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Leveraging Innovation Networks and Connecting the Dots Through Semantic Intelligence

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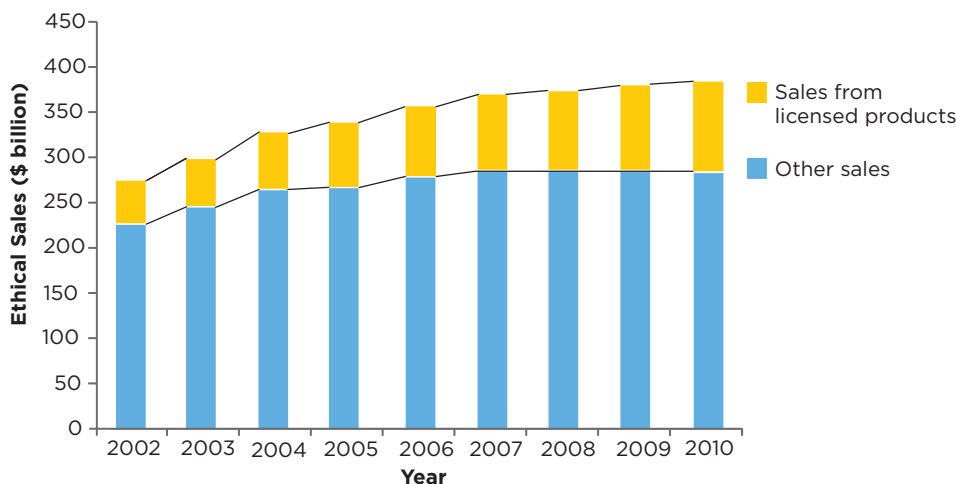
The self-contained “we can do it on our own” product development era is long over. **Payers are unwilling to pay for clinical differentiation alone.** While clinical development costs rise, payers are demanding biopharmaceutical companies to prove (or help prove) that actual product performance and value delivered “in the real world” meets or exceeds the claims that are made. Large pharmaceutical and biotech firms have nearly exhausted their product expansion and are now looking towards partnering with other organizations such as academic medical centers, universities and small biotech firms in order to compete in the pharmaceutical market. Such alliances are accentuated by the financial and shareholder pressures on these firms; they must not only fatten the pipeline, but also accelerate co-development efforts. Currently, this alliance trend is prevailing with over 40 percent of R&D budgets devoted to in-licensing.

Specifically, in-licensing involves the acquisition and integration of specific molecules, methods or complete products into a firm’s portfolio. In-licensing revenue at the top 20 large pharmaceutical companies in 2004 reached \$63 billion, up from \$38 billion in 2001. It is estimated that by 2010, one full quarter of large pharmaceutical sales would be derived through the licensing channel. Moreover, in-licensing is no longer just for the large pharmaceutical companies; in 2005, 43.8 percent of mid-pharmaceutical company revenues were attributable to in-licensing¹. As companies embark upon these significant partnerships, they will need to gather information in order to make careful and expeditious decisions that affect their finances and reputation.

The industry, in 2005, witnessed a record 66 percent growth in in-licensing activity.

Licensed products are forecast to be a key growth driver of the top 20 pharmaceutical’s ethical sales over the next six years.

Figure 1: Source: Datamonitor, “Licensing Strategies,” DMHC2139, 10/2005



Market Drivers

The industry faces the challenge to design complex drugs specific to diseases instead of symptoms. Biotechnology can produce medicines that can be tailored to a specific cell receptor or even a specific patient’s genetic makeup. Academic life sciences research and small biotech start-up firms are using the latest techniques in genomics, proteomics and biotechnology and have produced over 4,000 products. They account for a growing share of new drugs in clinical trials; eight of the 31 new active substances launched in 2004 were biotech drugs. The call for more complex drugs coupled with the steady decline in internal innovation has helped launch the in-licensing trend.

¹ Source: Datamonitor, “Mid Pharma Sector: In-licensing and other externalization strategies” DMHC2191, 6/2005.

Also fueling the trend to in-license is the growing number of post-marketing adverse reactions. Widely publicized issues such as Vioxx have put pressure on the market to enhance safety by increasing the number of clinical trials, eliminating unsuccessful drug candidates before they reach the market and conducting increasingly complex trials. In-licensing can help identify processes to make drugs safer by integrating expertise of the licensor and the licensee.

Most importantly, the financial numbers make good business sense. A billion dollars invested in in-licensing results in much higher returns over the same billion invested in internal development.

Taking the In-Licensing Pulse	
Amount invested in in-licensing in 2005	\$17 billion
Revenue generated by in-licensing at Top 20 pharmaceutical companies in 2004	\$63 billion
In-licensing-based revenue at mid-tier pharmaceutical company in 2005	43.8 percent
Returns on \$1 billion/year invested in internal R&D	\$14 billion
Returns on \$1 billion/year invested in in-licensing of Phase III drugs	\$22 billion

In-Licensing

In the light of these challenges, pharmaceutical companies are looking for ways to fill the product pipeline faster and are turning to in-licensing as a potent solution. In-licensing complements internal R&D efforts by allowing companies to react more rapidly to industry trends. This trend also benefits smaller firms which often lack the capital to support the expensive R&D process estimated to cost around \$900 million and last up to 10 years per product.

As a result, large biopharmaceutical companies are intensely competing with each other to form alliances with small biotech firms and other research organizations. For example, traditionally pharmaceutical companies would in-license compounds in Phase II and drive them through the final testing and marketing stages. However, an increasing number of agreements are now being negotiated for compounds in early stages of development where costs and competition are low. Pharmaceutical companies are even beginning to offer high-success-dependent payments for substances in early stages despite the 6 to 7 years it generally takes to transition a drug from this phase to a marketable product. Moreover, biopharmaceutical companies are also seeking alliances with small biotech firms, thus fueling market competition.

The industry, in 2005, witnessed a record 66 percent growth in licensing activity — a whopping \$17 billion was spent on licensing-based transactions. Synergy between networks of large pharmaceutical, large biopharmaceutical and small biotechnology firms are likely to become even more prominent. These collaborations allow for organizations with diverse capabilities and resources to leverage their strengths. As more experience is gained, and as collaborative practices become institutionalized, returns on investment in alliances are expected to increase.

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Challenges

There are several challenges to the current paradigm of licensing. Mounting transaction costs exceed \$1.0M per deal. Being late in the game increases risk of overpayment, missed channel placements cause losses in hundreds of millions of dollars, managed care input is not solicited early in R&D thinking leading payors to push back on clinical differentiation alone, and poor scalability forcing re-synthesis outside of patent scope.

The good news is that there is no dearth of proposals and solicitations for licensing. Companies are flooded with proposals, which have to be evaluated for fit-for-purpose. This imperative process is time consuming and involves identifying the right candidates, as well as revenue enhancing opportunities. Scientists from organizations canvas conferences for presentations and poster sessions, lawyers vigilantly scan recently filed patent disclosures, and medical researchers pore through journals in search of the next licensing opportunity. Gathering these large volumes of information and locating experts to review and make recommendations is costly and time-consuming. Thus, the current process of finding beneficial licensing ventures is neither effective nor efficient.

For example, a company sends a scientist specializing in cardiovascular diseases to a conference to gather information on the latest products and developments. This scientist would naturally focus more on sessions that pertain to his or her

In the face of the “bidding war” for late stage compounds, pharmaceutical companies need to take a venture capital portfolio approach to innovation. The “outside world”, using collaborative networks and observational data, is continuously motivated and positioned to know more (or claim to know more) about your products’ comparative effectiveness and risks than you do. In future, pharmaceutical companies will need to cast the net wider to search for innovation.

area of expertise and likely neglect the rest. However, there could be a novel process in another therapeutic area which reduces development time by three years that would be overlooked. In another illustration, a medical researcher goes through several articles on anti-infectives, but due to the sheer volume of data across multiple public and subscription-based databases, he/she fails to correlate context across journals and articles. Even exemplary proposals and solicitations that are presented to the company could take time to investigate. These delays could translate into missed opportunities in the competitive marketplace.

Considerable oversight also occurs when a pharmaceutical company proceeds with license acquisition on a process or technology that was already developed in-house, but was lost in the volumes of data sitting in corporate repositories. This dismissed wealth of internal knowledge results in an unnecessary loss of opportunities. In this increasingly competitive and demanding market, companies can no longer afford to ignore this crucial component of in-licensing.

It is very difficult to rapidly screen and decipher opportunities as integration of complex data sources is required to see the “whole picture” and to make an informed decision. The cost of “missed opportunities” is in millions of dollars.

Traditional Approach

There have been numerous solutions to obtain improved search results. Certain programs allow for simultaneous queries of different sources resulting in greater numbers of results. Others employ clustering that tries to group results with similar keywords. Semantic searching with ontology support gives the search engine an understanding of a part of the word, enabling it to expand a query with synonyms of specific search terms and propose broader or narrower categories. Ontologies, however, require enormous effort to be set up and maintained, particularly for dynamic topics like life sciences. Additionally, integration of multiple sources with different ontological structures is extremely complex. Finally, text mining extracts meaning out of large amounts of text and displays only a fraction of the original text.

Effective Licensing

In the face of the “bidding war” for late-stage compounds, Pharmaceutical companies will need to take a venture capital portfolio approach to innovation.

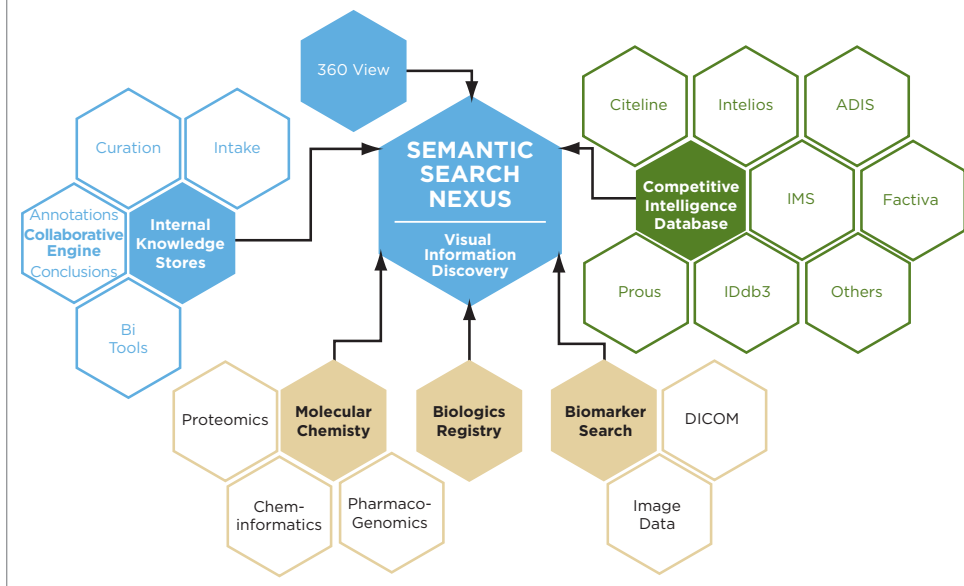
Many pharmaceutical companies are narrowing their therapeutic focus and will have less financial wherewithal to pursue everything in their labs in the years ahead. It is very likely that companies will out-license assets that they are unable or unwilling to develop internally. Pharmaceutical companies have sometimes been risk-averse in their attitudes toward out-licensing — preferring to hold on to something rather than give away the next big thing to a competitor. But now, with companies deciding that it is no longer strategic for them to compete in certain spaces, pharmaceutical company managers may be less reticent. This could create opportunities for investors that can pair promising clinical candidates with experienced entrepreneurial in-licensing teams to commercialize these assets. These out-licensing and in-licensing trends will get an additional boost from the need to boost R&D efficiency. As a bottom-line focus further constrains research budgets, pharmaceutical companies will need to fundamentally revisit the cost-benefit of their R&D expenditures and search intensely for the most efficient means of pursuing their product development goals. As they do so, it is quite likely that some firms will see more efficiencies and higher returns from conducting a greater share of R&D — particularly in discovery and early clinical trials — in concert with external partners.

The solution is inspired by cognitive neuroscience that changes the way search technologies process information. The human brain represents information in cross-linked multilayer networks. The brain retrieves information using associative activation spreading along paths that are formed by learning processes and experience. The solution represents and processes knowledge in networks, researches direct and indirect associations, and draws insights from neuro-linguistics for sequence and interaction of syntactic and semantic analysis.

Currently, pharmaceutical companies search for and pick winners after a viable product has already been developed. There is increasing competition for in-licensing and innovation is likely to come from unexpected places. Pharmaceutical companies will need to search and cover a broader range of early development activities, allowing products to evolve whilst retaining an interest. They should take numerous bets with greater coverage by adopting a venture capital type approach in partnerships until they mature and can be brought in-house through the usual BD approach. External innovation will need to be sourced from a much larger geographic footprint than today with a focus on determining the landscape of technologies and people, influential innovators, IP sources and capabilities and competitor portfolios.

Making sense of all this connectivity is challenging. Scientific and commercial value is waiting to be unlocked via mining vast sores of connected data. To combat this dilemma, CSC has built a solution around semantic integration of structured and unstructured data and brainlike information management. This solution can provide scientists with powerful research-friendly environments. They can quickly and effectively explore the wealth of connected information. This new “semantic engine” can organize and present information in a visually appealing manner, highlight connections, and help scientists rapidly find correlations between previously unavailable data.

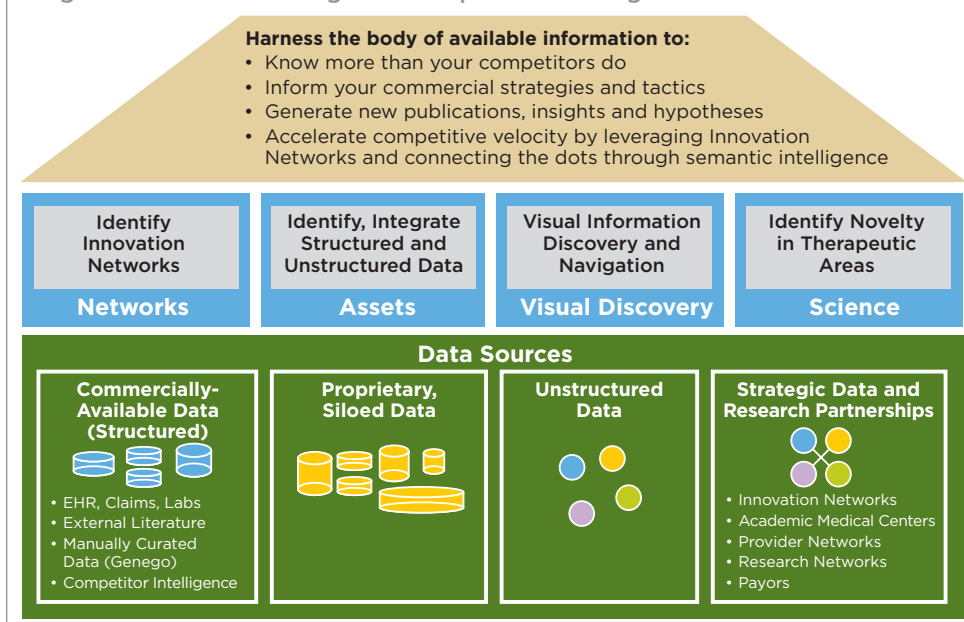
Figure 2: Semantic Search/Competitive Intelligence



CSC’s Licensing and Competitive Intelligence Framework

CSC’s solution framework can also help in novelty identification in a therapeutic area, in drug repositioning, and semantic intelligence to accelerate competitive velocity.

Figure 3. CSC’s Licensing and Competitive Intelligence Solution Framework



- Companies will have the ability to mine innovation networks and find correlations across various types of data to make better business development decisions
- Semantic Intelligence will help researchers make discoveries across and among information sources which previously had no connectivity.
- Use semantic network models tied to disease traits to generate potential new indications for compounds.
- Use multiple sources to prioritize and fast-track compounds for new disease indications — Competitive Information is not just stored in unstructured scientific documents but also available to purchase through competitive intelligence vendors and manually curated data providers. As scientists we want to bring all of this information together to make an informed decision.
- Understand the different landscape for different questions posed — Working in new disease areas, we don’t have the full context. We need to be able to assimilate thousands of documents and understand the landscape quickly.

In order to justify high prices for products, pharmaceutical companies will need to combine the simple offering of a therapeutic with financial solutions to help payers shoulder the cost burden, information/evidence packages with a heavy focus on health economics, and “soft” end point and additional services (e.g., assistance with compliance management). Real-world healthcare data is being amassed and used by others (including your customers and competitors) to influence decisions about how your products are used and valued — globally. Licensing the right compounds indeed requires a new approach and meaningful insights.

- **Rapidly identify potential new opportunities for our compounds and drugs** — We have millions of compounds with focus on several major disease areas. There are opportunities where these compounds could be used for new disease areas in areas of unmet patient need.
- **Get alerted to Novelty in therapeutic areas, visualize complexity and make portfolio prioritization decisions with stronger considerations for reimbursement pathways, not just regulatory approval** — For new opportunities, without working in areas for many years and knowing the subject matter intimately, we need to be able to access breaking science and find new ways to filter this information.
- **Increase the efficacy by targeting multiple targets with a single compound** — Only around 1 in 9 compounds make it through development and into the clinic. The major causes of attrition are efficacy (~30 percent) and safety (~30 percent). Biological pathways are complex and by inhibiting one target, feedback loops and processes can circumvent this, decreasing efficacy.

It is important to get early insight into emerging innovation for in-licensing. The wave of out-licensing will also create opportunities for investors and biotech entrepreneurs, spawning new start-ups and creative business models. To build sustainable, competitive pipelines, pharmaceutical companies must be more effective at searching for innovation from a wide range of sources. The key to searching will be better use of pharmaceutical company resources, with the whole organization becoming the eyes and ears of business development. Taking a company-wide CRM approach may help systematize the searching process and allow companies to look for ways to include deal sourcing as part of the performance management system for scientists. Pharmaceutical companies will also need to develop new collaboration approaches to access diverse sources of innovation. Wider and different types of collaborations will require new management approaches for value creation.

We believe that semantic information management will bring a fundamental shift to licensing — users are not only able to obtain information much faster, but they will also be able to discover interesting, unknown and relevant material, thereby making it true competitive intelligence rather than a competitor intelligence solution. CSC’s solution will lead to the discovery of otherwise unknown connections, identification of R&D opportunities, as well as a comprehensive overview of the most current and revolutionary technologies and processes on the “research market.” Data illustrates that the number of companies choosing to in-license continues to grow; this innovative semantic intelligence will bring competitive velocity by leveraging innovation networks and connecting the dots across internal and external data, structured and unstructured data, and by providing meaningful insights into strategic planning.

Will your licensing candidate be the next blockbuster, or a small product used for third line treatment?



About the Author

Sanjeev Wadhwa is a Partner, Senior Strategy Expert and Global Leader of R&D solutions within CSC’s Life Sciences Practice. He directs CSC’s Life Sciences R&D Practice, where he concentrates on making organizations competitively agile, determining strategic investments, and fueling organic and acquisitive growth through identification of attractive industries or market segments for investment focus, with excellent exposure to end markets and corporate spending arenas within life sciences and healthcare industries.

Mr. Wadhwa provides board-level advisory services to executive management councils at several companies to streamline development of business and technology strategies in personalized medicine, comparative effectiveness research, consumer-directed healthcare, biomarkers and adaptive trials. He has led the corporate strategy and large-scale business improvement operating model efforts for several *Fortune* 500 companies conducting global rationalization studies to enable identification and commercialization of promising candidate innovations.

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CSC makes a special point of understanding its clients and provides experts with real-world experience to work with them. CSC is vendor-independent, delivering solutions that best meet each client's unique requirements.

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