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D I S T R I B U T E D R & D

Introduction

In todays business environment, there are significant pressures on organization's research and development (R&D) budgets with R&D leaders being asked to do more with less. There is a drive to increase innovation and productivity beyond the revenue growth of the company.

The pharmaceutical industry is not immune to these pressures. Pharma's cost problem is driven by the spiraling expense of research and development, which is in turn a function of the high number of "late stage" failures: compounds in which large investments have been made before discovering adverse side effects, unexpected toxicity in humans, and so forth. As a result of this falling productivity, the average cost for each approved drug has been skyrocketing to between $800 million and $1.7 billion. Why has this happened? Some industry commentators point to increasingly stringent FDA guidelines in the wake of the Fen-Phen debacle in the late 1990s and more recently the withdrawal of Vioxx from the market in late 2004. The result is that pharmaceutical companies are delivering fewer drug therapies to market.

Declining research and development productivity has led Pharmaceutical companies to respond predictably enough. At the strategic level they have focused increasingly on "blockbuster" drug therapies that command high prices and appeal to large number of patients. This only makes sense: if it costs an average of nearly a billion dollars or more for each drug actually launched, than on the average every drug launched will have to generate at least that much revenue if the company is simply to break even.

According to a recent U.S. Food and Drug Administration (FDA) report, since 1993 the industry's expenditures have risen 250%, while the number of submissions to the FDA has dropped 71%. The cost per new approved drug has increased more than 800% since 1987. In other words, the industry is spending more and more to deliver less and less.

The result is not only rising medication prices. What is more worrisome is that an increasing number of disease states are in danger of getting left behind because pharmaceutical companies simply cannot afford to research treatments for conditions that afflict too few people to constitute a profitable market. After decades of spectacular success, the Big Pharma business model seems decreasingly able to deliver economically viable compounds (1).

Few in the industry are unaware of the magnitude of the R&D productivity problem, and many are working diligently to solve it. Three strategies are currently popular: (1) mergers and acquisitions (M&A)--firms purchase the R&D pipelines of other organizations in order to drive revenue while hopefully cutting their own costs; (2) in-licensing new compounds--companies buy the rights to use compounds that others have discovered rather than relying solely on drugs developed in-house; and (3) contract research organizations (CRO's)-firms primarily use these during Phase 1-IV clinical trials.

Though each of these strategies has merit, none of these have yielded savings on a scale that would offset current (and future) R&D budget demands. Successful mergers have captured some economies of scale in sales personnel, headquarters real estate, and research facilities, but the savings typically achieved fall far short of compensating for diminishing R&D productivity. In-licensing is beneficial to the licensor, only if it receives compensation for the full cost of its development efforts. This means that licensees are paying for any failures a licensor might have encountered on the way to developing the product or process being licensed. Consequently there is no structural improvement in research productivity. CRO's cannot deliver the level of economization the industry needs either: currently, CRO-driven savings are variously estimated at up to $133 million on costs of $800 million-$1.7 billion in total drug development costs. These are surely worth having, but at the high end of drug development cost estimates, the impact amounts to a reduction of less than 8% (1).

Unfortunately, then despite well intentioned efforts and any money savings so far, the underlying pathology of dismal productivity remains.

The typical pharmaceutical company's engine has been a monolithic, vertically

integrated, organizationally contained R&D functions populated by thousands of scientists and researchers. For decades success stemmed from *solving* problems. That is to say, a bricks and mortar R&D infrastructure and the idea that the innovation must predominantly live within the four walls of the company. "Invent it ourselves" has been the mantra and for almost the last fifty years this approach has served the industry, and its customers, very well, resulting in a stream of new drugs that have improved life expectancy and quality of life for hundreds of millions of people around the world.

However, this is no longer a sustainable business model if one is expecting continued high levels of top line growth. The costs associated with the current model have increased to the point that the industry can no longer deliver new drugs that are both commercially viable and meet the needs from those suffering from anything other than those conditions affecting tens of millions of others. In other words, the industry is far less able to innovate and improve in ways that its customers are willing and able to pay for.

Along with the decline in productivity and the business pressures discussed above, companies are finding themselves in an era of incredibly rapid knowledge creation and technological change. These advances in science and technology driven research have yielded dramatic increases in the volume of scientific knowledge. This explosion of knowledge makes it nearly impossible for most organizations to stay current with significant new trends and identifying and locking up key sources of knowledge for competitive gain. Joy's Law (attributed to Sun Microsystems cofounder Bill Joy), "No matter who you are, most of the smartest people work for someone else", points out this essential knowledge problem that faces many enterprises today. Many companies have come to this realization that although they hire the best and brightest people in their fields, there are thousands who they could tap into, that are outside their walls. This law can be applied to most organizations that are responsible for continually delivering innovations to stakeholders (2).

Over the next five to ten to fifteen years, there are some key demographic variables that companies will also have to contend with. Fewer and fewer people are being trained in the sciences in the United States and Western Europe, while at the same time there is a

growing number of scientific talent that is nearing retirement in many organizations (the first of the baby boomers are at "early retirement" age-59). The baby boomer brain drain will be especially acute in the so-called STEM careers: science, technology, engineering and mathematics (3). All of these STEM disciplines are critical to the future of Western economies.

Distributed R&D Models to the Rescue

So how do companies continue to have high levels of top line growth through more productive innovation methodologies? How can companies tap into the world's best scientific minds in the research and development arena in the most efficient manner possible?

Distributed innovation systems are an alternative complementary approach to organizing for innovation that seem to meet the challenge of accessing distributed knowledge. These systems are an important addition to an enterprises' portfolio of innovation strategies. This will require a fundamental reorientation of views about incentives, task structure, management and intellectual property. The Distributed R&D model provides R&D leaders with the ability to manage all of these fundamental shifts that they are going to be dealing with over the next five, ten or twenty years. An open innovation approach provides companies with dramatically expanded access to talent that includes all the retirees who are going to leave the regular workforce. However, that doesn't mean they (retirees) are going to stop working; they are already participating in these external distributed innovation networks.

If ever a tool was made to order for the establishment of a distributed global scientific community it is the Internet. There are no limits of geography or time and there is access to rich sources of data. It can be the ultimate meeting of the minds. The opportunity to collaborate with limitless others from widely varied backgrounds exists. The Internet affords the opportunity to share knowledge across all boundaries and borders--providing potential limitless access to global R&D capacity. The speed of R&D can be significantly increased and there can be gains in productivity and creativity. The core premise is not only that somebody "out there" may already have solved your problem or something similar, but that they can be found and contacted quickly and efficiently by way of the

Internet.

For distributed R&D to work it is crucial to know what one is looking for, or where to play. The success of a networked strategy depends upon the ability of companies to articulate the problems they want solved, and to define in advance and in detail exactly what constitutes an answer. However, there are benefits to broadly exploring different paths to achieving a solution. A tightly integrated and well-resourced internal R&D function is critical to finding viable solutions while tapping the global network. Companies striving to organize and tap this diversity of talent, specifically for R&D-like commercial applications include entities as diverse (topically and business-model wise) as YourEncore, NineSigma, Innocentive, and Science24Seven to name a few. Every one of these companies approach to Distributed R&D differs in its breadth, focus and value proposition.

Innocentive

Innocentive was launched in 2001 by Eli Lilly as a result of the R&D productivity issues facing the pharmaceutical industry. Innocentive was created as an online market place between corporations with R&D challenges (narrowly defined, discrete scientific problems) and external Scientists (Solvers), who could approach problems from many different angles. Using broadcast search techniques, Innocentive posts scientific problems from it's clients (pharmaceutical, biotechnology, consumer goods, specialty chemicals; traditionally closed enterprises) to a global network of 120,000 registered solvers. Firms can post discrete scientific problems together with a cash prize for an acceptable solution. Problem posters and prospective solvers remain anonymous to one another throughout the process. Such an innovative approach gave top scientists around the world the opportunity to solve the problem of their choice (self select) and earn financial rewards. Innocentive's business model is a hub and spoke model. The scientific problems are broadcast to the large global community of solvers however, the solvers work independently and do not share their knowledge and solutions with each other. This naturally can limit the innovative capability of this distributed network. Solutions can and do arrive from unexpected sources. For example in one case a seeker firm's research and development laboratory was having significant difficulty with a

toxicology study. They posted their problem on InnoCentive.com. The problem was solved by a PhD in protein crystallography using methods common in her field to solve the toxicology problem. The solver would normally not be exposed to toxicology problems, however in this case, she successfully applied knowledge from crystallography to the toxicology problem. In another case, a physicist, a small agribusiness owner, a transdermal drug delivery specialist and an industrial scientist all submitted diverse winning solutions to the same scientific problem: identification of a polymer delivery system.

YourEncore

YourEncore helps companies accelerate innovation by connecting them with a network of retired and veteran scientists and engineers with proven expertise and experiences. YourEncore, founded in 2003, has built a network of over 4000 (and growing) network of retired and veteran scientists and engineers from 150+ companies. Client companies (pharmaceutical, chemical, aerospace, food science industries to name a few) can tap into a network of experts with deep experience and new ways of thinking from other organizations and industries to solve their toughest problems. YourEncore provides corporations access to a stream of highly qualified and readily available technical help in time of need to address the toughest challenges of innovation. For example, a retired Ph.D. chemist from Kodak with 30 years experience in photographic color stability was able to solve a consumer products company color stability challenge in a new hair color product. A retired rocket scientist with expertise in avalanche predictions found a way to stop powdered detergent from caking and an Aerospace engineer assists consumer products Baby Care division on how to apply virtual modeling concepts and techniques to the design and prototyping of diapers. Again these experts were able to apply a different lens and set of experiences to the client's problems.

Distributed innovation systems thrive when organizers embrace openness, transparency, and IP regimes that sustain continued collaborative participation. To this end, YourEncore has launched the Innovation Community, an online collaboration platform for scientists and engineers. The Innovation community bridges the gap between closed

innovation and open collaboration and breaks away from the hub and spoke models that have been the standard until now. The Innovation Community enables open innovation in a secure online environment while allowing experts and clients to participate in professional communities. Community participation provides experts with the ability to converse with like minded peers, answer questions posed by clients and participate in problem solving forums and clients with the ability to ask questions, conduct ideation sessions and manage project work more effectively. To date, clients have been using these forums extensively for technology scouting and ideation sessions.

NineSigma

NineSigma uses a similar operating model as Innocentive. Nine Sigma's mission is "to work on behalf of its clients to source innovative ideas, technologies, products and services from outside their organization quickly and effectively by connecting their organization to the best innovators from around the world. NineSigma serves as a broker in the business of sourcing ideas. NineSigma's posts request for proposals (RFP) to a community of solvers worldwide. Anyone can submit a non-confidential proposal back to NineSigma. The idea is not to get back specific solutions for a discrete scientific problem, but to identify people most likely to be able to provide solutions on a contract basis. NineSigma will connect the company and the solver to discuss and negotiate next steps.

The following is a NineSigma success story: a consumer products company had developed prepackaged pouches holding laundry detergent. The plastic pellets holding the liquid detergent were leaking and staining the packaging. A small company from Britain that had experience in packaging agricultural concentrates using a similar type of film worked with the Consumer products company to solve this problem. As it turned out, they had solved a similar problem and so were able to take their learnings and apply it to the consumer products company's problem.

Science24Seven

Science24Seven will provide a global scientific network to empower and accelerate innovation processes. Science24Seven's platform will provide corporations, academia, non-profits and governments the following products and services: customized networks

specifically tailored to clients requirements, a global pool of scientific, engineering and medical experts, an innovation marketplace and the ability to collaborate directly between scientists worldwide. Science24Seven will launch in the Summer of 2008.

Summary

Distributed R&D innovation systems recognize that knowledge is unevenly distributed, and that it can be found in the minds of many and that often this knowledge does not necessarily reside within the walls of a company. Innovation can come from the free exchange of ideas between scientist from different horizons and backgrounds. The origin, quantity, diversity of solutions and the breadth of solvers and/or experts continue to surprise client companies who have employed these methodologies.

This approach mandates a cultural change within the enterprise. Scientists have been hired to be problem solvers--they must transform from being solely problem solvers to solution seekers and celebrate solutions that come in from outside the four walls of the organization. The not invented here culture cannot be tolerated any more. The cross fertilization of ideas, scientific disciplines, experiences and minds and the ability to tap creativity on a scale that is beyond the reach of scientists working in academia, government, industry, to name a few, efficiently and cost effectively are hallmarks of this approach.

One of the unexpected benefits of a distributed R&D approach is problem definition. By not using a distributed innovation system, organizations lose the opportunity to begin to thinking about their challenges in terms of problem definition and remain stuck in the old paradigm of problem solving. Without the rigor that working with a global scientific network brings to the problem definition process, R&D functions are likely to perpetuate the practice of treating every problem as though it were its own Gordian knot and never learn how to decompose truly complex challenges into solvable components. The world cannot answer a question that a company does not know how to ask-the reality is either can a company. In the future, the source of competitive success will lie in *defining* problems, and relying on a distributed global network of preexisting researchers to find specific solutions. In other words, rather than searching ever more vigorously for ever-

scarcer needles in an ever-growing haystack, the successful company will learn to use a magnet and let the needles find them (1).

There are some limitations to the distributed innovation systems. In general, distributed innovation systems will thrive when they are open and transparent and IP regimes that sustain continued collaborative participation. It is important to note that some distributed innovation systems such as Broadcast search used by Innocentive cannot be used in the traditional R&D organizations to deliver innovations on demand and according to annual plan. Contributors to these communities are not employees and they cannot be expected, nor do they care to be in tune with the pressures and methods of the sponsoring company. However, today organizations do have at their disposal an arsenal of distributed innovation models that can deliver innovations on demand.

Taking advantage of this distributed innovation approach to R&D is not easy because it requires a fundamental shift in how R&D departments operate and entirely new ways of thinking. There can be within traditional organizations a great deal of internal resistance to embracing distributed innovation systems. Many organizations are quite good at absorbing external knowledge for internal consumption, but few are comfortable being transparent about internal issues and problems that need to be resolved. Concerns about Intellectual property protection are immediately surfaced when a distributed innovation alternative is being considered. Staff often believe that revealing knowledge about internal developments will put the organization at risk and might tip off competitors about future plans. Many insiders also believe that they have a monopoly on relevant knowledge and are already in contact with knowledgeable external experts, rendering it a waste of time interacting with random individuals outside the organization. A stronger but generally unstated reservation is the fear of loss of employment (2).

Fully absorbing the internal costs of R&D is becoming increasingly difficult for fully integrated enterprises and is not a sustainable model. Distributed innovation represents a complementary approach to organizing for innovation and addressing the challenge of rapid knowledge creation and technological advances. Distributed innovation systems bring to bear a greater diversity of ideas and resources than would ever be possible when limited by internal staffing. It allows organizations to assemble a diverse array of

scientists and professionals independent of organizational affiliation or geographic and/or temporal boundaries around a common problem/goal. This approach effectively exploits the distributed scientific network structure as sources of ideas and collaborators. However, it is important to note, these approaches do not just happen on their own. There are internal resources and infrastructure needed to run an effective Distributed R&D effort. It is important to hire dedicated staff that is tasked with driving this approach. This will likely require developing a new set of skills and learning and mastering these innovation processes and methodologies.

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