requirements

4.1.1 In order to be obligated to file, must meet three tests: 1) either party (which includes a party's parent) is engaged in commerce or any activity involving commerce, 2) one party has at least $100 million in total assets or annual net sales and the other party has at least $10 million in total assets or net sales and 3) that after the transaction, the acquiring person will hold either 50% or more of the voting securities of an entity which has at least $25 million US sales or an aggregate total amount of voting securities and assets of the acquired person valued in excess of $15 million.

4.1.2 The FTC has taken the position that exclusive licenses are to be treated as asset acquisitions if transferred assets valued > $15 million or $10 million if contributed to a joint venture at the time of formation.

4.1.2.1 Fair market value to be determined in good faith, estimate royalties over life (FTC's present position is that no net present value discount is permitted)

4.1.3 Filing fee is $45,000 with a mandatory waiting period of 30 days but could be extended if FTC decides to investigate

4.1.4 Fines of $10,000/day for non-compliance

4.1.5 Recommended Action: effect a Safe Harbor Filing (pursuant to § 6(a) of the National Cooperative Research Act, 15 U.S.C. 4301 et seq.) to limit recovery of antitrust plaintiffs to actual damages under the specified circumstances if wrong in determination (e.g., cuts off treble damages and attorney's fees)

4.2 Improper tying arrangements

4.2.1 extending the basis of patent coverage to unpatented items for "convenience"

4.2.2 Example: Bogart patent re use of HCG levels as an indicator of pre-natal open tube neural defects

4.2.2.1 patent claims 18-24 gestational week window to obtain sample, but license demands royalties on all samples, even those collected 16-18 weeks on the basis of potential error of judging gestational age - a nonsense argument given the precision of the window which is claimed and the existence of the same potential gestational error at the time of filing

4.3 European concerns

4.3.1 Black, White and Grey listed items

4.3.2 Notification to the Commission if in doubt or do not qualify for an exemption

4.4 Grant-back clauses

4.4.1 If a licensor: nice if you can get it but avoid demanding an exclusive grant-back which is per se illegal and could invalidate the entire license

4.4.2 As a licensee: avoid these like the plague, especially if there are triggers for licensor to reduce or eliminate the underlying license (e.g. due to lack of diligence) → if there is a falling out or even if not and licensee merely stumbles, licensor could wind up with far more than he should equitably be entitled to

5 Additional Thoughts

5.1 Intentional aggregation (patent pooling) of IP by an entity could create a duty to license in order to avoid transgressing upon Sherman Act Section 2 monopolization principles if license is indispensable to competition

5.2 However, given the complex nature and substantial number of IP rights held by different entities required for modern biotech products, traditional antitrust concerns

regarding the intentional acquisition of all rights might be mitigated if licensing them is preordained

5.2.1 Net result of overcoming the too many IP license straws will be more parties making more products generating more revenues and benefiting society

5.3 Gene therapy is a particularly exciting area of technological development but carries with it a substantial licensing complexity given the various areas of requisite technology: production of genetic elements, expression regulation, vectors, mode of action, genetic sequence information, disease treatment methods and combinations and permutations thereof

5.3.1 Each area will present varying degrees of exclusivity, not only in terms of license/cost availability, but also in terms of alternative technological routes

5.3.2 These will all have to be balanced and weighed in the competitive environment of the specific fact situation before intelligent licensing choices can be made → without a thoughtful scheme in place, a staggering array of possibilities will arise which may or may not ultimately meander their way to the desired goals

5.3.3 Success will come earlier to those who recognize these aspects and conscientiously deal with them in a consistent and integrated fashion