IP Due Diligence

1. What is due diligence?

- It is an evaluation, performed by investors or their agents, into the details of a potential investment or purchase, where the evaluation involves a verification of all the material facts relevant to the investment or purchase.

- It involves gathering information about assets and systematically identifying risks.

- Due diligence may be carried out by a University that is deciding whether to support an in-house inventor or staff member with their invention. Or it may be carried out prior to licensing or assigning IP, entering into projects in collaboration with others, or forming a spin-out company.

  These are the types of things that a due diligence investigation looks at:

  - What IP does the University, staff member or collaborator have?
  - If owned, does the University, inventor, etc. have good title?
  - If licensed to the University, what are the terms?
  - Has the University granted any rights to Third Parties?
  - What is the IP's value, if anything at all?
  - Is any of the IP being infringed or challenged?
  - Is there any competing or blocking IP?
  - Are any materials being misused under a MTA?
  - Are all IP payments and filings up to date?

2. Why is due diligence done?

- It is useful for finding out if the deal in question will be a good deal or not. Due diligence helps to determine transaction viability. *Should you go forward with the transaction at all?* Due diligence also helps with understanding and maximizing the value of the deal.

  The following are some further benefits of carrying out due diligence:

  - To avoid being in breach of agreements with third parties
  - To enable you to give any warranties that may be requested
  - To manage risks and liabilities

3. Main Headings in Due Diligence

The following are the main headings to look at when a University is considering adopting an invention made by an employee or student at the University:

3.1 Strength of the invention (incl. patentability)
3.2 Ownership of the invention
3.3 Market potential
3.4 Cost of further development of the invention
3.5 Risks associated with the invention
3.6 Legislation affecting due diligence

The above headings will now be looked at individually in more detail.

3.1 Strength of the invention & its patentability

The strength and patentability of an invention are directly related to its value. To assess patentability it is very important to consider the **novelty** of the invention. Does the invention meet the strict requirement of absolute novelty? It is advisable to carry out a novelty search, but it should be kept in mind that novelty searches can never be conclusive as it is not feasible to search all the records that exist globally.

If patents are granted on the invention will they be broad and strong or narrow and weak? Will the competition be validly stopped?

3.2 Ownership of the invention

It is important to check whether a University staff member or student offering an invention actually owns the invention in question.

Possible problem areas with regard to **ownership** relate to the true identity of the inventors, as well as potential claims that may be made by third parties (e.g. former employers) and sponsors or funders of research.

Regarding **inventorship**, there is the question of whether a person actually qualifies as a true inventor. A second issue is whether there were any other inventors who have not been identified. Both of these scenarios can have a big impact on patent rights. The Patents Register cannot be relied upon if these matters become contentious since it is not definitive as to patent ownership.

Who is the true inventor?

An inventor is someone who makes an independent, original and conceptual contribution to at least one claim of a patent. To be an inventor, a person must have been involved in the *initial conception* of an invention.

In the case of ***IDA Ltd & Others v University of Southampton & Others*** [2006] EWCA Civ 145 (02 March 2006), *Southampton* filed a patent application for a novel cockroach trap that used electrostatic powder. There were some problems with the electrostatic powder, for example it had to be pre-charged, and an employee at *IDA* suggested the use of magnetic powder. Southampton tested this new idea and filed

a patent application for a cockroach trap using magnetic powder. The England and Wales Court of Appeal held that the patent belonged to *IDA* because its employee was the sole inventor.

Were any inventors left out when the patent application was filed?

The case of ***Ethicon, Inc. v US Surgical Corporation***, 135 F.3d 1456, 1467-68 (Fed. Cir.), cert. denied, 525 US 923 (1998) demonstrated how a phantom co-inventor can come out of nowhere and destroy patent rights. *Ethicon* licensed a patent for a surgical device from a single inventor. *Ethicon* later sued *US Surgical* for infringement of the patent. However, *US Surgical* identified another inventor who was not named on the patent but had collaborated on the project, and got a retroactive licence from him. Even though the 2nd inventor was a co-inventor for only 2 out of 52 claims, the court was obliged to dismiss the infringement action against *US Surgical* (since *US Surgical* was now a valid licensee of a co-inventor).

When it comes to determining whether there are **IP rights of third parties** involved (i.e. of people or companies other than the inventor and the University) it is important to make in-depth queries and to check carefully with the inventor because these rights don't always spring to mind. For example, in an invention related to biotechnology: was a vector used that was not owned by the University or the inventor, to transfer DNA into a genetically modified plant? As a second example, do you REALLY own the micro-organism used or was it from a culture collection. If so, the rules of the culture collection may restrict you to non-commercial use.

Sponsors or funders of research may also have rights to any IP resulting from the research. Funding can come from charities, commercial third parties, State funding programmes, etc. Sponsors rights can also arise under collaboration & consortium agreements, or Material Transfer Agreements ("MTAs").

Where the sponsor is a private entity one needs to look at the terms of the particular sponsored research agreement to **determine the sponsor's IP rights**, as the terms of such agreements can vary substantially. ***Where the sponsor is the South African government, the University will be entitled to keep title to the IP but must comply with formalities under IPR Act.***

Still looking at the ownership aspect of due diligence, we shall consider now the issue of **former employers**. An inventor may start work as a new employee at a company or University but may have brought information, data or an invention from a former employer, for example an outside company. This scenario can open a new employer to claims of patent infringement and misappropriation of proprietary information.

For example, the case of ***Regents University of California v Genentech Inc. et al.***, No. 90-CV-2232 (N.D. Ca.) shows how caution needs to be exercised when an inventor is linked with a former employer. In this case, the former employer was a University. The *University of California* claimed that a researcher took DNA from them which they had patented. The University claimed that the defendant company, *Genentech*, had used the DNA for experiments that led to *Protropin*, which was *Genentech's* first blockbuster drug. (*Protropin* was a synthetic human growth hormone used to treat dwarfism.) The University asked Genentech for $400 million

in back royalties, and indeed asked that this amount be tripled to $1.2 billion by way of punitive damages, as the University argued that *Genentech's* infringement was willful, i.e. that the company had known that their employee had misappropriated the DNA. Eventually the case was settled for $200 million in favour of the University, of which $85 million went to the three (actual) inventors at the University.

3.3 Market Potential

An invention may meet all the criteria for patentability (novelty, etc.) yet still not have a market. Many technologies which have been patented have never become commercial successes. As a rule of thumb, one should expect only 1% of new technologies to become successful in the market.

To assess market potential of a new technology one should ask the following questions:

- What is it? What does it do and what does it do better than the competition?
- Does the technology have any "Unique Selling Points"(USPs) that the competition do not offer?
- Who are your customers?
- Who are the competitors?
- Where are your markets?
- What is the total market size and monetary value?
- What are the Strengths, Weaknesses, Opportunities and Threats associated with the technology (a "SWOT" analysis)?
- How should the product be marketed?

One can get various reports done to help in assessing the commercial potential of a technology. Two examples of such reports are a *Technology Assessment* and a *Patent Landscape*. An IP professional such as a patent attorney can provide these reports.

3.4 Cost of further development of the invention

There are usually significant costs associated with developing a new technology. It is important to get a good idea of the projected costs. The inventor can provide useful information regarding the costs of further research but cannot be relied upon blindly as such estimates can sometimes include unnecessary expenses such as conference attendance, and can overlook critical costs associated with items such as:

- due diligence investigations
- patenting
- production
- marketing & commercialization
- investment

- time commitments

Once the projected costs have been assessed the true costs of the project should be tracked on an ongoing basis so that the expected "return on investment" or "earn" on the project (necessary to cover costs) can be continually updated. This will assist in establishing pricing or determining whether to terminate a particular project or to keep it running.

Experience at *Isis*, the Technology Transfer company for Oxford University, has shown that it is helpful to carry out *weekly* budget & expenditure reconciliations with the inventor(s), as this develops financial discipline in a given project.

3.5 Risks associated with the invention

Do issues exist that could lead to unpleasant surprises (such as litigation, inability to market products, or other reductions in the value of the acquired assets)? Do employee agreements and third-party agreements adequately protect the intellectual property assets? Are there restrictive provisions in any of these agreements that will prevent commercialization of a product?

There may also be ethical implications connected with a particular technology. For example, the technology may be linked to animal testing. Most research is reviewed by an ethical committee before it is undertaken, but there may be ethical issues which arise afterwards, or during commercialization. These can cause a negative public backlash which can render a given technology unmarketable.

Bad public relations can also arise from other areas and can destroy a market for a product.

E.g. Frankie's vs Woolworths

Woolworths was forced by public sentiment to withdraw a range of soft drinks from their shelves even though the store had good legal arguments on their side. A large groundswell of opinion had grown up against the store in the press and on social networking sites like Facebook. Woolworths was portrayed in the press as stepping on the "little person," in this case Frankie's Olde Soft Drink Company. Frankie's argued that Woolworths had copied the look & feel of its soft drinks together with the use of the term "Good old fashioned" which was not trademarked by Frankie's. The risk of negative sentiment which might arise if Woolworths pressed its legal claims outweighed the income that it derived from the soft drinks – which made up less than one percent of its product offering – so Woolworths backed down.

3.6 Legislation affecting Due Diligence

A due diligence exercise needs to take account of various laws which can affect how an invention can be commercialized.

For example, many countries have competition laws (called **Anti-Trust laws** in the USA). These can impact the scope of a patentee's rights vis-à-vis its competitors, and can affect what sorts of terms can go into a licence or other agreement.

Competition laws prevent the formation of cartels, the imposition of excessive pricing, the abuse of a dominant position (such as denying competitors access to essential facilities), and other so-called "exclusionary practices."

In South Africa, licences to manufacture various anti-retroviral medicines (ARVs) were awarded to Aspen Pharmaceuticals and three other companies after the Competition Commission found that GlaxoSmithKline ("GSK") and Boehringer Ingelheim ("BI") had fallen foul of some of the above **anti-competitive practices**, including imposition of excessive pricing*. [Note: GSK and BI could have applied for exemption after this finding, based on their rights under the Patents Act, but did not do so and elected instead to award the licences].*

In Europe the so-called "Technology Transfer Block Exemption" ("TTBE") affects what can be put into a licence agreement. For example, no price fixing or output limitations may be agreed upon with a partner or licensee.

The European Commission and the US Department of Justice have put Apple, Microsoft and Google on notice that the use of **"standards essential patents" (SEPS)** in litigation could be investigated as antitrust abuse. SEPS would cover patented subject matter that was necessary for all competitors to use because it constitutes a *standard* in the industry in question.

Another piece of legislation to keep in mind, which can affect patent rights and therefore needs to be taken into account for purposes of a due diligence investigation, is the ***Intellectual Property Rights from Publicly Financed Research & Development Act***, No. 51 of 2008 (the "IPR Act"). According to Section 12 of this Act, a University or other Institution affected by the Act cannot enter into an IP Agreement with an offshore entity, e.g. an offshore company, unless it has first shown that there is insufficient capacity to develop the IP in South Africa, and that the Republic of South Africa will benefit from the offshore transaction.

There is legislation in South Africa relating to traditional knowledge & indigenous resources. Where these have been used in the development of IP there are certain formalities that must be complied with, and a benefit share must be given to the relevant community. The ***Patents Act***, No. 57 of 1978 and the ***Biodiversity Act,*** No. 10 of 2004 are two examples of legislation relating to this area.

Novelty Searches and Search Tools

There are various different kinds of searches which can be carried out in respect of patents.

Novelty searches aim to determine if the subject matter of an invention has been disclosed previously, i.e. whether there is any relevant prior art. **Infringement searches** are carried out for a particular country or territory, and aim to determine if any patents will be infringed if a given technology is put into practice. For infringement searches we search patents only (not other literature or sources), and only those patents which are in force will be relevant. **Equivalent searches** are done to determine whether, for a given foreign patent, an equivalent patent application was filed in South Africa. These searches are carried out using the names of the inventors and patentee, and the priority details.

In the following we are looking at how to carry out a novelty search. Ideally, novelty searches would be carried out world-wide, and would cover not only patent disclosures but all forms of printed, written, oral, televised and other disclosures. This is because "absolute novelty" is required for an invention to be patentable. Since an all-encompassing search of this type is clearly impractical, however, novelty searches can never be conclusive or comprehensive. No matter how thoroughly a novelty search is carried out there will always remain a possibility that a relevant prior art disclosure could have been missed.

Steps for carrying out a Novelty Search:

1. Identify the main features of the invention;
2. Classify the invention;
3. Search using the search tools;
    i. Patent Resources;
    ii. Non-Patent Resources;
4. Make a spreadsheet of the essential integers and mark off those integers which are present in each prior art disclosure found;
5. A disclosure is prior art if it contains ALL of the essential integers.

These steps are explained more fully in the following:

Step 1: Identify the main features of the invention

Divide the invention into separate main features or "essential integers." The novelty of the invention will only be destroyed by a prior art document if that document discloses all of the essential integers.

Step 2: Classify the Invention

It is very useful to classify your invention before starting to search the records of the various Patent Offices. Approximately 2 million patent applications are filed every year and around 40 Million have been granted over the years, so it is helpful to be able to narrow the number of "hits" down to your particular field of interest when you search. You can do this by classifying your invention into a few, relevant patent classes, and then searching only in those classes.

Classify your invention by browsing the *International Patent Classification* ("IPC"): http://www.wipo.int/ipcpub

The IPC divides all of science & technology, engineering and human needs into 8 sections (A to H). The general scheme of the IPC is as follows:

SECTION A — HUMAN NECESSITIES
SECTION B — PERFORMING OPERATIONS; TRANSPORTING
SECTION C — CHEMISTRY; METALLURGY
SECTION D — TEXTILES; PAPER
SECTION E — FIXED CONSTRUCTIONS
SECTION F — MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING
SECTION G — PHYSICS
SECTION H — ELECTRICITY

As explained above, you can access the website of the International Patent Classification system at http://www.wipo.int/ipcpub. After browsing to the website, click on the "Terms" Tab and enter a broad search keyword into the "Word(s)" box.

Example:

Classifying a *wheelbarrow*: Click on the "Terms" tab, then enter *wheelbarrows* into the "Word(s)" box. This returns the class: **B62B 1/18**. The coverage of this class is set out below. You can now use this class when searching the records of the various Patent Offices, to keep your search results within the field of interest.

SECTION B — PERFORMING OPERATIONS; TRANSPORTING
B62B: HAND-PROPELLED VEHICLES, e.g. HAND CARTS OR PERAMBULATORS; SLEDGES

***B62B 1/18**: Hand carts having only one axis carrying one or more transport wheels; Equipment therefor,*

- *in which the load is disposed between the wheel axis and the handles, e.g. wheelbarrows*

Step 3: Search using the Search Tools

Patent Resources

Use the following resources to find patents within the IPC class(es) of interest. Enter the IPC class into the relevant search field provided for it. Because of the vast numbers of patents filed in each clause, you will then probably need to narrow down the returned search results by using keywords in combination with the class(es). However, avoid relying too heavily on keywords. Ideally one should read through the abstracts of all patents in the relevant class(es).

WIPO PatentScope http://www.wipo.int/patentscope/search/en/search.jsf
PCT patents and the patents of numerous national and regional patent offices.

Google Patents www.google.com/patents
Search over 8 million patents.

USPTO http://www.uspto.gov/patents/process/search/
The US Patent Office.

Espacenet
http://worldwide.espacenet.com/advancedSearch?locale=en_EP
The European Patent Office ("EPO"), with access to patents from over 80 countries, as well as European and PCT published applications.

Canadian Patent Office
http://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/introduction.html

WIPO PatentScope covers patents filed under the Patent Cooperation Treaty ("PCT"), and since applicants from all around the world file PCT applications this is an excellent starting point. However, *PatentScope* has some limitations. For example, it won't pick up older US patents. *Espacenet*, the *USPTO* and *Google Patents* are useful for accessing older patents.

It is advisable to use the option of "Advanced Search" wherever possible. This will allow you to enter search terms into separate fields. This allows a more directed and refined search.

Non-Patent Resources***

Google Scholar http://scholar.google.com/advanced_scholar_search
Articles, patents, legal opinions & journals.

SciVerse ScienceDirect http://www.sciencedirect.com/
10 million journal articles and book chapters.

IEEE Xplore®
http://www.ieee.org/portal/innovate/search/search.html
Technology articles relating to the electrical, electronic and computing fields and related areas of science and technology that underlie modern civilization. IEEE stands for the Institute of Electrical and Electronic Engineers.

****The above resources may also be available in unlocked format on your Institution's internal network.*

Web History: When searching the internet generally (e.g. using Google) be cautious of the tendency of certain search engines to capture and store your search terms. If you disclose the essential integers of a new invention in a search phrase, this phrase could be recited to a different user of Google, and this in turn could constitute public disclosure and destroy the novelty of your invention.

You can disable Web History in Google if you have a Google account. It is recommended that you do this before using Google Patents, Google Scholar and the general Google search engine.

- *Sign in to your Google account*
- *Go to "Account Settings" in Google*
- *Then "Services"*
- *Then "View, enable or disable web history"*

Step 4: Check patents cross-referenced by most relevant patents

Most patents will have a section near the top of the document which sets out ***References Cited*** (patents that came before) and ***Referenced By*** (patents that came afterwards). These references are usually on the same subject matter and should be checked, at least to the first level of the tree, to see if any patents mentioned there are of interest.

Step 5: Make a spreadsheet of the essential integers against the prior art

Key: √ = Presence + = Partial Presence

PRIOR ART	**Is Essential Integer present in the Prior Art?**

	a)	b)	c)	d)	e)
CN201882019U	√	√	√		
JP2011025897A	√	√		**+**	√
JP2008147417A	√	√			
WO2006081942	√	√	√	√	√

Step 6: Determine if any of the disclosures are prior art

An invention is "anticipated," i.e. its novelty is destroyed, only if ALL its main features (essential features) are disclosed in a prior art document.

In the above example table (which does not relate to any particular invention), only the PCT publication (WO2006081942) discloses ALL the integers of the invention and therefore anticipates the invention. However, the other patents may be relevant to the question of the *obviousness* or otherwise of the invention.

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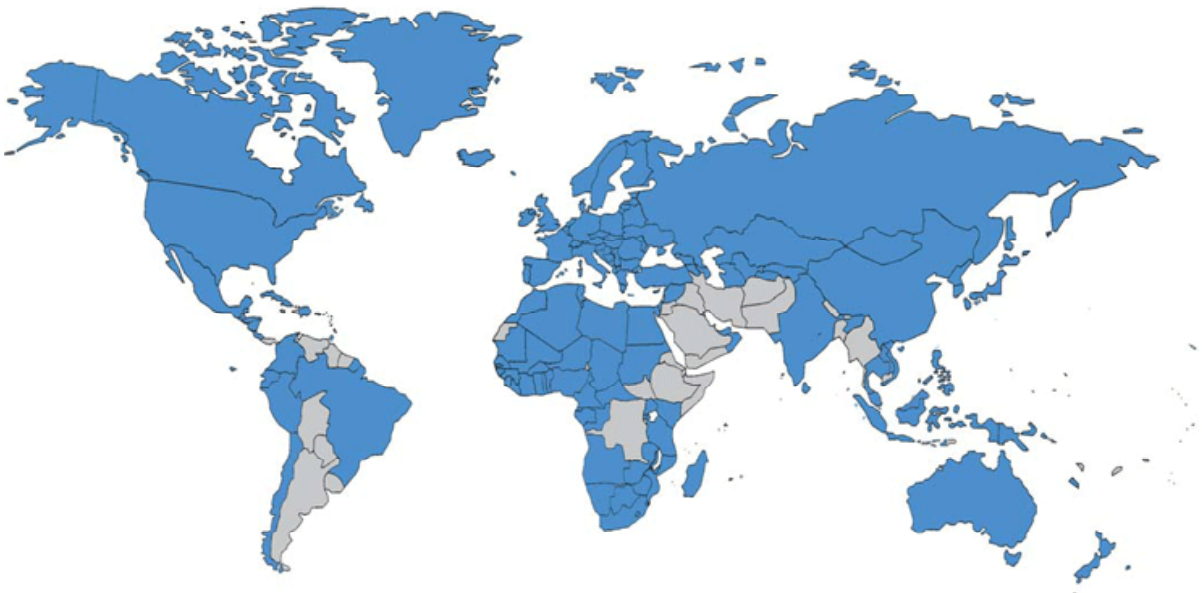
PCT Patent Applications

There is no such thing as a "world patent" covering all the countries of the world. Patent applications have to be filed in each separate country or region where patent protection is needed.

However, there is a mechanism which allows a patent applicant to cut down significantly on costs and administrative burden, by filing just a single patent application in the early stages of the process. Later, however, that single application will still have to be extended by lodging into the various countries and regions where patent protection is needed.

The single, early stage patent application is made possible by the *Patent Cooperation Treaty*, abbreviated as "PCT". The PCT is an important treaty in the world of intellectual property, and by March 2012 it had 144 Contracting States (Countries).

The shaded areas on the following map show the countries which are members of the PCT.



(Source: WIPO)

144 Contracting States of the Patent Cooperation Treaty

The PCT is administered by the World Intellectual Property Organisation.

A PCT application starts out as a single patent application called an International Application. The International Application can be filed at a country's local Patent Office (e.g. at the South African Patent Office) as Receiving Office. From there the application is passed to the *International Bureau* and the *International Search Authority* ("ISA"). The ISA carries out a novelty search and examination on patentability. In the days before the PCT, the same search and examination had to be carried out over and over again in each country where the patent applicant required protection. There was accordingly a great deal of duplication of work at the various Patent Offices, causing escalation of costs for the applicant. Now, under the PCT, a single search and preliminary examination can be had, cutting down on costs. If it turns out that the invention is not patentable, possibly because it is not new, then the single PCT search and examination can give the applicant this information at an early stage and possibly save on unnecessary further prosecution and costs.

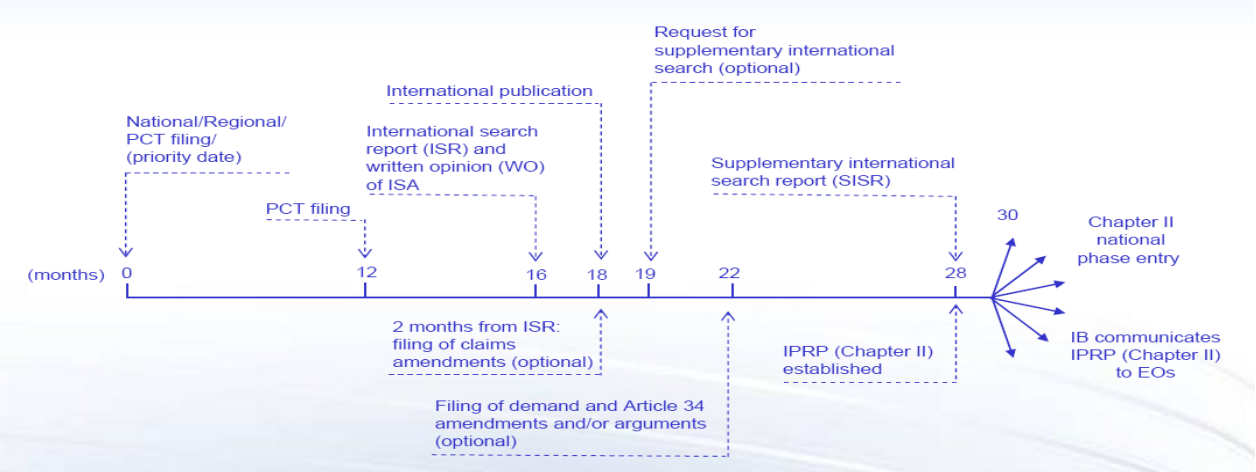
In summary, the PCT search and examination give the following advantages:

- early evaluation of an invention;
- insights necessary to reallocate resources to other inventions, if appropriate (know when to "fold 'em");
- a single search and examination which can be used by the various national regional/patent offices, saving costs and repetition of work; and
- a breathing space, or delay, during which an invention can be developed by an applicant before expensive national patenting costs become payable.

The examination carried out by the International Search Authority is split into a number of steps. A preliminary examination gives rise to a written opinion called an *International Preliminary Report on Patentability: Chapter I* ("IPRP-I"). Later, and for an extra fee, a full examination can be requested, involving dialogue with the Examiner and amendments. The examination report that is issued after this examination is called an *International Preliminary Report on Patentability: Chapter II* ("IPRP-II"). This report was previously known as the *International Preliminary Examination Report* ("IPER"). It is not compulsory to request the Chapter II examination.

While the PCT application is undergoing search and examination by the International Search Authority it is said to be in the *International Phase*. This phase lasts for two-and-a-half years from the priority date. Once the International Phase is complete, the applicant must either abandon their application or file it into the various countries of regions in which it requires patent protection. This new phase of filing into individual countries or regions is called the *National Phase*.

The following diagram illustrates various deadlines in the International Phase, which runs from the priority date to the date of entry into the National Phase at 30 months.



(Source: WIPO)

PCT Timeline

Choosing the countries for the PCT National Phase:

When the two-and-a-half years are up and you get to the end of the PCT International Phase, how do you choose the countries in which to file National Phase applications for your invention? The following ideas are extracted from an article entitled "The Wicked Which" by Justin Simpson, President of PCTFILER, LLC:

www.napp.org/disclosure/linked_files/Wicked_Which.doc

"To Market, to Market…"

It seems obvious, but the first question an applicant should ask is *"Where are my main markets*?" For consumer goods, applicants might want to consider covering their local country (if they don't already have an application filed there), as well as any other jurisdictions where they already make sales. For general consumer goods, the US is usually a good addition—for many products a US patent gives a good bang for the buck.

Applicants that manufacture and sell, say, mining equipment should be looking at where that equipment will be used; if there's no iron-ore mining going on in the US at the moment, there's little use in getting patent protection there, even if it is the world's largest (general) consumer market. In short, applicants should look at where their products will sell, not where products in general sell.

Also, more emphasis should be placed on those markets with the potential for growth–and bearing in mind that patents last 20 years from filing in most countries, potential for growth should be considered from a long term perspective, not just what might happen in the next financial year or two.

Similarly, we often find applicants wondering about the worth of protection in countries like China or India, due to concerns about the strength of IP law in those countries. Our suggestion is look at how far China has come in IP law terms in the last 10 years, and try to imagine where it might be in another 10 (at which time a patent entering the national phase now will still have 8-10 years to run). And then look at the growth of the consumer market

there over the same period and try guessing where that might be in 10 years. Looking at the drastic positive change in both market size and the effectiveness of IP law, the long-term picture for some applicants can make countries like China, India and Korea essential.

Competition

Where are the applicant's competitors operating? Particularly in high-tech and fast-moving fields, markets are far from established, and you may not yet be competing directly with your competitors in some markets. Don't wait until both you and your competitors are there slugging it out to consider extending patent protection.

Also, it may pay you to consider covering at least some of your competitor's more important markets to give yourself some leverage. For example, one of our clients' major competitors is based in Austria, and has a particularly strong market presence in that country. This client considers Austria a special case because of this, and even for less important inventions that might not be worth the cost of a European application, they file in Austria anyway to give them extra leverage in this market where their competitor is particularly strong. It's a nice ace to have up your sleeve if you one day find yourself negotiating a cross-license with your competitor!

Think about the countries where your competitors are operating, and determine whether there is long-term advantage in giving yourself some leverage there, even if you aren't considering taking them on there yet.

"If you build it…"

We're sometimes surprised by how often applicants say they're filing in a particular country simply because that's where they intend to manufacture the product. If money is no object, there's nothing wrong with this approach. However, unless there is something special about that country's manufacturing sector that makes it likely a competitor would need to get a particular product manufactured there, applicants should consider whether this money might be better spent protecting markets where the product will actually be sold. Choosing to manufacture in Korea rather than China is a trivially easy way to avoid a Chinese patent, for example.

The Snowflake Principle

No two inventions are the same, and different patent applications may have different importance to your business. It may not make sense to your business to always proceed in the same combination of countries with all applications. Perhaps your budget would better be spent by getting wide coverage for important inventions, and lesser coverage for inventions that are less central to your business.

The *Gross Domestic Product* ("GDP") *per capita* of a country can also be taken into account. The *GDP per capita* of a country can give an indication of how

much money the people in that country have available to spend on your product. A list of countries ranked by *GDP per capita* is available at:

http://en.wikipedia.org/wiki/List_of_countries_by_GDP_(PPP)_per_capita

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Intellectual Property Rights & Development

Intellectual property impacts trade on a global scale. Since IP benefits favour the inventor (in order to promote innovation), access to technologies which could improve basic living conditions in developing countries are too expensive to license from Developed countries (which initially came up with the international treaties and agreements). Examples of these include medical diagnostic tests for prevalent diseases in Africa, which are too expensive to buy from the US and too expensive to manufacture because of potential licence fees. Even though the tests can save lives, the cost associated with them could cripple an economy.

A need has been identified to establish more balance in the global economy in order to eradicate poverty. The United Nations, as a governing body for international treaties and agreements, identified and defined this need and has implemented a long term plan with goals. Significant resources have been set aside to assist Developing countries/economies (South Africa included) in developing IP Policies and regulations which stimulate growth of innovation, address the needs of their economies and complement the existing agreements on Trade.

Further Reading: "**Harnessing Intellectual Property Rights for Development Objectives**: The Double Role of IPRs in the Context of Facilitating MDGs Nos. 1 and 6."

Further Reading: (Extract from article):

***Facilitating Humanitarian Access to Pharmaceutical and Agricultural Innovation,* Amanda L. Brewster, Audrey R. Chapman, Stephen A. Hanse,** *Science & Intellectual Property in the Public Interest (SIPPI),* American Association for the Advancement of Science, 1200 New York Ave., NW, Washington, DC 20005, USA, achapman@aaas.org or shansen@aaas.org

One of the most noted examples of humanitarian IP management involves vitamin A-enriched "golden rice." Although developed mainly with public sector funding and research, around 45 patents associated with golden rice are owned by approximately 30 companies and public institutions in the US, and only a few patents are held in developing countries.8 The inventors of golden rice licensed their inventions related to golden rice to Greenovation, a biotech spinoff company from the University of Freiburg, that is owned by the inventors themselves. Greenovation then exclusively licensed its golden rice-related patents to AstraZeneca (now Syngenta). Subsequently, Syngenta entered into a license agreement with the inventors that allowed them, and Syngenta, to license golden rice technologies to developing countries.

Other companies holding golden rice-related patents also agreed to the same arrangement. That arrangement allows both Syngenta and the inventors to grant licenses—with the right to sub-license—to any *bona fide* research organization for the development of golden

rice. The rice can be used royalty-free and allows farmers to earn as much as $10,000 per year from its sale. Higher sales would require farmers to acquire a commercial license from Syngenta.9 The example of golden rice illustrates that it is possible to make IP available for research and commercialization in developing countries.

Yale University offers another example of humanitarian IP management. It holds a key patent on stavudine (d4T), a widely used HIV/AIDS antiretroviral drug. After Yale licensed this patent to Bristol-Myers Squibb, they renegotiated to incorporate renegotiated humanitarian terms, allowing the drug to be subsequently licensed for generic production in South Africa. The university also negotiated a price cut, immediately reducing the price of d4T in Africa by thirty-fold.

When the generic product came on the market, it further reduced the price by as much as 40%.

Other examples of humanitarian IP management include Cornell University's transfer of ringspot resistant papaya to Thailand, as well as several projects brokered by the International Service for the Acquisition of Agri-biotech Applications (ISAAA).

The latter include local varieties of potato transferred from Monsanto to Mexico, as well as ringspot virus resistant and delayed ripening papayas transferred from Monsanto and Syngenta, respectively, to Southeast Asia.10 Finally, a recent agreement between Gilead Sciences and the South African drug maker Aspen Pharmacare is another example of humanitarian IP management for health products.

Gilead will allow Aspen to produce generic versions of the HIV/AIDS antiretrovirals Truvada and Viread, and university inventors who own foundational patents for both drugs have agreed to waive royalties in the developing countries served by Aspen.11

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