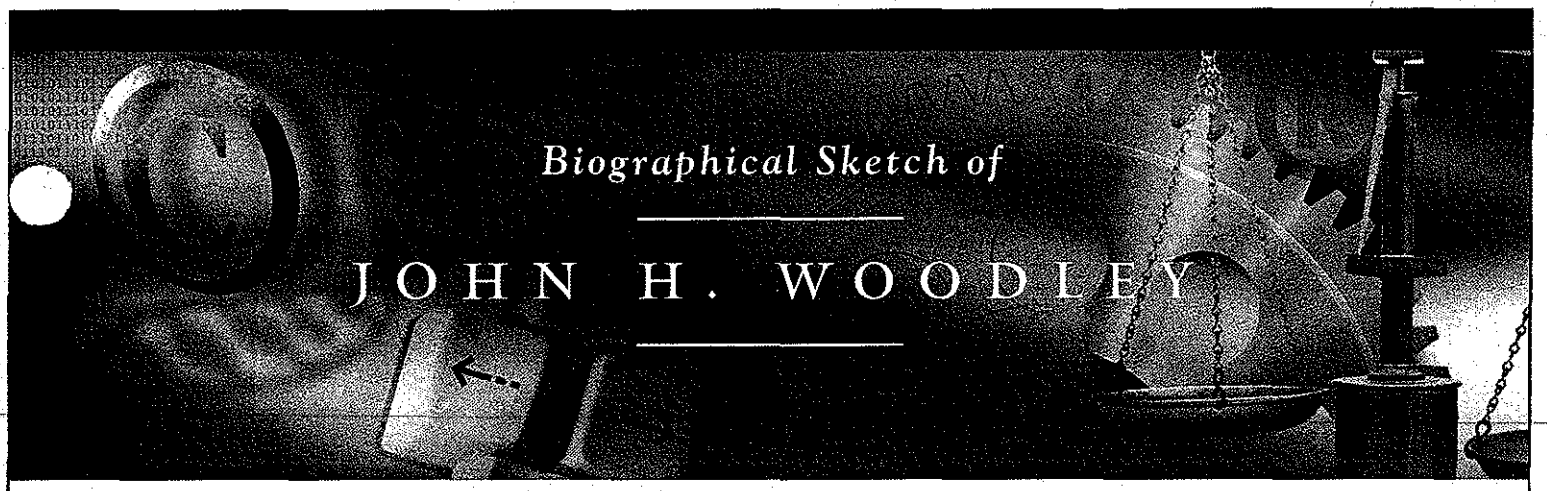


Biographical Sketch of

JOHN H. WOODLEY



BORN:
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Registered Patent Agent (Canada, 1973)
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JOHN H. WOODLEY *brings extensive experience to his practice as a Patent and Trade-Mark agent focusing primarily in the fields of biotechnology, health care and chemical engineering.*

Mr. Woodley entered the field of Patents and Trade-Marks in 1971. After twelve years of practice, including a partnership with another firm, he formed an association with **Sim & McBurney**, *becoming a partner in 1986.*

He holds a degree in Chemical Engineering from Queen's University and after graduation worked as a process engineer with a pharmaceutical company.

Mr. Woodley, in conjunction with the biotechnology group, has developed elaborate strategies for considering protection of biotechnology related inventions and the necessary due diligence studies required in this field in respect of investment considerations, takeovers and licensing. For larger corporate clients he has developed customized databases which track their patent portfolio providing effective intellectual property management.

He has addressed many societies on Patents and licensing of technology. He has co-authored a book with Roger Hughes, published by Butterworths and entitled "Hughes and Woodley on Patents" which relates to the patenting of technology in Canada and enforcement of patent rights. On behalf of the World Intellectual Property Organization, he co-authored a book "Guide on the Licensing of Biotechnology". He has been very active with the Licensing Executives Society USA/Canada serving as President of the Society - 2000/2001.

He is an avid tennis player, with the odd-break to pursue his fascination with woodworking.

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PATENT/LICENSING STRATEGIES – COORDINATED INTERPLAY FOR INCREASING RETURN

INTRODUCTION

The rapid pace of growth of high tech industries and their related intellectual property has been phenomenal over the last five years. Regardless of the economy, intellectual property continues to grow at almost exponential rates. Very active companies are filing well in excess of a thousand patent applications per year, which can result in tens of thousands of active patens in an IP portfolio in any one year. A considerable cost is associated with a portfolio of this size and the organizational requirements are onorous.

In conjunction with the rapid pace of growth in high tech industries, has been the significant increase in technology transfer. Product development by "licensing in" has become far more attractive than reinventing the wheel. People are reviewing their patent portfolios to assess what can be "licensed out" to extract further returns from their IP portfolio. This is all to familiar a territory for us. As we expand beyond familiar territory it becomes essential that we understand the important interplay between patents and licensing. The way and manner in which you get patents will have a direct impact on technology transfer. We can all appreciate that a strong patent program should attract significant rewards in a licensing program. However, when these strategies are not coordinated, problems develop which greatly detract from the licensing rewards.

INTERPLAY

The purpose of this paper is to provide you with insights to the important interplay between a patent program and a corresponding licensing program. Today's fast pace in the technology community demands a clear strategy for protecting developing technology. You must be in a position to answer the tough

questions that people bring during a due diligence study of your Intellectual Property Program. Such careful study of your IP Program arise regardless of whether you are selling the technology or licensing the technology.

So if Licensing involves all this extra work - WHY LICENSE? More often than not you need a commercial partner to help:

1. Develop international markets
2. Develop the technology
3. Provide better manufacturing facilities
4. Have regulatory approval expertise
5. Add creditability to the start up company.

INTELLECTUAL CAPITAL

So why is it such a big deal to develop an IP Program which gives birth to a licensing venture? – INTELLECTUAL CAPITAL - the combination of Human Capital with your Intellectual Assets which includes Intellectual Property. Human Capital is one of the most significant resources of the company in valuing its Intellectual Capital. The employees are the drivers behind an expanding increasingly valuable Intellectual Capital. Very important care must be taken to ensure that this resource has proper guidance, is respected and is provided with a working environment which stimulates creative thinking. In providing the proper guidance, all necessary employee contracts need to be in place to ensure that each employee clearly understands their working relationship with the company and what is expected of them in contributing to Intellectual Capital. On the other hand, Intellectual Property is something that can be quantified by strategies which ensures that new developments are being properly protected.

You need to have a packaged IP program to receive the greatest value in the license program. The IP program needs to be in step with early stage venture capital financing and must include trade secrets and know how with proper confidentiality programs in place.

IP PROGRAM

You might then ask "what do I need to do differently with my IP Program?" You need a plan that works with your Research and Development

people, with your Marketing/Sales people and with your Executive. If you do not have a fit in these areas, you need to provide a fit. An IP program that is not in step with these three areas will greatly detract from the potential revenues that ultimately can be realized from technology transfer. The IP program may be sufficient to protect what is happening today in the marketplace, but what are the future opportunities in that IP portfolio to license others to exploit the technology in other areas. At each level of Research and Development, Marketing/Sales and the Executive there must be a consistent philosophy with respect to the importance of Intellectual Capital and how it can be exploited. Patents, trade-marks, copyright, industrial designs, trade secrets, know-how must be coordinated in a way that an IP package is being developed for each technology.

Clearly, this will be done for the technologies that are being commercialized, but the intellectual property counsel needs to consider other ways in which the technology can be exploited.

The high tech industry continues to gain momentum even in difficult financial market situations. There are hundreds of IPOs on going this year raising billions of dollars in funding which is directed to further research.

PATENTS – INWARD FOCUS

So how do you make an IP Program work? The basis for an IP Program is to be as concise as possible. There is always an inward focus in an IP program, distilling all the IP information to its roots. This is the essence of a patent system in evaluating any technology from the standpoint of patentability. It is essential that the technology be reduced to its basic principles to allow one to assess if those basic principles, when patented, are going to provide a strong complement or addition to the IP patent portfolio. This is what is demonstrated in Figure 1, with all of the arrows pointing inwardly.

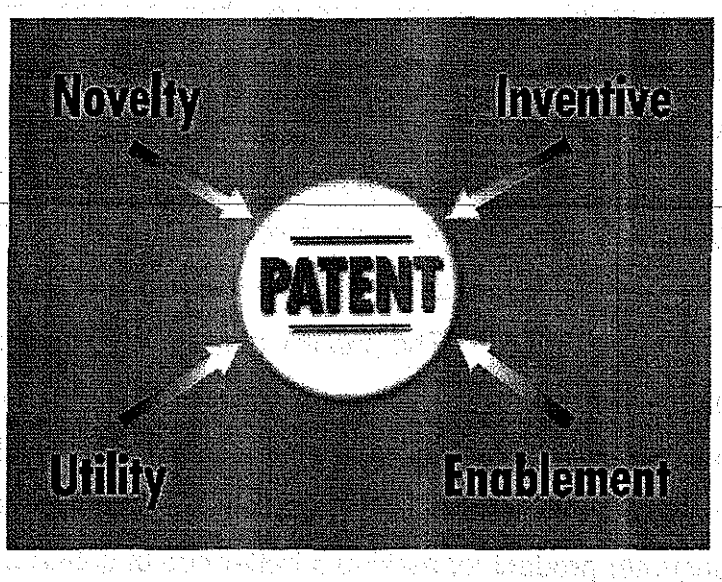


Figure 1

This inward focus is excellent from the standpoint of developing a strong patent strategy which should afford the broadest possible patent protection on the particular development. However, in an effort to capture the essence of the invention and demonstrate it with one or two embodiments, this may lead to patent claims which miss important fields of use for the technology and for that matter might even miss the way in which the company might later choose to exploit the invention.

This demonstrates the need to coordinate and have a consistent policy amongst the R & D group, the Marketing/Sales group and the Executive to ensure that the patents being obtained are contributing to the Intellectual Capital.

CORNERSTONES

What are the significant factors to be kept in mind in an IP program? When it comes to a patent portfolio, we always look at novelty, inventive step, utility and enablement regarding the technical development. These are the cornerstones of any patent program. The inter-relationship of these four cornerstones are closely linked. A weakness in any one of these four criteria can greatly undermine a patent's contribution to the IP program. When determining

the commercial application of the technology, it is always important to evaluate the various commercial applications based on these four cornerstones. This will ensure that, as the IP program is developed, each commercial application or potential application is protected.

You must be thinking long term about how this development will be commercialized. You must identify various fields of use so you're patent program follows that course. By field of use, we mean the various commercial applications of the technology. The primary purpose of the patent holder may be to commercialize a technology which produces a drug to treat a specific disease and we certainly realize the painstaking process that effort involves. Alternatively, the patent holder may choose to exploit the technology as a particular consumer product for making a better cup of coffee by way of a superior heating system. These two examples clearly house other fields of use. The drug development program is no doubt based on a discovery which could also be commercially exploited as a diagnostic. Suitable description to enable the claims to this diagnostic feature must be included in the patent program to permit the company to transfer this technology and to receive very important short term rewards while continuing to develop the drug. With respect to the coffee maker design, the heater could also have application in providing hot water for use at the tap. If the claims in the patent are all directed to a coffee maker, then this patent is of little value in attempting to license this heater technology in tap hot water production. The usual driving force, when considering the scope of patent claims, is to encompass all potential design around areas of the single commercial use, rather than look at alternative commercial uses of the technology. Each of these separate and distinct technological fields of use can be licensed to separate companies or separately attract a different royalty level. Usually you will want to press early for patent protection on early stage technologies because that is the first technology to reach the market and is usually the most easily protected.

How does that relationship work? In the above examples, there are several possible scenarios in respect of the drug development. Clearly, the

diagnostic, which normally would not require governmental approval, can be commercially exploited immediately. The diagnostic can be fabricated in the form of kits, and sold to healthcare professionals to determine if a patient is susceptible to a particular disease which ultimately will be treated by the drug program. Normally, such diagnostics and kits are of a relatively straightforward nature and on which patent protection is readily available.

Similarly, with the water heater concept, the commercial embodiment may be the coffee maker on which patents can be readily secured. As to claims to the heater, this may present further difficulties, but again assuming that the IP policy prevails, there is impetus to continue to obtain the heater claims with a view to subsequently exploiting them through technology transfer.

Matter of fact early to market or at least proof of principle is indeed what the venture capitalist likes to see. They are looking for not only the long term growth, but require the short term hit. As you appreciate the venture capitalists must see some early returns to survive.

ENABLEMENT

There is considerable pressure to protect the early stage technologies along with late stage technologies. What is the biggest problem with this approach? Enablement!! It is convenient to describe the early stage technology, because normally everything has been geared towards that effort. All of the research and development work provides all of the necessary information to enable this commercial application. As to other fields of use, this can greatly tax the IP professional, because support is needed at the R & D level and the Marketing/Sales level to properly describe those commercial embodiments. The Executive must be on side to ensure that the IP policy is consistently applied and hence efforts are made to develop these other fields of use so that they may be properly described and enabled, thereby resulting in strong patent claims. Enablement issues can be dealt with in different ways in different countries, however you must do your absolute best at the patent application drafting stage to include the correct information to support the breadth of the patent claims. We need look no further than many recent US and European court decisions on

commercially significant inventions to see the patent knocked out for lack of the right information to support the breadth of the claim. Exemplary cases include in the UK – Bristol-Myers Squibb Company v. Baker Norton Pharmaceuticals Inc. v. Napro Biotherapeutics Inc. [1998] EWHC 603 (10th, July 1998) and in the US, for example, the recent decision In re Jones, No. 00-1414 (Fed. Circuit. March 16, 2001).

IMPROVEMENTS

This is particularly the case with respect to improvement patents where the disclosure is incomplete in describing the unexpected result which is usually relied on to support the claims to the improvement. All aspects of that unexpected result must be investigated at the time of filing to ensure that the correct language is in place so that when one encounters prior art there is sufficient information to back up the arguments on how the improvement is not obvious in view of the prior art.

All too often, improvement patent applications are filed with incidental statements about the improvement without supporting explanation or data to back up that position. That can become a major issue during patent application prosecution in mot countries, particularly in the US and Europe.. It is important to anticipate the types of prior art rejections you will encounter during patent prosecution. This necessitates prior art searching and investigations to establish what type of rejection you may encounter. This will ensure that, during the drafting phase of the patent application, all of the necessary language, data, and other evidence is in the application to support the arguments to be advanced in distinguishing the claimed improvement from the prior art. If the improvement resides in a reduced toxic effect, due to the way in which the drug is administered, it is not enough to simply mention that feature. Instead it is important to demonstrate in the application clear support for this feature of the invention. Although data can be later submitted by way of affidavit, this can cause problems during the prosecution and can weaken the enforceability of the resultant patent claims. Also, arguments advanced during prosecution,

particularly the US, can create file wrapper estopel with respect to the doctrine of equivalents and thereby further limit the scope of the patent claims.

FOREIGN PATENTS

Every effort should be made during the convention priority period to include any additional information before international filings are undertaken. This requires planning. Foreign filings cannot be left to the last minute. I usually recommend that, about six months out from filing of the first application, the inventors meet to assess the developments in the technology. If there are improvements, a decision be made as to whether or not further priority filings be attended to. I also emphasize that, if improvements are made after the first filed case and within the 12 month period, any publications or the like on the improvements be carefully reviewed and again priority filings be attended to, particularly if publication or public use of the invention is immediate.

during the convention period if there is an opportunity to add additional information which supports the base claims, you cannot leave that step to the last minute. Any updates to the priority case should be made well in advance so that the impact of those descriptions can be evaluated with respect to the scope of the patent claims. In addition, any unique aspects of foreign protection on the particular technology must be taken into consideration and the specification and claims correctly revised. This will ensure that, during prosecution, any subsequent revision required in the claims due to local laws can find support in the specification.

PIONEER TECHNOLOGIES

Pioneer inventions warrant special attention. Although they offer the broadest scope of protection, from a patent standpoint they can be the hardest to protect because of the pressure to obtain unduly broad patent claims. Utility and enablement become big issues during patent drafting and prosecution of pioneer inventions. Witness the impact of the FESTO decision (Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F. 3rd 558) on day to day practice in the United States. This decision has severely limited the doctrine of equivalence based on amendments made during prosecution. More than every before, there

is a need for advanced planning before filing the US application to ensure that the specification and claims are not only enabled by the description, but as well, clearly distinguish from all prior art of which the applicant is aware. Careful attention has to be paid to these areas during the drafting stage to make sure you can achieve optimum results during prosecution.

Improvement patents offer up a different set of problems, namely; novelty and inventive step. Here it is important during the drafting phase to emphasize the unexpected advantages of the improvement to overcome inventive step objections and to support those statements with data and examples.

The race to the patent office is a dangerous thing – you must make sure you are ready to file. Before you race to the Patent Office, it is important to evaluate the information that is going into the application to ensure adequate support for all fields of use of the improvements. If information is lacking, it may be prudent to hold off on the filing until that additional information can be generated. This will ensure that the data is in the application to support features of the improvement, and in particular information needed to overcome obviousness rejections based on prior art.

OWNERSHIP

Two last considerations before we move onto licensing issues are ownership and where was the invention developed. The claims of a drafted application must be carefully reviewed with respect to who invented them. This can impact greatly on ownership particularly in an academic environment . Academia often are confused in thinking that inventorship is the same as authorship. Furthermore, academia do not want to leave out anyone who might have been involved with the invention, because of political pressures. This, of course, can lead to disastrous conclusions in respect of ownership and perhaps patent validity for improper naming of inventorship. Extreme care has to be exercised in naming inventorship, particularly in respect of obtaining patents in the United States, because improper naming of inventorship can lead to patent invalidity. I highly recommend a rigorous analysis of the patent claims and a

frank and thorough discussion with the inventors to ensure that the correct inventors are named and it is not simply a listing of authors.

If outside parties are involved then it can be extremely difficult to sort out ownership before the application is filed. I have fallen into this trap. It takes a long time to get out of it. Once inventorship has been established, the relationship of the inventors, particularly if they are not employees, needs to be carefully reviewed along with any and all contracts. Assignments have to be prepared and executed by the inventors before the application is filed to avoid any subsequent disputes over inventorship and ownership. I appreciate there are times when a statutory bar necessitates the filing before ownership is clarified. Sometimes the issue cannot be avoided, but every attempt should be made to deal with all the inventorship issues before filing.

TERRITORY

As to where the invention is developed, this is determined in by inventorship. If the invention or part of the invention was developed in a country, which has technology export provisions, such as the UK and the USA then appropriate steps must be taken in the first filing to ensure the proper procedures and the appropriate export licenses are obtained.

TRADE SECRETS

A very much overlooked item, as a matter of fact it did not even make onto Figure 1 is TRADE SECRETS. In a rapidly developing field, the emphasis is on getting the work out the door first, and publishing the results, particularly in the academic community. From the very beginning in a research environment proper provisions must be in place to ensure that the trade secrets are properly protected and guarded.

Trade Secrets form an important aspect in contributing to the value of intellectual capital. Any technology transfer is immediately of more value if Trade Secrets can be transferred in conjunction with the patented technology. Trade Secrets often lead to turnkey set ups which permit the licensee to spring into the market faster. In order to ensure that the Trade Secrets have value, the owner must demonstrate that proper steps are taken to ensure that there is a solid

Trade Secret program. In the past, I have advocated that the following ten rules should always apply with respect to a Trade Secret program.

1. All trade secrets must be committed to print. An organized filing system must be developed to guarantee exhaustive and sufficiently detailed records of all trade secrets.

2. All documented trade secrets must be stored in a safe place. The commitment to complete trade secret record-keeping is easily wasted if records are destroyed by fire, vandalism or workplace accident.

3. Only a chosen few are to be given the privilege of access to any of the trade secrets. A conscious effort to keep employees from knowing all the firm's trade secrets minimizes the risk of serious commercial loss in the context of an ex-employee competing with the firm.

4. A restricted area must be provided in plants where control over who observes trade secrets can be maintained. This procedure will provide a certainty and uniformity of practice, contributing to overall efficiency while primarily assisting in the physical control of printed and computerized information.

5. All plant visits by non-personnel must be documented, and such visits must always be conducted under escort. In the event that a trade secret does pass beyond the yard fence, a log of plant visits provides a starting point in determining the source of the information loss. Perhaps more important is the deterrent effect that carefully logged and supervised visits will have on potential trade secret appropriators.

6. All printed publications must be reviewed to guard against inadvertent release of trade secrets. In the heat of commercial battle, the need for self-promotion in advertising and contractual materials may inadvertently "give the store away".

7. All employees must be made aware of the value of trade secrets, how they can be misappropriated and the consequences if they are illegally exploited. A comprehensive trade secret management system should strive to ensure that each employee is not only committed to

following trade secret housekeeping procedures, but to promoting those procedures.

8. Employee agreements must include confidentiality provisions.

9. Employees must be rewarded for developing, recognizing and disclosing trade secrets to employers.

10. All licensees of relevant technology must be required to maintain the confidentiality of trade secrets.

LICENSING – TECHNOLOGY TRANSFER

What is so special from a Licensing perspective? Well as you can see from Figure 2, all of the arrows are pointing outwardly. Constantly pushing the technology envelope outwardly.

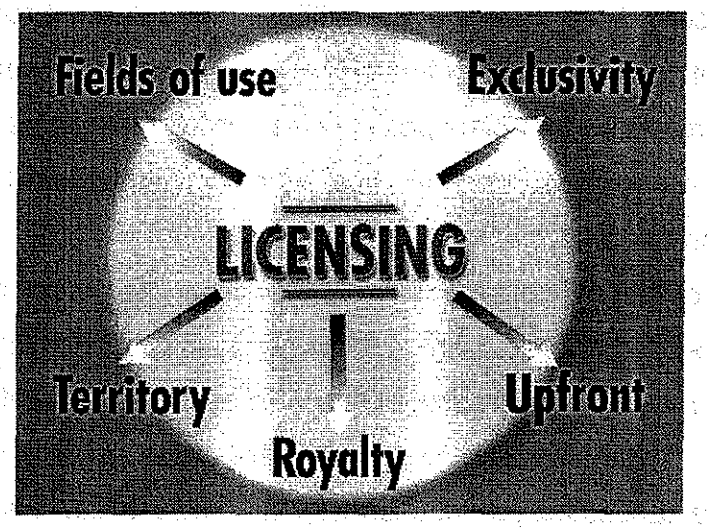


Figure 2

Quite the opposite to the way in which patents are viewed as demonstrated in the earlier Figure 1. There are several issues which deserve special attention in formulating a technology. How does the patent strategy play out in terms of fields of use and territory? Hybrid agreements often play a role in a licensing situation because of the desire to optimize royalty return based on trade secrets and patents. Exclusive versus non-exclusive positions are often contested when establishing a base agreement with the licensee. Ownership of improvements is

an extremely important issue which must be sorted out in advance. Termination can be a very touchy issue but again must be resolved before the agreement is complete. Who has carriage of enforcement proceedings and infringement proceedings? What happens if part of a licensed patent is invalidated?

Many of these issues are addressed when the other party is conducting their due diligence on the deal. The other party is looking at financial strength, corporate philosophy, fit of the parties, extent of patent portfolio, potential for lawsuits, depth of research and clear title to the technology, to name a few.

So let's look at some aspects of an IP Program which cries out for coordination with the Licensing Program.

Fields of Use

When considering the issues of utility and enablement for a patent one must look at all potential uses of the technology. This step will ensure that you have patent protection for all the potential and predictable fields of use for the technology. The base patent application must contemplate and claim as many uses as can be enabled.

This is critical. By pushing hard on alternate uses, quite often the patent application is strengthened. Such activities draw out further discussions of the invention and may well emphasize further features in the essential principles of the invention. This information can greatly strengthen a patent application and ensure a more successful prosecution with presumably less limitations in the patent claims. You should not include arbitrary uses that you can not enable because publication of this application may be citable prior art against a later application directed to that earlier arbitrary use. One has to work very hard in selecting predictable fields of use from the information in the patent application. This strategy will put you in a very good position to optimize rates of return on the new or existing technology. This is particularly true if a concerted effort is made to file the necessary back up patent applications on improvements as new information is developed. One can attract a considerably broader range of potential licensees if the patent portfolio can be broken down into various fields of use rather than just ways of designing around the patents.

Thought has to be given to the patent strategy to ensure that these various uses are claimed. Existing uses and predictable uses have to be described in the patent application in order for them to be claimed. It is important that the claims encompass all aspects of the commercial uses so that when it comes to licensing or other forms of technology transfer, it can be demonstrated that the patent portfolio contemplates such uses. Although attempts can be made to reissue patents, it can become awkward. It is better to contemplate the uses up front and claim them, so that future mining of the patent portfolio can be enhanced.

Ownership

When considering novelty and obviousness this directs you to what subject matter is patentable. This in turn should give you an idea as to who the inventors are and who the inventors work for. In addition this should give you an idea as to who contributed to the program and who might have rights to the invention.

Most certainly, a clean bill of health from an ownership stand point is invaluable during technology transfer negotiations and withstanding the due diligence tests. A poorly managed chain of title in a patent portfolio can be a "value killer" when establishing a licensee or purchaser of the technology. One must conduct their own due diligence on ownership to ensure that all aspects have been investigated, all contracts have been reviewed and all assignments are in place. Breaks in the chain of title sometimes cannot be corrected, either for refusal of parties to execute the necessary documents or the parties no longer exist.

Territory

Foreign filing of patent applications are always a difficult decision process. The initial decisions may be relatively inexpensive but the long term commitments are enormously expensive and time consuming. So you need to make sure you are spending your resources wisely. For smaller companies the use of the PCT system makes a lot of sense because it does give some time to decide if this particular technology is commercially feasible and can be exploited.

Granted the PCT system does add some upfront costs but in the short term it is far easier on cash flows. WIPO is mounting another campaign to achieve harmonization of certain aspects of patent law in all member countries which is now over 110 countries. The six primary areas of harmonization are:

1. definition of prior art
2. novelty
3. inventive step (non-obviousness)
4. industrial applicability (utility)
5. sufficiency of disclosure (enablement)
6. the structure and interpretation of claims.

Long term these efforts to harmonize patent laws will greatly facilitate foreign filings.

You must have a foreign filing strategy that is in step with the technology to be developed. It is best to establish early in the patent program a foreign filing strategy for each class of technology. This can be done in several ways. I highly recommend setting up several different filing strategies based on the type of technology. These filing strategies can be categorized where country filings for each strategy are selected based on the type of technology and its stage of development. This process can greatly save time, avoid overlooked countries and considerably reduce patent filing costs.

Improvements

Novelty and inventive step considerations focus ones attention on what to do with improvements. Should they be kept secret or should they be patented. How significant is the improvement? Can it be reverse engineered from the commercial information that becomes public. Does the improvement fit with the product pipeline and does it fit with the existing patent portfolio? Patents on improvements can greatly increase revenues from the technology transferred. But the timing has to be right and instep with your proposed licensing program and financing program.

An analysis has to be conducted to decide on patent protection for improvements. If the improvement can be reverse engineered from what is

commercialized, this clearly points up the need to do your utmost to protect the developments by way of a patent. If, however, the improvements cannot be reversed engineered and there is a proper trade secret program in place, one might consider protecting the improvements as part of the trade secret package.

Again, one needs to evaluate the interplay between trade secrets and the patent portfolio to ensure that the value of the portfolio is being increased by the decision to either patent or keep the development as a trade secret. In addition, ownership in respect of the improvements is extremely important, particularly if the improvement comes out of a joint research and development program. Ownership in the improvements needs to be established before the joint research and development program is entered into. Both parties are bringing technology to the table which establishes the base line. Any changes to the technology can impact greatly on the parties ability to carry forward independently if the R & D project terminates.

You should decide up front who owns the improvements. This can be determined based on inventorship, or it can be determined based on the area of the technology developed and the claims to the related technology. Something to avoid is joint ownership in the improvements and only in certain situations where the parties cannot agree is joint ownership a last resort.

In that event, there must be a clear understanding with respect to the rights of the parties in the event of termination so that the parties have a clear understanding how they can exploit the jointly owned improvements. There is an excellent review of these issues in the December 2000 issue of les Nouvelles, a publication by the Licensing Executives Society.

Trade Secrets

The most often overlooked commodity in the book. How often have we embarked on a licensing program to find that there are no controls on how technology is shown to people making visits to the facility, nor on what is published. This problem is particularly prevalent in start up companies and small companies. This is when their IP program should be highly structured. They do not take the time to set up proper procedures to protect their trade secrets and

then loose out on valuable revenues later. Proper employee agreements must be in place. Plant visits must be controlled. Publications should be reviewed. IPO materials should be reviewed for sensitive information.

Trade secrets should only be disclosed to those who have a need to know. Trade secrets need to be documented and kept in a safe place and there should be regular meetings to remind employees of the importance of trade secrets. Make sure all consultants are under proper contract and that all the necessary assignments to complete ownership in intellectual property are executed by the consultants. This not only ensures that the corporation is well protected, but as well, it helps the consultant because they have a clear understanding as to their obligations and what they can and cannot disclose or use in other consulting arrangements. Take these steps on Trade Secrets and considerable value can be added to your Intellectual Capital and corresponding technology transfer

CONCLUSION

I trust this paper has provided you with a better understanding of the important interplay between patents and licensing. The five areas of cross-over that I have focused on ensures that a strong patent program attracts significant rewards in the licensing program, or any other form of technology transfer. This coordination is essential at all times to ensure that, during the complex aspects of protecting technology with patents, activities are being coordinated with the technology transfer strategy. Decisions that are made in one country directly affect what happens on the other side of the globe.