

Managing the High Cost of Patent Infringement

Indicators of senior management advocacy and business alignment tell a story about biopharma's ability to protect the company jewels

by Robert Williamson and Chris Stone

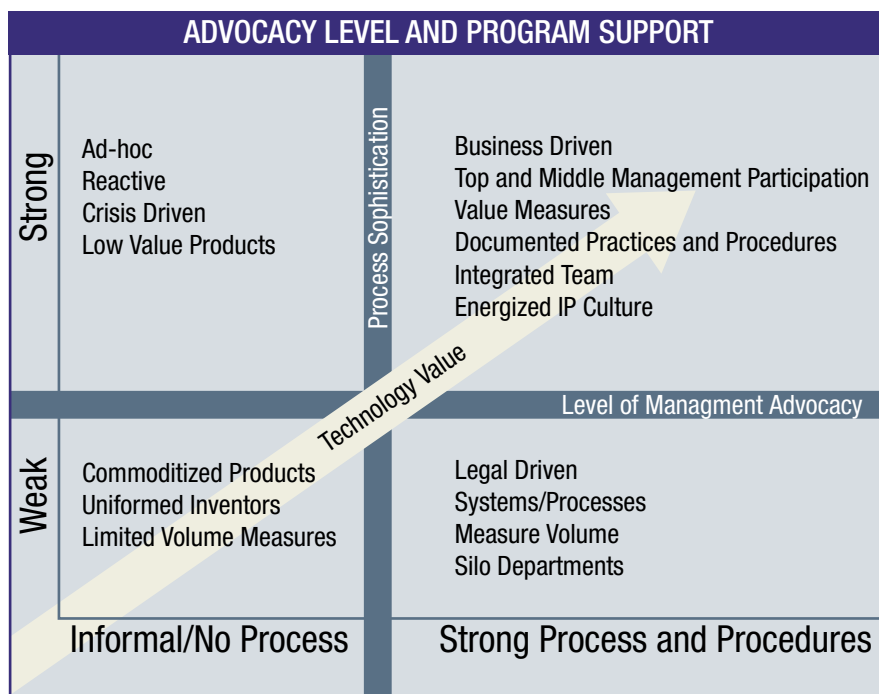
Senior management in today's technology industry is under increasing pressure to produce blockbuster innovation to fuel corporate growth. This is nowhere more apparent than in the pharmaceutical industry, where new drug discoveries are designed to translate into market monopolies that garner high margins and huge sales. New drugs must enjoy market exclusivity and consequent high margins to justify the cost of drug development. Of course, imitation is the sincerest form of flattery, and such hard earned market exclusivity will be tested by the concerted efforts of competitors who wish to enter the market with an identical or similar product. Given that exclusivity is often the result of tight patent protections, the predictable result is a showdown over patent rights.

This scenario plays out again and again over the most successful drugs. Large pharmaceutical company efforts to retain monopolies covering multibillion dollar drugs have resulted in frequent litigation against potential competitors, with potentially enormous financial consequences for all parties involved. Patent lawsuits centering on best-selling drugs such as Pfizer's Norvasc (2005 revenues of \$5 billion) and Celebrex (\$3 billion), Lilly's Zyprexa (\$4.7 billion), and AstraZeneca's Nexium (\$5.7 billion) illustrate well the business risks attendant in patent issues.

The growing convergence between big pharma and the nascent biotechnology based pharmaceutical (biopharma) industry has become apparent in recent years as biopharma companies have been bought by big pharma, and fully integrated biopharmaceutical companies have emerged. Accordingly, it is not surprising that biopharma companies have had similar experiences with high profile patent litigation around their most successful therapeutics. For example, Amgen's EPO and Genentech's Herceptin, both benchmark biopharmaceutical products, have been subject to patent litigation.



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Benchmark surveys and industry experience show that biopharma companies, although having a high level of advocacy, lack the rigor and program support of their big pharma counterparts.

Given the criticality of patent monopolies to the bottom line in big pharma, it is natural to assume that companies there have developed sophisticated procedures, processes, and policies for assessing the business value and business risks associated with the management and procurement of patent rights. It is further natural to assume that high level management support and adequate resources are available to ensure that intellectual property management enforcement achieves business goals.

Based on ipPerformance Group's "2006 Strategic Intellectual Property (IP) Management," a survey of more than 150 R&D driven companies, we took a look at those assumptions. Our goal was to assess business sophistication regarding patent management within a select number of large pharma companies ("big pharma") by analyzing indicators of senior management advocacy and business alignment, and to compare those results with those of a select group of companies representing the rapidly emerging but comparatively immature biopharmaceutical industry.

TOLL OF INFRINGEMENT

Patent infringement takes a significant toll on an organization. Senior management will recognize the financial impact of external legal, expert, and consultant costs, and such direct costs seem well understood.

Indirect costs, however, typically receive far less attention. For example, internal legal department expenditure is very tangible and can result in fewer

patent applications filed, fewer counseling sessions between IP counsel and the projects, fewer opportunities to educate the business and technical communities about developments and strategies relevant to competent IP management, and others. Other indirect costs result from distraction of key personnel from discovery and depositions, the use of R&D resources for litigation purposes instead of product development, contingency planning for litigation outcomes, and maintaining customer relations, all of which can be significant. The shift of such internal resources to litigation support and response represents a very real threat to future opportunities for the business. Additionally, litigation can take an emotional toll on an organization that is difficult to quantify.

Given such significant direct and indirect costs, it is imperative that litigation be fully aligned with the business strategy

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of the patent holder and that the costs of infringement are fully assessed and justified before entering litigation.

SENIOR MANAGEMENT ADVOCACY

The high profile of patent litigation in both the biopharma and pharmaceutical arenas would be expected to lead to a high level of senior management advocacy regarding patent issues in both industries. Our data support this premise and show very high levels of advocacy on the part of senior and middle management with respect to patent issues. In fact, all of our respondents in both big pharma and biopharma stated that intellectual property litigation is "very important" to the business. Both industries agree conceptually that a primary value of patent assertion is exclusion, not promotion of licensing opportunities. Thus, enforcement of IP as a business tool is clearly a primary motivator in both industries, as it should be.

We sought insight into whether IP advocacy within senior management translates into operational action by assessing resistance by line managers to allocating financial resources to intellectual property matters. Big

pharma industry line managers are significantly more accepting of IP costs than are those in biopharma. Big pharma's acceptance of costs could be the result of the lesser relative impact of an IP budget there than in cash-strapped biopharma. However, relative cost intolerance could also suggest that biopharma companies are less willing to make the financial and resource commitment necessary to maintain high performing IP operations.

The sophistication with which a company approaches the generation of value from an IP function is reflected by its IP success criteria. Thus, IP success metrics provide insight into the value senior management applies to patent activities. Big pharma considers a number of factors as critical to success, including freedom from litigation, settling IP disputes on favorable terms, obtaining exclusivity on key products, and quantifying value to the business. In contrast, in the biopharma industry, obtaining more patents was considered the number one criteria for measuring success. Moreover, when asked how companies would allocate additional resources for IP, all biopharmas selected getting more patents as their first choice. The emphasis on naked filing numbers implies at best a simplistic and often inaccurate understanding of business value and at worst a complete disconnect between the business and the IP function.

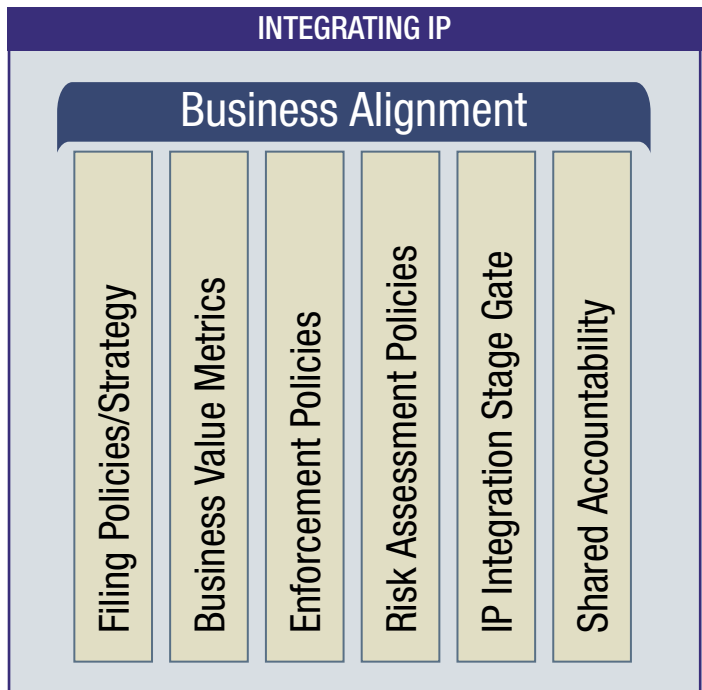
SOPHISTICATED MANAGEMENT PROCESSES

Both biopharma and big pharma senior management are strong advocates for IP value within their companies. However, the manner in which this translates into business integration and process sophistication differs significantly.

Big pharma companies are generally much more likely to have formal IP processes than biopharma companies. For example, formalized IP training programs are maintained by many more big pharma companies. Moreover, big pharma companies uniformly have documented policies and procedures whereas a significant number of biopharma companies do not. Although it may be possible for small biopharma companies to efficiently gather decision makers and resources on an informal basis, this model will be greatly taxed as these companies begin to grow and mature.

Big pharma shows a far greater tolerance for the cost of litigation. In fact only a small percentage of big pharma respondents stated that they avoid litigation because of high costs whereas half of biopharma respondents indicate that they avoid litigation because of cost. Although this can be at least partially explained by the relative impact of litigation costs, this same explanation suggests that small biopharma companies should review litigation opportunities with great diligence and include

all interested parties in such discussions. However, to the contrary, senior management participation in IP decisions in big pharma is higher than in the biopharma arena. Just as pertinent, however, participation of non-R&D business functions in IP matters is higher in big pharma than in biopharma. This suggests that small biopharma is allocating scant nonlegal and nontechnical resources to assessments of infringement. This finding is consistent with other data showing that marketing and senior executives are more likely to be represented on the patent review board in a big pharma company than in biopharma. The absence of business representation in



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creation and enforcement decisions should be of great concern given the extreme effect litigation can have on the business of a small biopharma.

We also surveyed the incorporation of IP strategy as a component of business unit strategy. Presumably, business unit operational strategy is vetted and approved by senior management as part of a formal process. The presence or absence of an IP pillar in a formal business strategy shows the significance senior management attributes to IP enforcement as a value generation tool and its willingness to allocate resources to development and implementation of such a strategy. Further, the incorporation of an IP strategy into a larger business strategy suggests strong business interest and focus on enforcement. In our survey, we found that less than

half of both big pharma and biopharma companies are incorporating IP strategy into their business strategy. In our opinion, both industries are missing an opportunity to fully leverage their patent estates.

Nevertheless, it appears that big pharma better understands the value IP enforcement can have to a business sector. For example, big pharma business units are three times more likely than biopharma to receive additional internal resources when they are successful in obtaining key patent assets, presumably that align with their business goals. This de facto reward system will likely encourage more active business participation in the development and enforcement of IP. On the other hand, the failure of small biopharma companies to recognize patents in their strategic business planning or reward business implies a gross dysfunction with regard to utilization of intellectual property as a business tool.

BUSINESS ALIGNMENT

Alignment of IP goals with business goals ensures that support and, ultimately, resource allocation are focused to improve the bottom line. Alignment should translate into processes that include the business perspective in creation of the intellectual property landscape within which the business must succeed.

Alignment between IP and business can be built into the corporate structure from the start.

Operationally, alignment of business goals and IP goals requires that business is a key part of the process, and at least partially accountable for the creation, management, and enforcement of IP.

However, our benchmark data suggest that within the biopharma industry, the stated importance of IP to senior management is not translated into day to day participation or a share of the responsibility for IP by business managers. Unless business managers have at least partial accountability for both success and failure of the corporate IP program, it may be difficult for them to justify funding IP from their scarce and valuable resources. Such a model can only lead to siloed IP operations and ad-hoc and/or crisis driven management when IP issues explode on the scene.

In the case of small start up biopharmas, business functions may not be fully developed because products are still in the early pipeline and sales are years away. In such a situation, the opportunity to create alignment between IP and business would seem to be particularly

attractive: that alignment can be built into the corporate structure from the start. Creating a culture of alignment at this stage of corporate development will require strong vision on the part of senior management because it may seem more important to allocate available resources to accelerate product development. The cost of delay, however, will be potentially more disruptive process and culture realignment down the road.

The benefits to a company of integrating IP strategy into its business unit strategy are very clear. When business is adequately involved in IP processes, crisis is less likely and the business is more able to be proactive. A company can't control the patenting, copying, or aggressive competitive behavior of other companies. But by participating in identification and discussions of infringement issues, business can participate in creating appropriate responses while options are available, and those responses make business sense, as opposed to responding after the crisis has come. Once an IP crisis occurs, risk assessments performed by legal may leave business very little wiggle room. It is important that senior management fight the tendency in business operations management to relegate IP matters to the lawyers. The effect of IP matters will be felt keenly by business and difficult decisions associated with IP issues require business acumen to evaluate how to proceed.

ASPIRATIONS FOR THE BIG PLAY

Most biopharma aspires to hit it big, whether that comes about as a result of an acquisition or rapid growth. Big pharma's sophistication in IP management practices can play out in acquisition due diligence processes. A potential acquirer will evaluate its target's procedures with as much scrutiny as it would evaluate pipeline products. It would be unfortunate to be a potential acquisition target, on the verge of achieving significant monetary value for hard earned technical success, only to have the acquisition premium scaled down as a result of acquirer diligence revealing poor IP management processes.■

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