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Considerations for Leveraging IP in the Life Sciences Sector

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Intellectual Property

Introduction

Patents have evolved to become more than tools to be weaponized against a patent owner's direct competitors on an as-needed basis. Patents are used more and more to generate significant additional return on research and development ("R&D") costs through licensing and, in an increasingly knowledge-based economy, to moderate the growth of competitors by increasing the cost of doing business in a field, particularly in patent-intensive industries. (*See* Neuenschwander, C., "Anatomy of Assertive Licensing," Int'l Patent Licensing Co., 16th Ann. Adv. Licensing Inst., Concord NH (Jan. 8, 2008), at 4.) In the life sciences sector, studies have shown that licensors consistently profit from licensing to a competitor, even for small technological leads. (*See* Lee, J.H., *et al.*, *Sustainability*, 10:3143 (2018) at 3.) This profit makes a difference; smaller biotech firms often rely on out-licensing revenue (Lee at 2) while large corporations manage large patent portfolios to further monetize their intellectual property ("IP") (*see* Neuenschwander 2008 at 5). Licensing occurs frequently, and about 75% of new biologics and small molecule drugs launched in the U.S. are sourced from external entities. (Sheridan, S., and Dobreva, Z., *Pharm. & Life Sciences News*, (Oct. 24, 2018), available at https://news.bloomberglaw.com/.) Indeed, the market for licensing patents in the life sciences sector has expanded over the past decade, although the very real challenges of out-licensing still temper many licensor expectations. (Dick, A., *Inventors Digest*, (Jan. 6, 2011), available at https://www.inventorsdigest.com/articles/license-sell-or-hold/.)

An early stage life sciences company may only just begin to reap its investments in R&D and IP initiatives with the issuance of patents key to its own commercial ambitions (aka "core assets"), before discovering that other players have already begun infringing their patent rights. If an infringer, whether having reached the market or not, is not a direct competitor, but rather operates in a different field of use or market altogether, the patent holder faces some difficult and nuanced decisions. As litigation, or even a worthy licensing campaign, can present unwanted distraction, cost, uncertainty, and risk to a smaller or early stage company, the option to overlook a non-competitive infringer could appear the path of least resistance. But, for the reasons described below, patent owners, particularly in the life sciences sector, should not simply ignore opportunities to license technology outside their own specific field of interest. This holds particularly true for developers of platform technologies (*e.g.,* drug delivery technology) that may accommodate various small molecule or biologic drugs, where several profitable and beneficial relationships could be established with several partners in different fields leaving the licensor to pursue commercialization of their most promising application of that core asset. Yet, the choice of the most appropriate licensee(s) and the best time and manner in which to

approach that target, if at all, is influenced by many factors, including (i) the asset(s) to be licensed, (ii) the relative positioning of the licensor/licensee(s), and (iii) the stages of technology development. Licensing patent(s) to the first—or at least relatively early—infringer(s) may affect opportunities to license to more suitable candidates. Thus, a well thought-out business decision must be made on the basis of many different considerations. And at the very least, early consideration of what may be beneficial to the business is recommended.

Assertive Licensing

"Assertive" licensing refers to the proactive invitation to a target licensee, who the licensor believes to be infringing the patent, to license the allegedly infringed asset. A faint line separates a soft (carrot-style) approach to assertive licensing, in which a license option is suggestively advertised to an infringer, and a hard (stick-style) approach to assertive licensing, in which litigation is essentially threatened. (Neuenschwander 2008 at 12.) Particularly for smaller and/or early stage companies, the strategic management of IP, including out-licensing strategies, can shape the company's image in the eyes of strategic partners, including investors and potential acquirers, as well as impact the company's future (*e.g.*, survival, success). (*Id.* at 16.) But, assertive licensing entails substantial considerations of cost, time, and risk. Successful assertive licensing can involve substantially more preparation and resources than routine patent licensing and can expose the licensor to an increased risk of attacks against patent validity and/or litigation. (*Id.* at 19.) Additionally, the costs of assertive licensing may outweigh the short-term revenue generated from successful deals. The business analysis also should be tailored to the scope of the contemplated license (*e.g.*, geographic, field of use) and the scope of the patent protection. (*Id.* at 71.)

Soft Assertive Licensing

Successful soft assertive licensing requires a threshold effort of due diligence, including an investigation of the alleged infringement that "produces something between Rule 11 and trial-level quality information," although keeping outside counsel from the negotiating table until necessary may help avoid scaring off the potential licensee or even a declaratory judgment action or post grant procedure at the U.S. Patent and Trademark Office. (Neuenschwander, C., "The Role of Assertive Patent Licensing," Law360 (Aug. 9, 2017) at 1, available at https://www.law360.com/articles/948836/.) Regardless of the perceived merits of a hypothetical litigation, prospects of achieving a license merely on the basis of directing a target licensee's attention to issues of infringement are highly doubtful, unless the licensor can also make a persuasive pitch that a collaborative relationship with the licensor would prove valuable to the licensee. (*Id.* at 2.)

Companies generally tend to ignore soft invitations to license without any additional incentives for as long as feasible, relying on the statistically probable hope that many patent holders will simply go away. (Neuenschwander 2008 at 13; Neuenschwander 2017 at 1-2; Lemley, M. *et al.*, "The Patent Enforcement Iceberg," *Texas L. Rev.*, 97:801 (2019) at 809.) Larger companies, in particular, generally receive large numbers of offers (Lemley at 810-811, 813) and may be more likely to ignore letters extending soft invitations without more, and some recipients may respond by simply stating a lack of infringement with hopes of avoiding findings of willful infringement down the road. (Neuenschwander 2008 at 13.)

Pursuing more collaborative approaches with a suspected infringer can strengthen a licensor's reputation and does not foreclose later implementation of hard licensing approaches if needed. Application of a collaborative licensing approach over a larger portfolio of assets, thus, tends to ultimately reduce overall litigation costs. (Neuenschwander 2017 at 2.) A collaborative approach

also more closely resembles routine patent licensing and technology transfer. Developing a relationship with an internal advocate at a target, particularly when approaching more sophisticated companies, can help navigate the hurdles to achieving serious consideration by key decision makers of the target. (Neuenschwander 2008 at 25; Wanetick, D., "Strategies for Negotiating Licenses" (2015), available at https://www.ipeg.com/strategies-for-negotiating-licenses-2/; Hessenbruch A., "Five Critical Questions Before Out-Licensing to a Pharmaceutical Company," (Feb. 27, 2012), available at http://archive.boston.com/business/blogs/global-business-hub/2012/02/five_critical_q.html.) Indeed, technical personnel may prove a more suitable advocate for early stage technologies, while business professionals may demonstrate merit as technology is closer to commercialization. (*See* Wanetick.) But corporate cultures of sophisticated licensees are not all the same; time should be invested, for instance, in determining whether the target uses a hierarchical approach or a more open team-based approach to decision-making on licenses. (*See* Hessenbruch.)

There should be little downside to at least attempting a soft collaborative approach with an infringer prior to resorting to hard licensing. (Neuenschwander 2017 at 2.) This seems particularly true during development and before any infringing product or service reaches the market (*e.g.*, after approval by the U.S. Food and Drug Administration ("FDA")). A recent survey, skewed toward the high-tech sectors, found that only a minority (41%) of patent assertions (negotiations of patent licenses for existing products) did not include any claim mapping, suggesting a majority of assertions related to on-market products take a more aggressive approach. (Lemley at 810.) This number reflects the significant challenge in politely persuading target licensees into serious negotiations (*see* Bhandari, C., "A Systematic Approach to a Successful Patent Licensing Program," (2015), available at https://www.ipwatchdog.com/2015/12/15/systematic-approach-to-a-successful-patent-licensing-program/id=63775/, at 8], although the number of licensing agreements in the biotech industry is estimated to be at least ten times that of other sectors. (Lee at 1.) Regardless, intensive preparation is generally necessary for any meaningful chance of out-licensing a patent outside of litigation. Given the efforts required, some sophisticated patent holders outsource their out-licensing preparation altogether, including to third party IP advisory firms or licensing agents. (*See* Bhandari at 3; *see also* Dick.)

Hard Assertive Licensing

Hard assertive licensing entails both a thorough technical and legal analysis of the patent assets and infringing products or processes, including trial-quality claim charts (*see* Neuenschwander 2008 at 57; Bhandari at 7) and well-developed business arguments (*e.g.*, market analysis, industry forecasts, competitive intelligence, prior sales, estimated sales, and revenue projections under multiple royalty rates and lump sum arrangements) (*see* Neuenschwander 2008 at 65). The aforementioned survey estimated that about one-third of all patent assertions and about one-half of all demands end in litigation. (Lemley at 801.) Licensors that are ultimately unwilling or unable to litigate their patents may waste substantial resources pursuing a hard approach, particularly if the target licensee was unlikely to be a suitable soft approach target from the outset.

Between soft and hard approaches, the hard approach often begets higher risk and higher reward, including increased revenue and a faster resolution. (Neuenschwander 2008 at 79.) That said, royalty rates should be calculated using methodologies designed for business negotiations rather than litigation, even under a hard approach. (*Id.* at 61.) The obvious risk to the hard approach is the enhanced risk of unwanted litigation and threat of patent invalidation proceedings, but also the concern of retaliation in the form of an offensive patent infringement suit (*id.* at 82) or simply just the lost chance to make certain choices in the first instance (*e.g.*, timing, forum) (Lemley at 809.)

Determining the Best Target Licensees

In general, litigation risks may pose a more significant deterrent for an early stage or struggling company that is not in a position to litigate. Ignoring an infringer altogether, however, may fall short of fiduciary obligations (Neuenschwander 2017 at 1) and the decision to pursue or balk at litigation may send unwanted signals to other potential infringers or licensees. (*Id.* at 2.) The relative risk of litigation may be mitigated by the comparative size of the alleged infringer, with smaller or even equally-footed infringers posing less of a significant threat. (Neuenschwander 2008 at 82.) Smaller companies are also likely to have less expansive portfolios to exploit in retaliation. (*See* Dick.) That said, smaller companies tend not to be so inundated with assertions that they cannot afford to litigate if pushed. (*See* Lemley at 813.) Large companies, though, while equipped to run up litigation costs that scare off smaller or less aggressive patent holders (*see* Dick), are unlikely to immediately pursue a declaratory judgment action in response to every assertion they receive, simply due to the volume of assertions received (*see* Neuenschwander 2008 at 83). Thus, patent holders of any size should feel comfortable in at least approaching a suspected infringer with a soft approach if done right.

Sophisticated out-licensors of IP likely employ coordinated progressive licensing strategies and may even lay the groundwork for more aggressive approaches before they need it (Neuenschwander 2017 at 2), although it makes sense for smaller licensors to weigh the costs and benefits of more aggressive approaches, at least as the needs develop. While more experienced patent licensors may be able to handle more in-depth and longer negotiations before calling in lawyers, lawyer participation may legitimize a patent holder's IP position and earnestness in reaching a deal while also accelerating the process, particularly when non-disclosure agreements and memoranda of understanding come into play. (*See* Strategies.) Thus, approaching a routine licensee may open the window for lawyer participation earlier than approaching an assertive licensee with a soft approach, given the desire to appear non-threatening, and may seem an attractive route for a licensor with limited or untested negotiation savvy.

The licensee in a routine patent licensing agreement of early-stage technology often bears the costs and risks of defending patent validity and enforcing assets. (Razgaitis, R., "Pricing the Intellectual Property of Early-Stage Technologies," in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, (2007), available at

www.ipHandbook.org, at 816.) While the forthright disclosure to a routine licensee that the licensor has identified a suspected infringer may complicate the patent valuation in a non-assertive licensing agreement, licensing an asset to a larger company may provide a litigation-wary licensor a compromise to the risks of pursuing assertive licensing with the alleged infringer. The infringing acts of another may even lend credence to the commercial viability of early-stage technology, including showing the activities it may extend to cover.

Additional factors impacting successful licensing efforts—at least for early-stage licensors in the life sciences sector—include (i) the patent holder's licensing experience and (ii) the technological breadth of the license (*see* Lee at 3). Thus, the added leverage of an infringement action may render assertive licensing a more realistic pathway to success for relatively inexperienced licensors and/or licensors of more limited patent assets. Difficulties in proving infringement may also be factors in whether to pursue assertive licensing. (Neuenschwander 2008 at 79.)

Ultimately, a patent holder may be able to build leverage by approaching multiple targets and carefully revealing the generated interest to other targets. The opportunity to land a deal that deprives a competitor from utilizing coveted technology undoubtedly sweetens a prospective offer.

This is particularly true for clinical stage companies reliant on the coveted technology to secure FDA approval or make commercialization profitable.

When multiple targets present themselves early in the process, approaching the most optimal target after some level of negotiating with less ideal targets can prove useful. Such an approach allows the licensor to test its pitch and approach its primary target in a better walk-away position. In addition, a relatively larger target may be more likely to respond positively when the licensor wields leverage such as objective evidence of value (*e.g.*, third party valuations). Regardless, sophisticated licensees are unlikely to act impulsively or bypass their internal vetting procedures and, instead, may be more likely to walk away from an overly aggressive licensor even if a proposed license is backed by objective evidence of value. (*See* Strategies.)

Asset-Specific Considerations

Beyond evaluating targets and approaches suitable for a particular situation, the licensor must also consider which assets are most appropriate to license and the preferred timing to offer a license for particular assets. These considerations often depend on the stage of patent prosecution and technology development (*e.g.*, clinical progress), relative to discovering an act of infringement. Investments of time in developing and publicizing the technology behind a patent asset can pay significant dividends in enhancing the asset's value during negotiations. (*See* Strategies.)

The valuation of early-stage technology is intrinsically less certain than ready-to-commercialize assets (Razgaitis at 813), and broader usage in the market greatly increases patent value (*see* Dick). Thus, a patent owner planning to commercialize its own technology in a discrete market would likely expect better returns on negotiations after achieving some level of commercial success or at least clinical progress in the case of a life science product. Also, as regular out-licensors of technology often package together multiple patents that relate to a product or aspect of a licensee's revenue stream (*see* Bhandari at 3), it may benefit a licensor to more fully develop a patent family or portfolio of related assets before pursuing a licensee around a particular patent. An estimated 55% of patent assertions entail more than 5 patents. (Lemley at 810.) Strategic patent prosecution with potential out-licensing in mind, particularly outside of the licensor's own industry or field of use, can ultimately maximize the value of patent expenditures. (*See* Bhandari at 4; *see also* Dick.)

Conversely, engaging in any strategic out-licensing exercises early in patent prosecution can inform better prosecution strategies, such as through targeting claim sets in continuation applications (*see* Neuenschwander 2008 at 51), and patents with less than five years until expiration may be of less value (*see* Dick). That said, with the delays to market due to regulatory review (*see* Sheridan), owners of life sciences patents may be hard-pressed to both demonstrate value and fully exploit their patent term within the terms of a license. The value of a patented technology may also diminish as time progresses and other advances begin to supplant the patented invention. (*See* Dick.)

Out-licensing a relatively early-stage technology can help distribute the risk of commercialization, particularly in a highly-regulated environment. (*See* Hessenbruch.) Proprietors of drug delivery platforms or other platform technologies may consider strategically developing and/or licensing platforms for use with approved drugs to expedite the adoption of their platform.

For larger portfolios or particularly valuable assets, it is worthwhile to identify and investigate a number of potential licensees, even ranking them, including such factors as confidence in the level of infringement for assertive targets. (Bhandari at 6.) Accordingly, a patent holder may want to delay pursuing licenses beyond the time when it first encounters an infringer. Rushing what should be a

careful process, especially if an exclusive license could be negotiated, may lead to less than the best possible outcome. If a patent holder is looking to commercialize early on, however, suspected infringers, even without an infringing product on the market, would seem to have made some internal assessment that early-stage technology is commercially feasible. (*See* Razgaitis at 815, 847.) Furthermore, if a license is reached with the infringer, the success of a commercial product could facilitate additional license negotiations with licensees outside the infringer's field or others within the same field if the license is non-exclusive.

An objective understanding of the strength of a to-be-licensed patent asset, more so than the technology in general, may sway the decision between routine licensee and an assertive licensee. Only strong patents should be subjected to the risks of assertive licensing, particularly if they comprise core assets. Patents that were drafted or prosecuted without the benefit of experienced patent counsel may not make the best choice of assets for approaching an apparent infringer with which the patent owner is not in direct competition. Strong patents will include at least one independent claim that readily demonstrates an act of infringement; will include broad claims and a broad disclosure that discourages design-around (and preferably continuations will remain pending), and will issue with a substantial record of prior art considered. (*See* Dick.) The most attractive patent assets to a potential licensee add value to an existing widely-used and lucrative product or service. (*See id.*)

Patents covering core assets should not be neglected from licensing considerations. This is true when the licensor is practicing the core technology, and is especially true when the target licensees would practice the core technology outside of where the licensor is practicing, whether in a different industry or for a different application. (Neuenschwander 2008 at 33.) Experienced licensors often employ different strategies for out-licensing core assets and non-core assets (*see* Bhandari at 3), with the proximity of a patent asset to the licensor's core assets inflating its value (*see* Lee at 3). This may be particularly useful when the asset spans beyond the licensor's industry or, at least, specific field of practice. Given the value of core assets to a licensor, a litigation-wary licensor may generally feel more comfortable pursuing routine out-licensing of core assets—particularly when the asset is not being fully utilized by the licensor—rather than subjecting them to the increased risks of assertive licensing campaigns.

Considerations of Licensing Terms

Licenses for adoptable platform technologies are inherently prone to the negotiation of combination product or royalty stacking provisions, in which the royalty rate is subject to an apportioned value of the product based on a measure of value added or in which the royalty rate can be subsequently reduced in a calculated manner based on additional licenses that cover the licensee's product, respectively. (*See* Sheridan.)

A study of 50 university license agreements from 2008 - 2018 involving discovery or pre-clinical stage technology platforms found that 45% included combination product provisions, 42% included royalty stacking provisions, and 24% included both. All those including royalty stacking provisions also included a royalty floor to protect the licensor's interest, whereas only 16% of those including a combination product provision included a floor. (*See id*.) Contrary to those licensee-friendly provisions, nearly all of the agreements included some calculation of consideration for sublicenses, and nearly one third of the agreements prohibited sublicensing or required licensor preapproval. (*See id.*)

Pursuing deals with assertive targets or even non-assertive targets with compatible products already

on market may take out at least some of the guess work in negotiating the numbers behind these likely provisions and could provide some certainty for a less savvy licensor.

Since successful out-licensing to either a routine licensee or an infringing licensee is more likely to involve creation of a collaborative partnership, many successful agreements will also include some form of a consulting agreement, research development agreement, and/or licensing of know-how. The same interpersonal relationships that propelled a deal to completion may provide a strong foundation for a post-signing working relationship necessitated by such provisions. (*See* Hessenbruch.) These supplemental agreements, along with the licensing of secondary patent assets and/or cross licensing or collaborative development agreements, can effectively lengthen the term of the contractual partnership beyond the expiration date of the primary patent licensed and may mitigate incentives for a licensee to sue a licensor, in wake of the Supreme Court's ruling in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). (*See* Strategies.) These types of agreements are especially appealing, therefore, to licensors who are looking to expand business relations with a strategic partner. (*See* Hessenbruch.)

Of all the approaches available to a licensor, a hard assertive approach would be the least likely to culminate in a contractual partnership, given that (i) the relationship may be contentious, (ii) the infringer has demonstrated the ability to implement the technology sans a partnership, (iii) the licensor may not have been in the market for a strategic partner, and (iv) the negotiations may have proceeded in a more expedited and formalized manner. Thus, a licensor's appetite for a strategic partnership in developing the technology could affect whether it pursues a routine licensee or assertive licensee. If a patent holder does pursue an agreement with an infringer, but does not want to foreclose other strategic partners, a non-exclusive license is a likely option.

Along the same lines, grant back rights may be more contentious with an infringer, which likely has already independently invested in the development of the patented technology (*i.e.*, infringing activity). For early stage licensors in which the invention is still relatively nascent, however, IP rights to future improvements in the technology could be a particularly crucial component of any agreement. In general, more sophisticated licensees will expect to out-invest a smaller licensor in the development of the technology and will be less likely to grant back rights to smaller operations. (*See* Strategies.) Thus, company size and existing commitments to development of a technology on both sides of the table may complicate the choice of licensee, particularly for early stage technologies.

Conclusion

Patents have evolved into life-sustaining assets to many companies. For early stage life sciences companies in particular, patents may comprise the company's most valuable commodity and an essential means for capitalizing investments in R&D. Opportunities to leverage these assets require the patent holder to consider a lot of variables. How such companies assess those variables and strategically manage their IP will ultimately help shape the company's image and may even determine the company's future.

The entire process of leveraging IP could wisely include the creation of collaborative partnerships. For early stage life sciences companies, pursuing a collaborative partnership—even with a suspected infringer—can strengthen the company's reputation and preserve its options should more aggressive approaches (*e.g.,* hard licensing approaches, litigation) be needed. There should be little downside in at least attempting a soft collaborative approach in the first instance as long as certain steps are taken in advance. For example, the company should analyze the business situation and tailor the

scope of the contemplated license to the scope of the patent protection and each specific business situation. The company should also consider multiple targets and different approaches, as well as which assets are most appropriate to license and the preferred timing of any efforts to offer licenses for particular assets. An objective understanding of the strength of the assets under consideration—and their importance to both the licensor and prospective licensee(s)—may determine the success of the licensing efforts.

Lastly, companies, particularly early-stage companies in the life sciences sector, should keep in mind their core values when considering licensing their IP assets, especially when those assets are core assets of the company. The real risks of litigation to such a company must always remain top of mind, especially when core assets are involved, although a savvy licensor can still find a number of avenues for participating in the technology transfer arena, whilst avoiding unwanted litigation. In general, a company that proactively contemplates the merits, risks, and prospects of out-licensing its technology, at least in an abstract sense, may find itself better positioned to react appropriately when a non-competitive infringer comes into play than one who waits to ask itself these important questions and may feel compelled to act hastily.

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