LEGAL CHALLENGES TO OPEN INNOVATION IN THE "PATENT CENTRIC" LIFE SCIENCES

OVERVIEW

In recent years, there has been a significant increase in the number of firms attempting to open up their organizational boundaries to external ideas in an effort to incorporate outside sources of innovation into their research and development. Large multi-national companies such as Kraft, IBM and 3M have active, robust "Open Innovation" programs that benefit these organizations by introducing new product ideas and lowering research and development costs, as well as, by financially rewarding inventors if their submissions are chosen. Marketing giant Proctor and Gamble estimates that as many as 1.5 million external users could contribute to research and development beneficial to the organization.

The economic benefits "Open Innovation" (OI) holds can be diminished if organizations do not systematically manage the legal issues and logistical challenges such as idea quality, quantity and processing efficiency that center on effectively sorting through the potentially high volume of "unsolicited" ideas to identify and select the relatively few that hold promise. In addition, as OI migrates to "patent centric" industries where intellectual property (IP) serves as entry barriers; legal issues can complicate OI effectiveness if not properly addressed. This paper examines the relationships between the primary challenges of OI and shows how an algorithmic based software platform integrates the best and emerging practices by using the corporate website as a single point of entry to provide a safe, economical means for life science companies to embrace open innovation.

VALUE IN ADOPTING OPEN INNOVATION

In broad terms, open innovation is the process of obtaining, evaluating, selecting and applying ideas from outside an organization to measurably improve products, services, processes or business practices. Alexy et al (2010) studied "open innovation" process at 150 top Fortune 500 companies including Johnson and Johnson, Pfizer, Glaxo Smith Kline, Xerox, Hewlett Packard and others. Using a combination of direct employee interviews, as well as, web based research, the study found only 32% of the world's largest firms employ an unsolicited idea process of some form. From a recent Forrester survey, 77% of the companies surveyed claim they have a mature or expanding OI program (16% mature, 61% emerging and expanding); 19% have an experimental program; the balanced of those surveyed have either a declining or non-existent program. Based on e-Zassi's market research 43% of the largest health care companies have a developed or emerging OI idea capture system associated with their corporate website.

PROBLEMS WITH ADOPTING OI & SOLUTIONS FOR MEDICAL DEVICE AND LIFE SCIENCE COMPANIES

From research by Alexy and many others, the primary obstacles companies face in implementing OI include idea quality, quantity, processing efficiency and intellectual property legal issues. OI is easier to adopt, for instance in the consumer product markets, if the ideas being submitted are part of the public domain and do not contain IP that needs to be protected. However, these submitted ideas tend to be lower quality because they lack novel content. Conversely, for "patent centric" industries, such as

medical devices, organizations need to be cognizant of legal and confidentiality issues, as well as, the financial rewards and burdens. Medical device and life science companies adopting OI, can control the costs and potential liability by understanding the following key attributes and using an automated system to optimize the effectiveness of their OI programs:

QUALITY OF IDEAS SUBMITTED THROUGH OI

The quality of ideas and innovations submitted through OI are most often attributed to the sources (individuals and networks) where ideas, regardless of technical value or strategic fit can be submitted. Logically, submitters without technical expertise or intimate knowledge of the receiving company's business plan may only contribute marginal value. In theory, as well as practice, the quality of ideas submitted through OI can be improved by receiving companies "signaling" to potential submitters, the types of innovations desired. It is also important to understand the utility of common OI sources such as "crowd sourcing", qualified "key user" groups, as well as, business partners, vendors and university collaborators in order clearly communicate the types of novel ideas the company desires.

QUANTITY OF OI IDEAS

In a truly open innovation idea capture process, the quantity of the ideas submitted are often so voluminous, they can significantly hinder the companies' OI process. Without a structured screening process, such a high volume of low quality ideas may make it nearly impossible to separate the valuable ideas from "interfering ideas." This results in constraining management resources and creating financial burdens to the point where some receiving companies may defocus their efforts to minimize cost and "file" the ideas without evaluation of merit.

IDEA PROCESSING EFFICIENCY

Idea filtration and selection, for many companies, is the key measure for OI success. The efficiency of identifying and selecting ideas, as well as, the economic impact on problem resolution and developing new products and services, constitutes a company's "Return on Innovation". Ideally, the goal of filtration is to economically and systematically apply selection criteria to sort through a high volume of ideas generated by OI and select the relatively few ideas that offer merit and fit the strategic direction of the company.

There are clear relationships between the quality and quantity of ideas obtained through OI, as well as, the compounding effects idea quality and quantity have on the level of effort and efficiency in processing and selecting ideas. Specifically, benefits of OI are maximized, when organizations clearly signal their interests to well matched collaborators and then employ an automated system to efficiently select ideas to incorporate into new product or process development. A company's "return on innovation" can be measured by the costs and the level of effort necessary to identify, process and select ideas and the subsequent financial benefits those ideas bring to the organization.

LEGAL AND TRUST ISSUES

Addressing Intellectual Property (IP) Legal concerns are often the most problematic and complex issues facing innovators and receiving companies. The potential for dispute over IP property ownership can forestall the OI process. This situation is further heightened by the recently promulgated Leahy-Smith America Invents Act (AIA) which goes into full effect in March 2013. With the new AIA, patent rights are being modified from the "first to invent" the "first to file" inventor. This increases "IP Paranoia" tenfold and at the same time, increases the urgency for companies to move rapidly from early stage concept to formal filing of patent worthy ideas.

As OI migrates and evolves from consumer oriented markets to more "patent centric" industries such as the life science and medical device markets, IP security becomes a key issue with the submitting party's need to protect invention details or trade secrets, as well as, with the receiving party's liability and litigation if the information is not submitted through formalized channels or handled with proper confidentiality. For the life sciences and healthcare technologies IP often holds significant economic value for recovering R & D costs and as an entry barrier for competing technologies.

In most cases, the ideation process involves a physician or small company submitting to a large company. In this situation, the submitting party fears having the idea stolen or overlooked. This is especially true with early stage, pre-patent technologies. At the same time, because of the high cost and protracted time frame in developing medical technologies, medical innovators need to partner with companies in order to develop and market their invention. Companies that foster OI need to establish and maintain a "trustworthy reputation" and be viewed as a viable development partner for the innovator. It is recommended that companies provide clear and prompt communications, access to OI officers and, to contain costs, exclude lawyers from initial technology assessment conversations. Finally, the firm may need to put in place mechanisms to prevent accusations of misappropriation of IP generated by others.

Specifically, there could be a dispute over the ownership of the submitted IP. Concurrently, there could be an issue if the received IP is very similar in scope to existing internal research. In these cases, documenting the timeframe and details of the submitted idea are important to preclude downstream litigation. As a precaution, corporate lawyers often insist on full ownership or limited disclosure of IP in conducting transactions with innovators. Corporations taking this stance will generally exclude early stage developments or innovations where licensing agreements prohibit clear IP ownership. As shown in Table 1, understanding the IP class of ideas submitted through OI is essential in bilaterally protecting the confidentially of the submitting party, as well as, the liability of the receiving company.

Table 1 Intellectual Property Classifications and Characteristics

IP Category	Characteristics	Examples	OI Issues to Address
IP – Class 1	Relatively simple, non-patented public knowledge or information	Recipes, clothes designs, paint colors	Potentially high volume, low quality need to be sorted for economical selection and

			application
IP – Class 2	Not always patented, however, patents or trade secrets can provide value	New combination processed foods, methods for producing a specific paint pattern	Idea sorting efficiency is key. IP protection becomes necessary
IP – Class 3	Patents and trade secrets essential as entry barriers and to recoup R & D costs	Medical devices, pharmaceuticals, semiconductors	IP protection from initial due diligence through licensing and technology development
IP – Class 4	Technology and trade secrets used for national or military security	Night vision goggles jet aircraft, weapons technology	IP and trade secrets typically cannot be openly shared due to national security concerns. Collaboration can exist with some basic R & D

Adopted from Glassman and Walton (2010)

To summarize, OI works well for Class 1 and some Class 2 IP, where the idea or innovation is in the public domain. For higher level Class 3 IP, where the IP is a technology differentiator and critical to the success of the organization, obtaining ideas or inventions for OI partners must be done in a documented, systematic fashion. Regarding the life science industry, if not properly conducted, the following issues could arise:

- Through an "unsolicited" OI process, the received IP could be very similar to current or planned research at the receiving company
- Allowing a wide variety of corporate IP Permeability – for instance by submitting confidential information through emails, at trade conferences or directly via a "contact us" portal on the website may inadvertently expose the company to IP litigation. The potential for digital IP permeability is heightened by not adopting a standardized format for idea submission.
- Downstream litigation could occur if a dispute arises over IP where clear ownership or development time line is not well documented or a claim of misappropriation arises
- If the IP is pre-patent protected, but covered by a CDA, it may restrict the receiving company from pursuing similar research
- Especially in technology markets like life sciences, some submitters may use a strategy of only disclosing certain aspects of the idea or include hyperbole to increase its perceived value

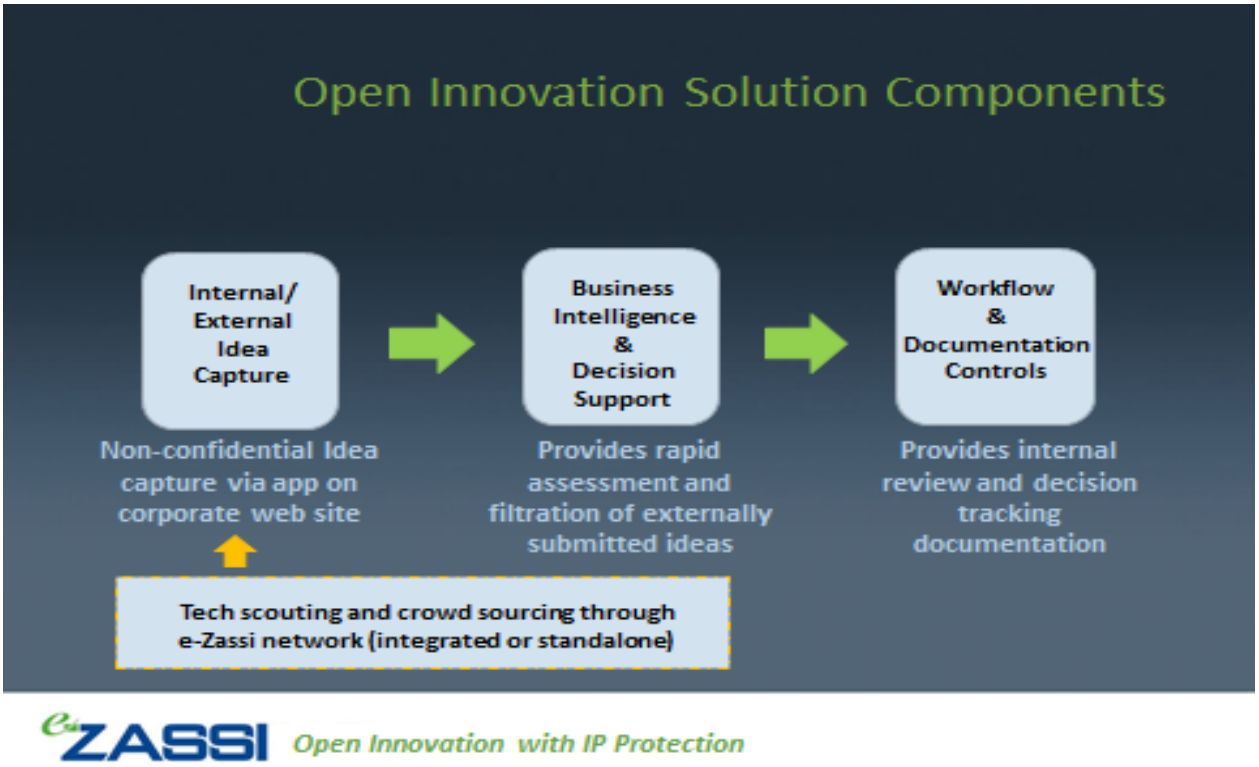

Figure 1 – Information Flow in OI Idea Capture and Analysis System

SOLUTIONS TO IMPROVE THE EFFECTIVENESS OF OI

Increasing the Quality of Incoming Ideas

A. In support of market research, e-Zassi has developed the following strategies, tactics and systems that help companies deploy, manage and increase the value of their OI ideas capture programs (see Figure 1, Figure 2). These include:

1) **Signaling (Garnering the right type of idea) –** while the objective of soliciting ideas from outside the firm is generally to "solve problems or fulfill product development needs", the challenge remains "how do we get the right people with relevant technical competence to submit" while still keeping the "open innovation" process alive? Conversely, how do exclude unsolicited ideas that have no value to our strategic direction or product pipeline?

   The key to addressing idea submission quality and alignment of incoming ideas involves the proper "signaling" to potential submitting entities. e-Zassi accomplishes this by establishing and promoting a website application as a customer facing **"Submit Your Idea Landing Page"** to share and publicize the company's current and future areas of research, medical specialization interests, organizational roadmaps and particular problems that need resolution. A further tie

in to e-Zassi's qualified network of medical device innovators allows company's "tech scouts" to actively search and match to synergistic research for collaboration.

2) **Structuring – (Standardizing the content)** this process involves establishing and enforcing company procedures during the front and back end of the OI process. Most commonly, the structuring process establishes prerequisites the submitter needs to meet such as technology focus (i.e., having a patent or patent pending on a technology), format or by accepting the receiving company's terms and conditions for submitting. e-Zassi's OI idea capture system provides structuring through a customized web portal **(with inclusion, exclusion and special treatment criteria)** to digitize and guide the unsolicited ideas into a detailed business decision support format with automated comparative and analytical functions. In addition, e-Zassi's process provides bilateral confidentiality and limits IP legal exposure through structured questions and answers to control the submitted content.

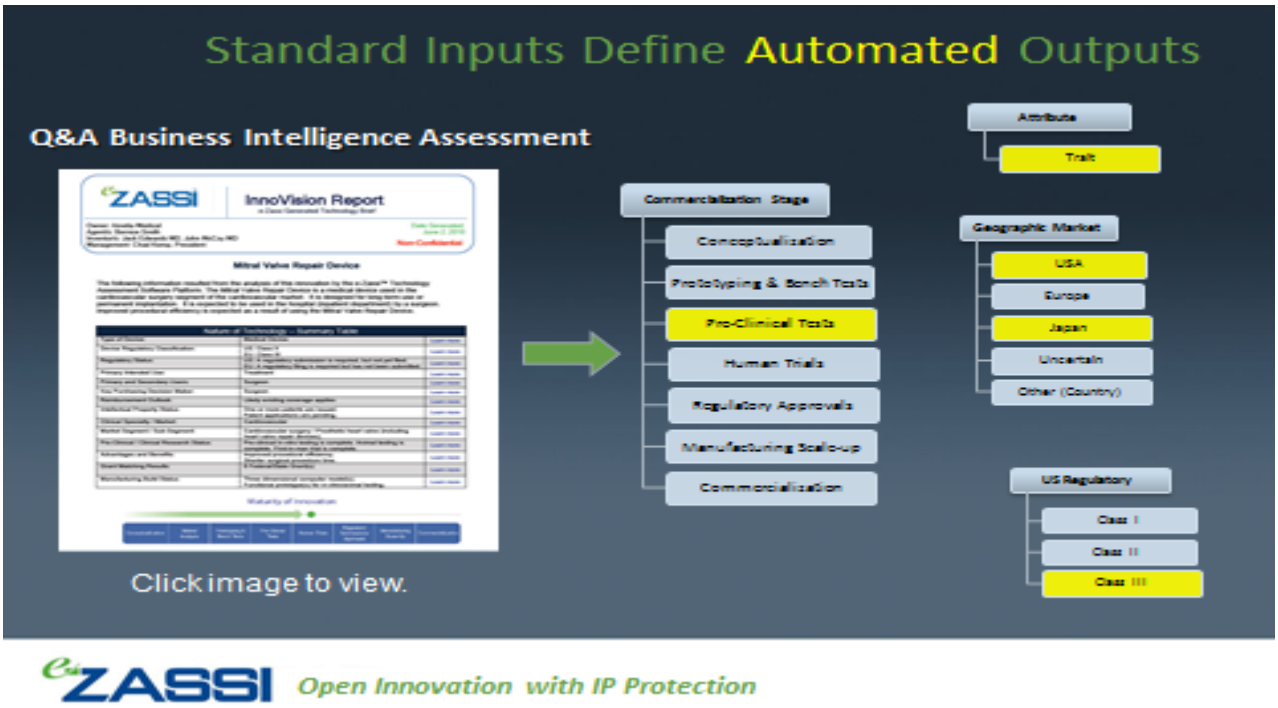

Figure 2 e-Zassi System Output – Innovision Report™

3) **Selecting (Workflows to aid in due diligence) –** Once ideas have been accepted by a firm, e-Zassi's process proceeds to evaluating the ideas for business value. This "selection" of incoming ideas involves establishing evaluation criteria and **work flows** to score, rank and share information in a repeatable assessment process. e-Zassi's system calculates factors such as regulatory burdens, market size and manufacturing requirements to provide a detailed assessment.

Typically, a cross functional team would then vote on the merit of each OI idea using the same criteria applied to vetting internal ideas, such as technological merit, regulatory class, maturity level current, reimbursement criteria, future market direction and strategic fit. Most firms will include both a technical and legal review. With some companies, these two types of reviews were conducted in sequence and in others the reviews were conducted in parallel.

CONCLUSION: OI PROBLEMS THAT NEW SOFTWARE SOLVES:

e-Zassi's cloud based SaaS system vastly improves the OI process for medical device and life science companies by automating the idea capture, filtration and selection process, and provides concurrent IP protection. The e-Zassi platform includes all OI solution elements advocated by researchers and successfully used by market leaders worldwide to optimize the quality and strategic fit of ideas for organizational benefit.

Through e-Zassi's algorithmic system, a series of simple questions allows innovators and companies to gain detailed, insightful information within the context of a robust Intellectual Property (IP) protection system that fosters trust and confidence essential in meaningful collaboration. e-Zassi's standardized format minimizes digital permeability and provides bilateral IP protection to eliminate the need and cost for premature Confidentiality Disclosure Agreements (CDA's).

Drawing on leading, market specific data bases, e-Zassi system's generates a detailed Innovision™ report that includes information such as regulatory criteria, FDA classification, reimbursement outlook, market potential, maturity level and manufacturing variables. From this comprehensive, decision support platform companies gain immediate insight as to the value of submitted ideas. Work flows then allow assessment teams to score, share and track external and internal product and process development information. e-Zassi's customizable system is being adopted by organizations worldwide to capture, process and select ideas through OI to provide sustainable benefits to their life science organizations and collaborative opportunities to academia and physician/clinician life science innovators.

References:

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