TRLABS 2009 ICT SYMPOSIUM, WINNIPEG, MANITOBA

A POTPOURRI OF LEGAL AND BUSINESS CONSIDERATIONS CONCERNING E-HEALTH, OR, GENERALLY HOW TO AVOID THE "GREMLINS"

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The IP/IT Landscape

The IP/IT industry is exploding, and its constant evolution requires business people and the legal profession to become more sophisticated. Nowhere is this truer than in the e-Health area.

- Although this is the case with the overall IP/IT landscape, we will here focus upon the software business.
- Large numbers of ‘start-up’ companies and the interest of big-money investors have created tremendous opportunities for new enterprises and the lawyers who serve them.
- These companies rely on essential information technology (IT) assets to launch and run successfully, and these assets are composed of several types of intellectual property (IP).
- Knowledgeable companies and their lawyers are becoming far more aware of and concerned about the protection of their IP rights in creating and dealing with their IT assets.
- In the e-Health area, one must be aware of and properly handle all of the issues that pertain to the software business generally, and also deal successfully with the critically important questions of privacy and regulatory compliance, which are continually growing in number and complexity.

Gremlins and the IP/IT Landscape

Despite the growing sophistication, 70-80% of software projects performed by independent contractors “fail” to one extent or another.

- Most such projects are completed late, or come in over budget, or fail to meet one or more of the thresholds of performance established by the contract.

- These failures can largely be attributed to underlying weaknesses or problems – ‘gremlins’ - that can derail agreements and projects.

- Gremlins are frequently hidden and hard to identify, but they have a powerfully negative and costly impact.

How Can Entrepreneurs and Their Lawyers Help Clients Defeat the Gremlins?

If business people and lawyers understand the e-Health technology industry and adapt core legal strategies, procedures and language to suit it, they can develop protective property rights tactics, and draft effective agreements that will form the foundation of successful technology projects and transactions. They will thereby ensure that their clients defeat the gremlins that undermine their strategies, documentation and execution.

The key thing is precision of thinking and language.

ENTREPREURSHIP, E-HEALTH AND THE LAW

The National Academies in the US have just published a report concerning the present state of e-Health in that Country. The first paragraph of the news release carries the gist of the report:

"Current efforts aimed at the nationwide deployment of health care information technology (IT) will not be sufficient to achieve medical leaders' vision of health care in the 21st century and may even set back the cause, says a new report from the National Research Council. The report, based partially on site visits to eight US medical centers considered leaders in the field of health care IT, concludes that greater emphasis should be placed on information technology that provides health care workers and patients with cognitive support, such as assistance in decision-making and problem-solving."

This might well be viewed as a present and significant challenge to those who are in the e-Health industry.

A FRESH APPROACH TO E-HEALTH

Ted Shortliffe's (Columbia University and University of Arizona) comments on the report:

> "The report calls for a change in approach to health care IT.
>
> This conclusion does not reflect negatively on the sites visited. To the contrary, their pioneering work and suggestions let the Committee see the way forward. It does not contradict calls for increased investment in health care IT. Better management and use of information are essential to improving the health care system.
>
> The report suggests that a larger dose of today's health care IT will result in both improvement and harm. It will cost more and take longer than people expect. Collectively, the result will fall far short of what is needed.
>
> For example, today's clinical applications tend to be monolithic and complex. Rather than enabling small improvements in practice, the many information system interdependencies actually slow down improvement! Instead, clinical applications should reduce barriers to clinicians and patients doing what is best for care - even if doing what is best requires rapid cycle, iterative change in clinical behaviors and work flows.
>
> A different outcome is possible. We do not need to wait for better IT before we move aggressively forward. However, near term success will require a fresh approach to managing the investment by health care organizations, our health care IT vendors and the government."

In Conclusion…

As business people and lawyers build experience and expertise in the e-Health IP/IT industry and adapt their skills to suit it, e-Health will evolve far more efficiently and effectively and the ‘gremlins’ will become easier to spot and defeat.

Thank You / Questions?

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TRLABS 2009 INFORMATION AND COMMUNICATIONS TECHONOLOGY SYMPOSIUM
FEBRUARY 10, 2009
WINNIPEG, MANITOBA

A POTPOURRI OF LEGAL AND BUSINESS CONSIDERATIONS CONCERNING E-HEALTH

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PRESENTATION

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A. The Technology And Intellectual Property Landscape:

The focus of my presentation will be upon the information technology ("IT") business, particularly companies that deal in software and the rights therein and thereto, as they relate to "e-Health". There are many benefits generated by what is generally known as e-Health, and some of them will accrue to the business people and entities that develop and provide software and services to that marketplace. But the business person and his or her lawyer or lawyers must do the necessary to use precision thinking and language to effectively "defeat the gremlins" and produce optimal business and professional results in order to attain the elusive goal of financial success.

To be very practical, I will deal with what I view to be the "fundamentals"; Corporate Strategic Approach, IP Audits, the necessity for solid contracts, and, additionally, what some feel is the coming shift in e-Health.

1. If One Is An E-Health Entrepreneur:

Much of the software business is done by "start-up" companies, which like start-up ventures in other areas, have a very high failure rate. Some would say that to be a start-up in the software business is far harder than in most other industries, because very often not only is the company incipient, but also its "stock in trade", i.e. a software product that is only a concept or an entrepreneurial dream and has yet to be designed and built.

There are some helpful guideposts to those who, despite the odds, still want to create a software enterprise, and they certainly apply to the e-Health area. They will enable you to defeat the "gremlins":

(i) If you take on a “partner”, make sure that he or she is trustworthy and true. Try to deal only with **“good”** people.

(ii) Somehow obtain the best development, marketing and management talent that you possibly can.

(iii) Marketing, marketing, marketing.

(iv) For most software companies, **“partnering” and making strong alliances** can provide helpful leverage in the marketplace. The industry lends itself to this approach.

(v) As early as possible, decide on and understand just what type of company you are trying to build; products, services, or both.

(vi) When embarking upon a software development project, always separate the **“design”** phase, from the **“build”** phase. **Never forget that dichotomy.**

(vii) From the outset, always retain the best professional advisors (lawyers and accountants) that you can engage.

(viii) Be prepared to work tremendously hard and learn as much as you can; constantly.

(ix) Analyze, plan and prepare to the “nth” degree.

(x) Execute, execute, execute.

(xi) **Do all that you can to get your first reference customer**, even if you have to practically give your product or service away, particularly if the customer is a well established firm, and especially if it is a **“blue chip”**.

(xii) Although it is beyond the scope of this presentation, if you must seek angel or venture capital, apply the foregoing principles in your quest for such funding, and again always try to deal with **“good”** people in that regard. That said, many

technology entrepreneurs use their own money to “boot strap” their businesses or seek financial assistance from family and/or friends.

The people who manage to “beat the odds” and attain success in software will be those who convert these notions, and others, into reality. In so doing, they will certainly discover whether they actually love the tech business as much as they thought they would.

Those who “make it” in software can enjoy the benefits of a business which is really quite different from most others. Some of the reasons for this are:

a. Once you have built a software product, the cost of replicating it many times over is usually very low.

b. Your gross profit margin on sales can be as high as, say 75-90%.

c. By selling licences to use your product, you will retain the underlying IP rights, from which you can keep generating revenues.

d. As time goes on, a software company can usually improve or enhance its existing products, and then market licenses for such creations to its installed base.

e. For some types of software, customers will want to contract with the vendor for maintenance services, and a software maintenance agreement can be an adjunct or add on to the original licence deal.

f. Similarly, some software sales require that the customer engage the licensor to provide installation, integration and/or customization services as well.

g. A product installation and integration may over time lead the customer to become “locked in” to using, improving and expanding upon the software that has initially been installed by the vendor. This is usually where the software has in fact delivered a real “solution” to the customer.

As companies come and go, and as technologies come and go, the surrounding geography of IP/IT changes to reflect that activity.

One thing that one can say about the IP/IT landscape is that it is always challenging, and always demanding.

2. If One Is In A Health Care Organization:

"Whatever the nature and focus of a particular health care organization might be, it's first step in this area should be the development, and then the ongoing maintenance of an appropriate "IP Strategy".

Intellectual capital in an organization is comprised of human capital and intellectual assets. Human capital consists of an organization's individual employees, each of whom has knowledge in the form of skills, abilities, expertise, and know-how. Intellectual assets are the tangible and physical manifestation of knowledge generated in the course of operating the business in which an organization can claim ownership rights. Intellectual assets that are legally protected are considered to be intellectual property, and they include trademarks, patents, copyrights, trade-secrets, domain names, integrated circuit topographies, and personality rights.

Many organizations mistakenly think that they do not have any material IP and hence feel there is no need to invest time and resources to protect such valuable assets. Nothing could be further from the truth. A recent study found that the intangible value of U.S. companies accounted for approximately 75% of the value of their assets. One suspects that the figure would be similar for Canadian industry. Nevertheless, a Statistics Canada study of manufacturers involved in new product development found that only 25% of the companies surveyed had an IP strategy.

An "IP Strategy" is simply a plan to develop, enhance, and protect the value of the IP assets in an organization. It need not be long or overly complex and can often be initiated on a single piece of paper. From there it can grow as may be necessary or appropriate. The

important thing is to be aware of the importance of IP in an organization and to be willing to establish a strategy that can be improved over time."

Most technology companies have established IP strategies and certainly those who participate in heath IT will likely be quite familiar with the concept.

Without going into any great detail at this time, these are the key steps in developing and implementing an IT strategy:

(i) Performing an IP audit with respect to the organization's registered and unregistered IP.

(ii) Identify any vulnerabilities that exist concerning the organization's IP, including renewing existing licences, assignments, and employment and consulting agreements in order to assure protective clauses and assess whether there are any gaps in the organization's registration rights.

(iii) Assess the risks to the organization and how those might be addressed.

(iv) Assess whether the acquisition, development, and exploitation of IP supports and facilitated the organization's overall business plan.

(v) "As the acquisition of IP can entail both in house development and the obtaining of IP from third parties the IP strategy must address both acquisition channels. Additionally, if there are collaborative efforts such as joint ventures, joint developments and strategic alliances, the organization must ensure that the ownership of both the existing and the newly developed IP and other intellectual capital is clearly defined and protected. Protection will entail an awareness of the applicable statutory regimes and the attendance to filings with respect to patents, copyrights, trademarks and industrial designs. Additionally, the organization must establish protective policies and contractual templates and ensure that both are effectively utilized as necessary and appropriate."

(vi) "When IP assets are properly identified, acquired, and protected, the organization will then be empowered and in position to exploit its intellectual capital. Exploitation involves the steps, arrangements, and processes that will maximize the organizations return on its investment in its IP assets and property. The organization should constantly seek to increase its revenue stream from those assets and reduce its risk and exposure with respect to them. Some elements of exploitation are as follows:

(a) Licensing arrangements, such as proprietary or open source;
(b) Exploitation alone or through collaborative models such as joint ventures or strategic alliances;
(c) Creating distribution channels, both upstream and downstream;
(d) Properly leveraging against IP in order to raise capital;
(e) Utilizing IP to obtain tax credits and other regulatory benefits;
(f) Using IP as a "shield" to avoid conflict; and,
(g) Breaking down IP into its specific elements in order to "unlock" resulting values."

(vii) The organization will always want to ensure that its IP strategy is in harmony with its overall business plan from time to time. It will also want to continuously monitor the development of statutory IP regimes around the world and be aware of its rights and remedies. Where appropriate the organization will want to develop its awareness as to its available remedies at law, both internally and externally.

(Quoted material above in this section is taken from the paper, *IP and IT Issues that Every Business and Lawyer Should be Aware Of,* initially prepared for the CLEBC course, Intellectual *Property for Solicitors - 2008 Update.*)

3. Fundamentals of the Effective Information Technology Agreement:

Within the last two decades the owners of intellectual property rights and their lawyers have become far more aware of and concerned with the protection of such rights. This is in part due to the increasing sophistication of the legal profession but is also a function of the explosive growth of the information technology business, including the development of the

personal computer, the powerful software industry, and the Internet, particularly the World Wide Web.

There are of course many types of IT agreement, but generically such a contract is used to set out the various rights and obligations of the counterparties to an IT transaction of one type or another. Therefore the "skeleton" of a sound IT agreement will, notwithstanding the format in which it is expressed, deal effectively and efficiently with the following fundamental elements (which certainly apply to e-Health):

(i) **A definition of the IP/IT that forms the subject matter of the contract,** including all relevant aspects thereof, which in certain cases will involve prescriptive terminology, as one party to the agreement may receive rights in and to IP/IT provided by its counterparty for the purposes of developing such a "horizontal" asset into a new or improved "vertical" application.

(ii) **A description of all rights in and to the subject IP/IT** during all phases of the currency of the contract, including all rights granted to a party to turn any part of the IP/IT to its own account and precisely how this may be done.

(iii) **A description of all obligations with respect to the subject IP/IT,** including those relating to integrity, security, confidentiality, privacy and other protective methods such as the obligation to make application for statutory rights, such as patent or copyright.

(iv) **A description of all consideration flowing** from one party to the other on account of such rights granted or created in and to the subject IP/IT.

(v) **An allocation of all risks that exist or will arise** under the contract during its currency.

(vi) All other material terms and conditions.

I see the ability to create contracts that protect and advance one's IP/IT rights and interests to be one of the most valuable skills available to both the entrepreneur and

the health care organization alike, and absolutely essential to achieving success in e-Health.

4. Approaching An Information Technology Transaction.

As in other industries, it is critically important that the management of an IT Company seek and achieve a proper balance between the two ends of the proverbial transactional continuum:

Execution * ---------- * Risk Management
(Getting the deal done) (Quality control)

Anyone who has managed and effected a commercial transaction will know about this continuum and its constant demand for detailed attention and informed judgment from the beginning of the matter to its conclusion.

However, it is fair to say that doing technology deals can involve perhaps even more uncertainty than other types of commercial transactions that involve the more solid concepts of “bricks and mortar” and “hard assets”. An IT deal can present the business person or solicitor with a sudden and steep learning curve that he or she must effectively negotiate in order to achieve the mandated result. There is no doubt that, in managing IT transactions, those who possess both a specialist knowledge and experience will likely have the ability and facility to balance the elements of the continuum and exercise effective commercial judgment. This will improve the chances that the parties will not have to deal with litigators after the transaction closing and completion.

Here are some of the broader IP/IT issues for which the business person and solicitor should be alert.

(i) Licensing as Opposed to Acquiring IP Assets:

This will normally be a consideration that the IT industry client will have reviewed and decided prior to speaking with a transactional solicitor, because it is so fundamental to the strategy of any IT business. An analogy would be the position of

Mick Jagger and Keith Richards as opposed to that of any other member of The Rolling Stones who has few, if any songwriting copyrights. The former have retained ownership rights that assure them a continuing stream of royalties, while the latter make do with performance related fees and other, lesser revenues. The former position is similar to that of the properly structured software products company, while the latter is similar to that of the pure software services company. Any lawyer who is asked about this issue should ensure that the client reflects long and hard before ceding its ownership rights in an IP product.

Strategically, by retaining ownership in its products, the software company or other owning entity will be in position to “sell” licences to its software many times over. Particularly if it has developed a “killer app”. This is the primary business model of the products company because it has the promise of economies of scale, high potential growth and strong profit margins. It is often an attractive concept to angel and venture capital investors.

Tactically, software and the rights therein and thereto may be acquired in a number of ways and by way of various types of transactions. It is often “bundled” or combined with hardware and related services and programs. The owner of software can deal with the rights in it as the owner of personal property. Because of the degree of flexibility inherent in possible software transactions, a solicitor must be knowledgeable and mindful of not only the strategic intent of the parties to any particular transaction, but also the elements of such transaction and the manner in which they must be identified, organized and dealt with in order to effectively achieve such intent.

An owner may deal with the various IP rights in software, such as those of patent, copyright and confidential information by way of a properly structured IT agreement or agreements. Such transactions can be in the format of assignment, sale or licence, and the use of each format requires that the solicitor pay detailed attention to the requirements of dealing with such rights effectively by contract.

For example, the concept of the licence of computer software, although superficially simple, is in reality a transaction that demands an informed understanding of the

terms and conditions being evidenced by the documentation and a facility in dealing with such factors.

As opposed to an assignment of rights in software or a sale of a copy of a computer program, a grant of a licence of software does not convey an interest in property, but rather comprises a grant or permission to use the software as provided in the licence agreement. Thus, a licence agreement enables the owner of software to grant a right to use the software without transferring title to, property in or ownership of the underlying IP. By this device the owner may retain its ownership of the property in the software while generating revenues by licensing the right to use same in consideration of licensing fees or royalties.

A properly drafted licence agreement will contain terms and conditions which will prevent the unauthorized use of the software and duly protect the property rights of the owner. Accordingly, the solicitor must be aware of the characteristics of properly drafted licence agreements and the nature of the law that will apply to same.

(ii) Are there any Applicable Regulatory Issues?:

An IT Company may be subject to statutory and regulatory requirements that are specific to its industry and with which a solicitor may not have any prior direct experience. Certainly anyone doing a technology transaction will have to be aware of the possibility that such obligations may exist and have to be dealt with. As regards transactions in the area of healthcare informatics, certain industry guidelines and statutory requirements concerning the standards concerning data and information, and the maintenance and safe keeping of records, in a word, **privacy**.

B. The IT/IP Landscape As Regards E-Health:

1. The Strategic Entrepreneurial Challenge:

I now turn to the direction of health informatics generally.

The National Academies in the United States have just published a report concerning the present state of e-Health in that Country.

The first paragraph of the news release carries the gist of the report:

> "Current efforts aimed at the nation wide deployment of health care information technology will not be sufficient to achieve medical leaders' vision of health care in the 21st century and may even set back the cause, says a new report from the National Research Council. The report, based partially on site visits to eight US medical centres, considered leaders in the field of healthcare IT, concluded that greater emphasis should be placed on information technology that provides healthcare workers and patients with cognitive support, such as assistance in decision making and problem solving."

As Ted Shortliffe (Columbia University and University of Arizona) observed:

"The conclusion does not reflect negatively on the sites visited. To the contrary, their pioneering work and results let the committee see the way forward. It does not contradict calls for increased investment in healthcare IT. Rather it focuses upon the need for better management and use of information as being essential to improving the healthcare system.

Today's clinical applications tend to be monolithic and complex. Rather then enabling small improvements in practice, the many information system interdependencies actually slow down improvement. Instead, clinical applications should reduce barriers to clinicians and patients even if doing what is best requires rapid cycle, iterative change in clinical behaviours and work flows."

The report calls for a fresh approach to managing the strategic investment by healthcare organizations, healthcare IT vendors and the Government.

If one considers the four major e-Health IT functions of automation, connectivity, decision support and data mining capabilities, the report suggests that a better balance would move some emphasis away from the present predominant focus upon automation, and onto connectivity, decision support and data mining.

This shift in direction would add support for the cognitive activities of e-Health IT – "helping providers and patients think about complex choices as they make decisions – and a learning health care system – mining related bodies of data to recognize and respond to patterns".

The report sees two types of change with respect to the healthcare system. These are - evolutionary change, and - radical change.

It says that; "in this context, evolutionary change refers to continuous, iterative improvement of existing processes, sustained over long periods of time that does not depend strongly on new technological capabilities." In the U.S., the Institute of Medicine's vision of healthcare as a "learning system" is one of a system designed to benefit from evolutionary change.

Alternatively, radical change; "means new ways of looking at health problems and revolutionary new ways of addressing those problems. Radical change often involves a new capability such as the advent of antibiotics in the 1930's and developments in genomics today. Some of the automatic data recording, use of novel sensors, data mining and visualizations techniques recommending in this report fit the radical, revolutionary mode of change."

It then goes on to say that; "Any approach to healthcare IT should enable and anticipate both types of change since they work together over time."

This Report came to me from the Waterloo Institute of Health Information Research and the National Institutes of Health Informatics. They feel that it ought to be reviewed closely by healthcare organizations and healthcare IT vendors in Canada.

The Report lays out a number of strategic "principles for success":

2. "Principals for Evolutionary Change:

1. Focus on improvements in care – technology is secondary.
2. Seek incremental gain from incremental effort.

3. Record available data so they can be used for care, process improvement, and research.
4. Design for human and organizational factors.
5. Support the cognitive functions of all caregivers, including health professionals, patients and their families."

3. "Principals for Radical Change:

(a) Architect information and work flow systems to accommodate disruptive change.
(b) Archive data for subsequent re-interpretation.
(c) Seek and develop technologies that identify and eliminate ineffective work processes.
(d) Seek and develop technologies that clarify the context of data."

To conclude, suffice it to say that there are a good many things that a participant must bear in mind when working in the area of health informatics. Chief among them is the importance of the "fundamentals" and the proper execution of them.

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