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Front cover:
Mexican independent film producer and director Roberto Girault (back to camera) guides leading actor Jorge Lavat (Chano) in the film El Estudiante, one of the most successful domestic Mexican films ever.

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ePCT: for even easier international patent filing

In an age of increasing globalization, companies large and small are seeking patent protection in multiple countries. WIPO's Patent Cooperation Treaty (PCT) provides essential services to facilitate this process and is an increasingly popular means of filing for international patent protection. In 2011 alone, over 181,000 international patent applications were filed under the Treaty. The patent system as it exists today, however, is still characterized by processes that are largely rooted in the physical exchange of documents. This can cause delays and impede the system's operational efficiency. In May 2011, WIPO launched ePCT, a new online service that will make the process of international patent application filing far easier and more efficient, and offers users and national patent offices a number of advantages. ePCT users are heralding it as the greatest innovation in the PCT system over the past 30 years. This article outlines the services available under ePCT and highlights some of its main benefits.

"Just 12 months ago, ePCT was a small-scale pilot scheme", notes WIPO Director General Francis Gurry. "Today it is being used by applicants from over 80 countries and has recently been made available to patent offices. It is proving to be extremely popular. It responds to innovators' need for an on-line tool to navigate the international patent system effectively, and is among the most important of the current improvements to the PCT."

The patent system has grown up with processes that are still largely based on the exchange of paper documents. This means that the same patent application and associated documents are often held by multiple actors working within the patent system. These include patent applicants and their representatives in different countries, patent offices, and patent searching and examining authorities. ePCT offers a virtual alternative enabling the electronic exchange of patent-related data between interested parties securely, quickly and easily. It establishes a single electronic platform that is accessible to all those involved in the international patenting process. Once the system is fully functional, applicants can submit their international patent applications online and these are instantly available to the 18 International Searching Authorities responsible for searching the prior art to determine the patentability of an invention. The results of this search are then readily available to applicants via their dedicated ePCT file.

**ePCT’s Services**

ePCT offers two types of service: public services that, by simply establishing a user account, enable users to upload documents relating to all international applications filed under the PCT; and private services that, by uploading a digital certificate, enable users to access and manage their international applications filed as of January 1, 2009.

With ePCT, users can monitor the status of their international application and modify it as necessary in real-time. They can also communicate securely with WIPO's PCT examiners, monitor deadlines (thanks to a running timeline feature) and receive notifications of events and necessary action. Users can also give access rights to others according to whether they are an "eOwner", an "eEditor" or an "eViewer". This feature allows a patent agent, for example, to share a file with colleagues, or with the applicants they are representing.

**A User’s Opinion**

"ePCT is part of the daily workflow of Oppedahl Patent Law Firm (OPLF),” says Carl Oppedahl, one of the earliest adopters of the service. OPLF encourages its foreign clients to use ePCT when they seek patent protection in the US by offering them a discount. “ePCT permits us to carry out the US national phase entry more efficiently,” notes Mr. Oppedahl. “Access to ePCT allows us to copy and paste bibliographic data rather than hand-keying it, and permits early access to important documents,” he explains.

Similarly, ePCT also helps the firm when its clients are seeking to enter the national phase outside the US. “It used to be that when we would entrust a national phase entry task to a patent firm [outside the US], we had to send lots of PDF files. It was all too easy to forget to send a file that might be needed in a particular country, or to send a file that was not actually needed, either of which wastes time or risks sending an email that was too large for the recipient’s email system. Now, with ePCT, when our client tells us to enter the national phase in a particular country, it is simply a matter of a couple of mouse clicks to give ePCT access to the international application to the intended foreign law firm,” he explains. “In this way, the foreign law firm has direct access to everything it needs to carry out the national phase entry".
PATENT OFFICES PILOT ePCT

In July 2012, ePCT was rolled-out for use by patent offices in their capacity as either a PCT receiving office or a PCT International Authority. Five national patent offices are currently piloting ePCT. With access to a web browser and a scanner, patent offices can use ePCT to simplify communication in relation to international patent applications in a secure on-line environment. “ePCT is of particular benefit to smaller patent offices which do not receive a large number of PCT applications,” explains Jim Pooley, Deputy Director General of WIPO’s Innovation and Technology Sector who oversees PCT matters.

The Moroccan Industrial and Commercial Property Office which received 84 international applications from Moroccan applicants in the last five years is participating in the ePCT pilot for patent offices. “ePCT is an easy, cost-effective and secure means for making PCT applications available to the International Bureau and International Authorities, and it is a big improvement over the paper system we used before,” says Mr. Adil El Maliki, Director General of the Moroccan Industrial and Commercial Property Office. He also stresses that “ePCT provides an important level playing field for applicants like small and medium-sized enterprises (SMEs) and universities by enhancing their capacity to administer their international applications.”

More efficient communication between offices also benefits applicants who rely on timely access to PCT work products, such as search reports and written opinions, to fine-tune their patenting strategies. “Applicants rely heavily on the information in the international search report and the written opinion for further business decisions, such as whether, or in what countries, to pursue the application,” notes Mr. Pooley. “ePCT enables users to receive PCT documents immediately, without any postal or other delay. They can then use this information to make sensible business decisions.”

PUBLIC PARTICIPATION IN PATENT EXAMINATION

In July 2012, ePCT’s third party observation system went live allowing any interested party to submit observations concerning prior art that may affect the patentability of an invention that is the subject of a published PCT application. “This additional feature is an example of using the power of the Internet to assist in quality outcomes in the patent process,” Mr. Gurry observes. “As of mid-September, 18 third-party observations had been submitted via the system. While relatively small, the seriousness of the submissions thus far vindicates the usefulness of the new facility.”

Observations are made available to all relevant International Authorities and national offices to support their evaluation of the patentability of related applications. ePCT’s third party observation system interfaces with WIPO’s largest database, PATENTSCOPE, which currently offers access to over 14 million patent applications.

“The main goal in involving the public is to help in identifying relevant prior art to assess whether an invention is patentable. This helps improve the quality of the international prior art searches carried out during the international phase of a PCT application and which are communicated to all national offices of PCT member states”, explains Michael Richardson, Deputy Director of the PCT Business Development Division. “While the quality of the international prior art searches is usually good, it can never be perfect. There can always be mistakes, as well as prior art that only persons working in the particular field will know about. ePCT’s third-party observation system gives third parties an opportunity to easily submit information referring to prior art which they believe is relevant to the question of whether the invention claimed in the international application is new and/or involves an inventive step,” he notes.
ePCT’s third party observation system is easy to use and unlike some other similar systems, is free of charge. Third parties can – under a cloak of anonymity, if so wished – submit their observations from the date of publication of an international application up to 28 months after the priority date specified in the application. Observations may be submitted in one of the 10 PCT publication languages, although copies of prior art documents may be submitted in any language.

To submit an observation, a third party holding an ordinary WIPO user account can go to the relevant international application within PATENTSCOPE, input their observations and press the “submit observation” button. All observations are published on PATENTSCOPE and communicated to the relevant International Authorities and national patent offices obviating the need to submit the same observations individually to every patent office concerned.

“This tool gives users a chance to intervene early in the patent granting process”, notes Mr. Richardson. “Instead of having to file lawsuits, potentially in many countries, against a competitor who already holds a granted patent on a given technology, users can intervene before a patent is granted on their technology and thereby reduce the risk of litigation and associated costs.”

FUTURE

A new version of ePCT, expected by the end of 2012, will introduce a number of new features, most notably, an online web-based filing system making it possible for applicants to file PCT applications directly via a web-browser and eliminating the need to download special software. This feature will initially be available to a group of pilot users for applications filed with the International Bureau as PCT receiving office and then will be gradually rolled-out to all other users and PCT receiving offices. “The web filing system will make it much easier to file patent applications, especially for applicants from developing countries and small offices which, unlike larger offices, can’t afford to set up their own electronic filing systems”, notes Mr. Pooley. The ePCT web filing system will be hosted and maintained by the International Bureau. In this way, small national patent offices will be able to receive applications electronically instead of having to develop and maintain their own local electronic filing system. This is a distinct advantage given the costs associated with developing such systems, which often exceed the fees smaller offices receive from patent applicants. “The web filing system will effectively allow smaller offices to offer their applicants the same level of service as their larger counterparts without any further investment,” Mr. Pooley explains.

WANT TO KNOW MORE?

Further information is available at https://pct.wipo.int/Logins-Forms/epct.jsp. The PCT Newsletter regularly contains up to the minute information about new ePCT developments, and a series of monthly webinars on the use of ePCT is currently running. Participation is free of charge, so if you are interested in learning more, why not sign up to the next webinar? Details are available at: www.wipo.int/pct/en/seminar/webinars/index.html.
The PCT in a nutshell

The PCT system has so far been adopted by 146 countries. It offers applicants a cost-effective, simplified and efficient means of seeking patent protection in multiple countries.

The PCT patent application filing system includes two phases: an international phase during which an international application is filed and an International Searching Authority undertakes an international search, resulting in a search report containing citations of relevant prior art and a written opinion on the potential patentability of the invention. International publication of the application also takes place during this phase, which includes an option to undertake international preliminary examination of an application. This is followed by a national/regional phase during which the decision is taken as to whether or not an application qualifies for patent protection.

The PCT offers numerous advantages. Applicants have more time (up to 18 months) to reflect on the desirability of seeking protection in foreign countries, to appoint local patent agents in those countries, to prepare the required translations and pay the national fees. Applicants are assured that PCT-compliant international applications cannot be rejected on formal grounds by any designated office during the national phase; they can also better evaluate the chances of obtaining a patent on the basis of the international search report and written opinion. Moreover, during international preliminary examination, applicants can amend their international application before processing by the designated offices.

Patent offices also benefit insofar as the search and examination work they undertake can be considerably reduced. Upon publication of the international application together with its international search report, third parties are better placed to formulate an opinion about the patentability of a claimed invention.
Changing Places: 
a new role for creators 
in the digital world

By María Alejandra López García, 
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With the invention of printing in the 15th century the book trade took off, giving birth to copyright as a means of regulating the “right to copy” literary works under common law, and of ensuring that authors reaped the rewards of their labor. For the next 500 years or so, although tensions between publishers and authors were all too frequent, the industry flourished. The consolidation of the major publishing houses in the late 20th century, however, and the advent of digital technology marked a dramatic shift in the industry. For much of the 20th century major publishers and distributors maintained an iron grip on book markets and distribution channels. Communication between authors and their readers was practically non-existent and, where it did exist, the terms were dictated by publishers. All this changed with the digital revolution, which continues to transform traditional business relationships, fueling new creative opportunities and breathing new life into the creative economy.

The music industry was, perhaps, the first to feel the full force of the digital transformation that signaled a marked shift in power from the record labels towards artists and live performances, on the one hand, and distributors of electronic content, on the other. Record companies were left in an uncomfortable and precarious position with little choice but to reinvent themselves and adapt to the realities of the new digital economy. Other creative sectors have had a softer landing but nonetheless can ill afford to continue with “a business as usual” approach.

To compete effectively in the digital economy, companies need a business plan built around strategic use of intellectual property (IP) that enables them to be nimble and responsive. The lessons of recent years underline the importance of consumer power and have shown that, in general, provided digital content is easy to access and reasonably priced, consumers are willing to pay for it. While some recording companies and publishers have been reluctant to break with established business models, certain creators have sought alternative ways to interact with their fan base and secure a return on their creative works.

Radiohead Makes Waves

In the music world, the critically-acclaimed rock band Radiohead was one of the first to venture into new territory. At the end of their contract with EMI/Capitol, Radiohead launched In Rainbows, in October 2007, exclusively via www.radiohead.com as a download using a pay-what-you-want model. The album was released as a standard CD later...
that year. Although precise figures are unknown, the album is thought to have sold over 3 million copies (in all formats). Radiohead claims it earned them more than their previous album recorded on the EMI/Capitol label, in spite of the fact that, as confirmed by the band, more people downloaded the album free of charge than opted to pay for it.

**STEPHEN KING: E-BOOK PIONEER**

In the book world, the master storyteller, Stephen King, was the first to test the water with the release in 2000 – through Simon & Schuster, using SoftLock technology – of *Riding the Bullet*, the first-ever mass consumption e-book. Despite a number of technical glitches, the work was downloaded over half a million times. The novel was later published in print format as part of a collection of stories by the author.

Later that year, undeterred by the problems encountered in releasing *Riding the Bullet*, Stephen King progressively released individual chapters of *The Plant* on his personal website. The initiative worked on an honor system, whereby readers agreed to pay a sum of money suggested by the author to download each chapter. According to figures provided by the author, the project generated about half a million US dollars. Ultimately, however, as less than 75 percent of readers settled their pledges, he did not complete the work.

**J.K. ROWLING AND POTTERMORE**

British author J.K. Rowling, of Harry Potter fame, one of the most successful writers of all time, recently took this model to a new level with the launch of her own e-commerce store.

In April 2012, Ms. Rowling publicly unveiled her new Pottermore website – *www.pottermore.com* – introducing a new, independent model for the publication and distribution of Harry Potter-related content. The site offers established fans “a little more of Harry Potter” and promises to inspire a new generation of digital readers. It can be expected to further leverage the value of the Harry Potter brand, currently estimated at around US$15 billion.

The site was developed by Ms. Rowling, TH_NK (a leading British agency in digital strategy) and Sony Corporation and serves as the permanent home for the Harry Potter book collection. By simply registering to acquire a user name, fans embark on a unique and immersive journey into the world of Harry Potter. They can follow the collection’s storylines, travel through different parts of the book, share their experiences, demonstrate their creativity and discover a wide range of unpublished content. “For me, this is just a great way to give something back to Harry Potter fans...
who made the books such an incredible success,” Ms. Rowling remarks. “This is a way for Harry Potter to live on in a medium which didn’t exist when I started writing the books,” she adds.

Through the Pottermore Shop, fans can purchase the collection as e-books (for the first time) or as digital audiobooks in multiple languages. The whole e-book series costs US$74.61, and individual e-books range from US$10.36 to US$12.95. On purchasing one digital copy, fans may acquire seven additional copies at no extra cost. Digital editions of the collection are compatible with all e-reading devices, and each download carries a watermark linking the purchaser to the e-book. While digital versions are only available from the Pottermore site, thereby eliminating other online bookseller intermediaries, Ms. Rowling’s partners all benefit from cross-platform advertising.

“It is my view that you can’t hold back progress; e-books are here to stay,” Ms. Rowling noted at the site’s launch. “We knew there was a big demand for e-books, but if it was going to be done we wanted it to be more than that… I wanted to pull it back to reading, to the literary experience, the story experience, and this is what emerged. It is a fantastic way for fan creativity to continue,” she adds.

Had it not been for Ms. Rowling’s foresight – whether by accident or design – in retaining the digital rights in her works, it is unlikely that Pottermore would have seen the light of day. Back in 1996 and 1997, Bloomsbury Publishing (UK) and Scholastic Inc. (US) secured the print publication rights in the Harry Potter collection. Ms. Rowling retained the universal rights to digital publication of her works and, having secured ownership of the pottermore.com domain name through Pottermore Limited, she has been able to launch her own e-bookstore, develop a direct relationship with her readers and retain most of the profits (an estimated 30 percent of sales). Similarly, in 1999 during negotiations with Warner Bros. Entertainment Inc. for the exclusive film rights and trademark rights in the characters, names and other indicia relating to Harry Potter, Ms. Rowling succeeded in retaining an unparalleled degree of artistic control over the adaptation of her works for the big screen.

Ms. Rowling’s shrewd stewardship of her works offers a useful lesson to all creators. It underlines the scope for developing new strategic partnerships with traditional industry players, as well as the huge dividends that can accrue to creators from effective and astute management of their IP rights.

SOME EXPERIENCES OF UNKNOWN CREATORS

While established creators who are, perhaps, better placed to take the risks associated with moving out of the mainstream have enjoyed some success with this model, what about as-yet unknown artists?

American singer-songwriter Frank Ocean started out as a ghostwriter for artists such as Brandy, Justin Bieber and John Legend. In 2010, however, he successfully launched his career with the critically-acclaimed mixtape Nostalgia, ULTRA. Frank Ocean self-released the mixtape free of charge, as he had become frustrated by the inactivity of his record label. After subsequently resolving his differences with his record company, the artist went on to release his debut studio album Channel Orange in July 2012.

Similarly, in the world of literature, the Internet was taken by storm with the launch of the graphic novel, Sullivan’s Sluggers, by Mark Andrew Smith and James Stokoe, on the crowd-funding platform kickstarter.com. After some experience with traditional publishers, the authors decided to go it alone in order to have full control over their work. “It was a matter of stay put and don’t rock the boat or take a risk for once and change everything,” Mark Andrew Smith said in an interview with Michael May of Comic Book Resources (http://tinyurl.com/cu29jh8). They were not wrong. While the authors initially sought to raise US$6,000 to complete their work, the response to their initiative was such that they ultimately generated some US$100,000.

Fifty Shades of Grey by E.L. James is another eye-catching case. Originally inspired by the popular Twilight series and produced as a work of fan fiction, Ms. James wrote the work, initially entitled Masters of the Universe, under the pseudonym Snowqueens Icedragon. Following comments concerning the erotic content of the novel, the author withdrew the work from Twilight’s fan fiction pages, changed the title as well as the names of the characters, and published it as an e-book trilogy entitled Fifty Shades of Grey on www.fiftyshades.com. Print versions of the work were later sold on a print-on-demand basis through The Writers’ Coffee Shop (www.thewriterscoffeeshop.com) and subsequently republished by Vintage Books in April 2012. To date, over 40 million copies (in print and electronic form) have been sold around the world. Universal Pictures and Focus Features recently announced plans to bring the first book of the trilogy to the big screen. Film rights to the work have been sold in 37 countries.

These cases demonstrate a new role for creators in the digitally-primed creative economy and underline the wide-ranging opportunities it presents for both individual creators and other industry players. Such business models will, without doubt, continue to evolve and to inspire others to redefine established business relationships and practices. However, without a clear understanding of the potential economic value of their creative works and an effective strategy to protect and manage their associated IP rights, many creator-driven ventures are unlikely to get off the ground.
In the past 10 years, Mexico’s film industry has shown signs of a return to its golden age of the 1940s and 50s, with the success both at home and abroad of its directors – Guillermo del Toro (Pan’s Labyrinth), Alejandro Gonzalez Inárritu (Babel) and Alfonso Cuáron (Harry Potter and the Prisoner of Azkaban) – and actors – Salma Hayek, Gael García Bernal (The Motorcycle Diaries, Babel) and Diego Luna (Milk). While government incentives have been crucial in fuelling this nascent revival, independent filmmakers still face a number of major challenges. In this article, independent film producer and director Roberto Girault discusses his experience in making the local hit film El Estudiante and shares his personal views on the Mexican film industry.

Three years ago, I co-produced, co-wrote with my partner Gaston Pavlovich, and directed my first film in Mexico. El Estudiante (The Student), released in 2009, became one of the most successful domestic films ever. Over a million people saw it in cinemas across Mexico, and over 4 million viewers tuned into the film’s premiere television broadcast two years later. DVD sales reached over 130,000 by the end of 2010. The film’s distributor, Quality Films, estimates an additional 300,000 units of the film would have been sold had it not been for the rampant piracy that undermines the economic sustainability of the creative industries in my country, as it does elsewhere in the world.

El Estudiante is not a thrill ride for teenagers, nor is it a big-budget action/adventure spectacular made according to an international formula; it features no special effects, has no big stars and neither exploits nor dramatizes the problems of gang violence that have beset my country. It was made with a modest budget – some US$1.5 million – made possible by the help of local private investors and a government tax incentive scheme. El Estudiante is the simple story of a quiet man in his seventies who finds the courage to fulfill his lifelong dream of becoming a student. This decision takes him on a last, bittersweet journey of self-discovery in which he himself becomes a “teacher” of the younger students in his literature and drama course. What he has to teach has nothing to do with academia but everything to do with the art of loving and giving. What they give him in return is the opportunity to witness their transformation and coming of age as human beings.
Wherever my co-writer, Gaston Pavlovich, and lead actor, Jorge Lavat, and I went with our film in Mexico, people thanked us for daring to reflect and celebrate the life-affirming qualities of Mexican culture. There is no doubt that *El Estudiante* caught the cultural mood and touched a chord in Mexico’s collective consciousness. Yet, despite its cultural impact and the economic added value it created, my film, like many Mexican film projects, came close to never being made.

**MEXICAN FILMMAKERS FACE TWO MAJOR CHALLENGES**

I want to make films in Mexico about real Mexican lives and stories, but this ambition is being made very difficult. Mexican film is beset by two major paradoxes that leave small and medium-sized creative film companies like my own in a precarious position. We struggle to earn a living from our creativity and to find adequate financing and distribution channels for the very films that are meant to express our national culture in all its richness and complexity.

**POOR MARKET ACCESS**

The first paradox lies in the cinema exhibition market. Mexico has a first-class cinema infrastructure. In 2009, with 180 million ticket sales, Mexico became the fifth largest country in the world in cinema admissions, ahead of the UK, Japan, Germany and the Russian Federation. Yet, for all its size (over 4,500 screens countrywide) and efficiency, local cinemas are largely failing independent domestic films. International blockbusters that enjoy huge promotional support and the promise of bigger audiences tend to be favored over any other films. Those Mexican films that make it to local cinema screens are often caught in a vicious spiral. Cinema chains take them out of their theatres after only a week to make way for films they deem more profitable. So begins the slow process of commercial asphyxiation. Deprived of an adequate opportunity to build up an audience through word-of-mouth, domestic films suffer from a lack of exposure.
To address this situation, the Mexican Government recently introduced a helpful “opera prima” regulation that makes it compulsory for cinema operators to keep a Mexican film by a first-time director on their screens for a minimum of two weeks. This measure, however, has had limited success in that operators have worked around the obligation by programming domestic productions during working hours or late at night when cinema attendance is at its lowest.

With El Estudiante, our distributor, Luis Calzada of Quality Films, fought hard to give the film a high-profile release. Uncharacteristically, for a Mexican film, 100 prints of the film were distributed thanks to funds from the government of Guanajuato, the province in which the film was shot. By the end of the first week, however, pressure from the cinema chains was such that the run moved into its second week with only half the initial number of prints being screened. By the end of week three, however, the power of word-of-mouth was beginning to pay off, and the film became a great success. In the end, El Estudiante beat all the odds and ran for 22 weeks – something unheard of for a domestic film in recent years.

While El Estudiante was a box office success, only a very small proportion of the local films made each year in Mexico ever make it to a cinema screen. Those that do are caught in a poverty trap resulting from low marketing expenditure, a small number of prints and short runs. Even when the films are good (and they often are), their commercial failure becomes a self-fulfilling prophecy. In 2009, the year I directed El Estudiante, only 16 of the 66 domestic films shown on the screens of Mexican cinemas reached or exceeded their forecast box office revenue.

PIRACY

The second paradox relates to film distribution and the protection of filmmakers’ rights. With such a narrow window of opportunity for films to be screened in cinemas, independent producers and directors like me and independent film distributors such as Luis Calzada are under enormous pressure to gain a foothold in other markets if our films are to be economically viable. While online film platforms are still in their infancy in Mexico, DVD sales and national broadcast television should be natural commercial outlets. Piracy, however, means most domestic films only realize a fraction of their actual value in this important market. Piracy is a scourge on filmmakers large and small. Its implications, however, are arguably all the more devastating for independent filmmakers given the economic uncertainties and constraints under which they work and their limited capacity to withstand any erosion of box office revenue.

For independent filmmakers, piracy is not just a direct hit in terms of lost box office revenue, it also means other potential sources of revenue elsewhere in the distribution value chain are undermined. If the streets are awash with illegal copies of our films when they are still struggling to attract audiences in the cinemas, their value is then diminished in other parts of the consumer market. Mexican television broadcasters are notorious for paying low licensing fees for rights to domestic films, arguing that once a film has been extensively pirated, its premiere broadcast value is seriously reduced. Piracy saps the very foundations of the independent film financing pyramid, which is fragile at the best of times.

In May 2012, I presented El Estudiante to an audience of WIPO delegates, in a showing organized by the Mexican and US Permanent Missions to the United Nations in Geneva. This was an excellent opportunity for me to draw the attention of policymakers to the importance of copyright and the exclusive rights it confers on behalf of not only Mexican filmmakers but all filmmakers and film entrepreneurs around the world.

In recent years, the Mexican Government has introduced important new incentives in the form of tax rebates, which have been crucial in supporting the domestic industry. Without doubt, these measures have stimulated local film production, making it possible for independent filmmakers to capture wide-ranging perspectives of contemporary Mexican culture in all its drama and depth. These incentives, in large part, also account for the reason Mexico now produces over 60 domestically-financed films each year. Ultimately, however, government incentives, no matter how helpful, can only go so far in building sustainable creative industries. Such incentives may help make the high-risk economic activity of film production a more attractive investment proposition but, ultimately, investors need to be sure they will get a return through the subsequent licensing of film rights in different consumer markets. Without such security, every creative industry eventually flounders and declines.

Ensuring that the creative industries, such as the independent film sector, enjoy effective copyright protection coupled with a determination to combat piracy, is key in fueling the sustained growth of the film industry. At a time when international film companies are looking for the safest and most conducive environments for making and distributing films, such an approach can strongly influence investment decisions. The long-term benefits are clear in terms of creating an operating environment that stimulates economic activity and job creation.

In the past 10 years, Mexican cinema has undergone a fragile renaissance. Directors and screenwriters such as Alfonso Cuaron, Guillermo Arriaga, Alejandro Inarritu or Guillermo del Toro have headlined major international productions, conquering the world with original and powerful works. The country’s best cinematographers are in global demand, and the competence and diligence of Mexico’s “line producers” and technicians are attracting major film projects to the country’s state-of-the-art studios and diverse shooting locations. Mexico’s cinema infrastructure is now one of the most developed in the world. These are all undeniable assets, but the Mexican film industry will remain vulnerable if the economic value of domestic films continues to be diminished by poor market access and if piracy continues to corrode the value of film rights.
In 2011, for the third consecutive year, Procter and Gamble (P&G), the world’s largest consumer products company, topped the list of applicants using WIPO’s Hague System for the International Registration of Industrial Designs with 167 international design applications.

Design plays a key role in the success of the company’s extensive product range which includes some of the world’s best known household brands, 25 of which each generate over a billion dollars in annual sales. Five years ago, P&G launched its Design Thinking initiative. WIPO Magazine recently interviewed Jean-Jacques Canonici, Director and Patent Manager, Innovation, who oversees P&G’s Patent Group in Europe, currently responsible for protecting P&G’s design portfolio, and Martha Depenbrock, Design Communications Manager at P&G, to find out more about the company’s approach to design.

What role does design play in Procter and Gamble’s business?

Design is in P&G’s DNA. Our design activities contribute to both innovation and brand building. Design involves bringing a unique perspective and particular skills to the creative thinking that can build innovative brands – brands that create emotional connections with consumers. We adopt a highly collaborative approach involving multifunctional teams from across the product development spectrum – from the front end of innovation through to the shelf.
Design helps improve the form of a product – how it looks, the function of a product – how it works, and its meaning for consumers; in sum, how the brand connects emotionally and engages with the consumer.

Designers bring many capabilities to their work, including empathy, intuition, intense observation, visualization and problem solving. These qualities help them to better understand consumers and bring brands to life.

What factors have influenced the evolution of design within P&G?

Initially, design was more of an afterthought in the product development process. All of that changed when our former CEO, A.G. Lafley, took over at P&G. He understood that technology alone is not enough to remain competitive. He believed that design adds value across the entire spectrum of a product’s development – from concept to shelf. In addition to developing packaging, identity assets and artwork, P&G’s designers work with the company’s research and development (R&D) team at the front end of innovation in conceptualizing consumer needs and creating solutions to fill those needs.

Design has also evolved to help solve tough business challenges by reframing problems, bringing together divergent thinking to find possible solutions and then prototyping and iterating in order to arrive at an optimal outcome.

Can you outline the “Design Thinking” initiative and provide examples of its success?

P&G’s Design Thinking journey began in spring 2007. Design Thinking is an interdisciplinary approach to solving “wicked” business problems. It helps develop bigger and better ideas, faster and more efficiently. This nonlinear process includes building empathy, reframing problems, and producing a series of low-resource prototypes. The company now has a global, multifunctional network of about 350 employees who volunteer to operate with a “pay it forward” mentality – coaching, facilitating and advocating for Design Thinking in P&G.

In April 2010, we organized a groundbreaking workshop on Design Thinking, to learn how to create products that would appeal to Chinese women with a US$2-a-day lifestyle. The two-day workshop generated over 250 ideas and identified six inspirational design targets via in-home interviews. Seven $2-a-day business models were created during this event.

The award-winning Olay Regenerist Night Resurfacing Elixir, Olay’s first daily night-time moisturizer, was also conceived during a Design Thinking session and developed on the basis of consumer insights.

What role do sustainability considerations have in P&G’s product design?

P&G has a long-term sustainability vision that includes using 100% renewable or recycled materials for all products and packaging. We believe that replacing nonrenewable materials with renewable ones improves the environmental sustainability of our products and enhances the security of our supply chain.

We have also established a goal of replacing 25 percent of petroleum-based materials with sustainably sourced renewable materials by 2020. A critical component of our renewable materials journey will be ensuring they are sustainably sourced. This is a fundamental part of our Life Cycle Assessment process, a disciplined, scientific approach to understanding a product’s full environmental impact across the product life cycle – from raw materials, through to manufacturing, distribution, consumer use and disposal. This approach enables us to understand where to focus our sustainability efforts and to make data-based decisions that genuinely improve the environmental profile of our products. Life cycle assessment also helps inform choices about product design, supply and logistics.

We recognize that just because a material is renewable, it is not necessarily better for the environment. We, therefore, go to great lengths to ensure that the renewable materials we use do not result in destruction of critical ecosystems, loss of habitat for endangered species or have other detrimental impacts on the environment or human communities. This includes assessing potential impacts on food availability and pricing. We work closely with the World Wildlife Fund (WWF) to understand these impacts.

“Design is in P&G’s DNA. Our design activities contribute to both innovation and brand building.”
P&G focuses on integrating sustainable product design into its core brands.

D&G’s Design Thinking is underpinned by a belief that technology alone is not enough to remain competitive. The company has adopted a highly collaborative approach to design involving multifunctional teams from across the product spectrum.
**Examples of P&G’s sustainable innovation products (SIPs):**

Pantene Nature Fusion is piloting the use of plant-based plastic in its packaging. This innovative recyclable material made from sugarcane uses over 70% less fossil fuel than traditional petroleum-based plastic. As the material looks, feels and behaves in the same way as regular plastic, there are no “trade-offs” in appearance or performance.

Gillette Fusion ProGlide uses breakthrough packaging in Western Europe comprising a new fiber material made from bamboo, sugarcane and bulrush. It has eliminated PVC from the design, and reduced the amount of plastic by 57% compared with a standard Fusion outer pack and razor tray.

Tide Coldwater and Ariel detergents require less energy and save consumers money, because there is no need to heat the water in the washing machine.

Downy Single Rinse, sold in Latin America and Asia, saves significant amounts of water. Instead of having to rinse clothes the usual three times to remove suds, consumers only have to rinse them once.

We focus on integrating sustainable product design into our core brands – bringing consumers products that meet their expectations in terms of performance and value, and that deliver an added environmental benefit. To this end, P&G is developing so-called “sustainable innovation products” (SIPs) that demonstrate a meaningful improvement in their environmental profile relative to current products, but for which there are no trade-offs.

**What experience does the company have of crowdsourcing?**

P&G’s “purpose and growth” strategy seeks to improve more lives in more parts of the world more fully — with an unrelenting focus on innovation. We often say that innovation is everyone’s job, not only in developing new products and solutions for consumers, but also in how we do our work and organize ourselves. With open innovation, we seek to partner with the best innovators everywhere, which is why “Connect + Develop” – our open innovation strategy – is at the heart of how P&G innovates. While this program tends to apply more to finding technology solutions, design does also fall within its scope. That said, P&G does have collaboration agreements with a number of design agencies around the world. P&G’s Design + Connect strategy has already resulted in more than 1,000 active agreements. Beyond that, we are constantly benchmarking, exploring and connecting with influential thinkers and other innovative companies to help us open up to new sources of inspiration and ideas.

**Why is industrial design protection important for P&G?**

Creating iconic assets is a key part of how P&G creates memorable brand experiences for consumers around the world. IP protection is essential to the company in seeking to differentiate its brands in the minds of consumers. This is also critical as counterfeiting increases. P&G is committed to delivering the highest quality products to its consumers.

**What is P&G’s strategy when it comes to protecting its designs?**

Before filing an application, the design team sits down with our IP attorneys to understand the essence of the design and to craft representations of it in order to file for design protection. The aim is to optimize the scope of protection, taking care not to include too much detail but also ensuring not to over-generalize. When it comes to international filing, we adapt our filing strategy to the requirements (e.g., dotted lines, renderings, number of views, colors) of the countries in which we seek protection.
What are the advantages of using the Hague system?

The Hague system greatly simplifies the registration process. Its main advantages are that:

- We can file one international application covering a number of countries with one IP office, significantly reducing the administrative work involved;
- The international application can feature multiple versions of a design applying to the same product and can be filed in one language with fees payable in one currency;
- It also costs less to file an international design application than it does to file separate applications with each national office.

How would you like to see the Hague system evolve?

We would like to see membership of the Hague system expand to include countries such as the US and China. This would make life easier as it would mean much broader standardization of design registration procedures.

Further development of the online filing procedure would also be useful.

What's the relationship between a product's design and its brand value?

Design adds value across the product development process by ensuring the product meets the often unarticulated needs of consumers. Design is integral to the brand. At its core, a brand encapsulates the emotional and psychological relationship we have with the consumer. Design helps manifest that relationship and ensures that everything about the brand is intentional and has meaning – from the logo, to the typeface, the colors used, the shape and the character of the brand.

Braun is an excellent example of this. Braun has linked technological performance with design to ensure simplicity, ease of use and consumer satisfaction for over 55 years.

Braun’s commitment to design is visible in both its products and its sponsorship of the Braun Prize – an international competition to promote the work of young designers and design enthusiasts.

What are the main design challenges P&G faces?

Sometimes it is difficult to break out of established paradigms. That is where design can be an asset. Designers think differently; they envision what could be and then figure out how to create that vision. Innovating is not just about new ideas; it is also about connecting something new with something familiar in a way that resonates with consumers, captures their imagination and makes them think the product will improve their life. That can be a big challenge.
INNOVATIVE LICENSING expands access to HIV treatments

By Catherine Jewell, Communications Division, WIPO
For more than two decades, the US research-based biopharmaceutical company, Gilead Sciences (Gilead), has been at the forefront of innovation in the battle against the human immunodeficiency virus (HIV). Its commitment to innovation has produced safer, more effective treatments for HIV and other life-threatening diseases. It has also significantly expanded access to more affordable HIV treatments in developing countries. Through its groundbreaking access programs, Gilead has demonstrated how creative use of intellectual property (IP) can help advance public health policy objectives. WIPO Magazine recently met with Gregg Alton, Executive Vice President for Corporate and Medical Affairs at Gilead to find out more about the programs and ongoing challenges.

THE BEGINNING

With regulatory approval of Viread® (tenofovir disoproxil fumarate), its first antiretroviral (ARV), in 2001, Gilead realized there was a desperate need for its HIV therapies in developing countries where the virus is most prevalent. Delivering these drugs to those most in need, however, proved quite a challenge. “We spent a lot of time looking at what was being done, but there was no model that made sense to us – so we had to think outside of the box,” Mr. Alton explains.

In 2003, Gilead established its global ARV access initiatives which sought to “sell ARV products at no-profit prices in developing countries.” The efforts first focused on Viread, followed by Truvada® in 2004 and covered 53 African countries and 15 least developed countries.

After various iterations, by 2006, some 30,000 patients in developing countries were receiving Gilead’s ARV products. Eager to enhance its impact, Gilead undertook a further restructuring exercise in 2006 which proved pivotal. Today, using this same model, Gilead delivers HIV treatment to some 2.9 million people in over 130 developing countries.

KEY LESSONS

Recognizing the importance of a local presence, Gilead began establishing partnerships with regional distributors to leverage their knowledge of how things worked in target countries – to register drugs, handle supply chain logistics, undertake pharmacovigilance and medical education activities. This enabled them to avoid the cost and complexity of establishing separate operations in each country. By 2010, Gilead had established partnerships with 11 local distributors and was servicing 130 countries. Gilead sells its branded products to these local business partners at cost and allows them a 15 percent mark-up.

The 2006 restructuring exercise also introduced licensing agreements with Indian generic drug manufacturers. Their proven ability to consistently produce high volumes of quality drugs at low cost made them an ideal partner, complementing Gilead’s strengths in innovative research and development. “We essentially offer licenses to any company in India that wants to manufacture our products. We provide our licensees with the know-how to produce our drugs, and they can sell them at a price they determine in over 100 countries around the world,” Mr. Alton explains. Royalties received by Gilead are then used to support product registration, medical education and training, safety reporting and the range of activities undertaken by Gilead’s local partners in developing countries.

Gilead’s access initiatives created competition in the market for generic versions of its products and, in boosting generic manufacturing capacity, ensured there was
an adequate and cost-effective supply of ARV drugs. “The beauty of the access model is that true business competition creates innovation in the supply chain. Our partners compete with Gilead and with each other. Everyone is incentivized to continue to make advances in manufacturing to drive sales. For global health funds, those efficiency innovations lower prices, and that means more patients receive treatment.”

“In 2003, the best we could do was US$39 per month for Viread. Today, because of the dramatic improvements in manufacturing efficiency led by our partners in India, we can treat patients with generic versions of Viread for US$4.49 per month,” Mr. Alton explains.

The access programs have also achieved financial sustainability. “In 2006 we were reaching 30,000 patients and losing US$20 million a year. We made some fundamental changes and today the program is absolutely financially viable,” Mr. Alton notes.

EXPANDING ACCESS FURTHER

“Our expectation is to continue down this path because it seems to be successful,” Mr. Alton says. “However, we continue to evaluate what works and to adapt and hopefully, in the future, will make not only HIV drugs widely available but other much-needed medicines, using creative approaches.” Gilead is also working on innovative treatments for hepatitis C, a curable disease affecting some 160 million people, many of whom live in developing countries.

Gilead is seeking to deliver its recently approved HIV treatment, Stribild®, to developing country patients within 12 months – an unprecedented feat. In the 1990s the time lag between when a drug became available to patients in developed countries and when it reached developing country patients was around 15 years. Today the average is 2 years.

THE ROLE OF IP

Predictable and enforceable IP protection has played a central role in the development of Gilead’s medicines. Mr. Alton explains, “We spend years researching and developing these products. Our patents drive our innovation. When there is no medicine and our scientists are spending years in trial and error to develop essential new therapies, our investors invest because they believe we will receive a patent for our invention, and that patent will deliver a return on that investment. Nobody would give us the capital required for research if they thought we could not protect our investment.”

“There is a view that IP allows a company to have exclusivity and raise prices in the developing world,” Mr. Alton continues. “It does. But you don’t have to do that, and I think we’ve proven that IP allows us to meet the needs of the developing world as well. Without the functioning system of intellectual property law that governs our licensing deals, we would not be able to safely transfer our technology to partners. These partnerships are the foundation of Gilead’s access efforts, and they are built entirely on the strength of US, Indian and international intellectual property law.”
In 2011, Gilead became the first pharmaceutical company to join the Medicines Patent Pool (MPP). Mr. Alton is hopeful this will help “narrow polarizing views on IP and access. We all share the same goal: we want to treat patients. So let’s figure out how we can do that better. The MPP is an exciting idea. MPP and Gilead’s access programs demonstrate that IP and access can not only coexist, but that IP can actually empower access. Without our partnerships, we would still be selling at $39 per month and reaching few patients. Because of a more creative use of IP in global markets, we drove down the cost of manufacturing by more than 75 percent. So we can now treat more patients, and that’s our goal.”

CHALLENGES

While adequate international funding to purchase HIV medicines is a persistent concern, Gilead faces a number of IP-specific challenges. Principal among these is the uneven global environment for patents. Take, for instance, the variable treatment of incremental innovation within national patent law. “There are a lot of people that believe innovation has to result in a brand new chemical entity with a whole new structure, as opposed to innovation in advancing and improving on existing structures. This belief is inconsistent with how science develops, in particular with respect to pharmaceuticals. I think it is very dangerous to say that incremental innovation does not qualify for IP protection when such improvements may in fact be what would benefit humans more than a whole new chemical structure or a whole new class of drugs. Again, the goal is to efficiently drive investment to what we actually need. Redirecting capital to chase new chemical entities just for the sake of chasing new entities wastes precious resources that can otherwise deliver more innovation for patients,” Mr. Alton notes, referring to the company’s experiences in relation to tenofovir.

Expanding Global HIV Treatment

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Gilead’s innovative use of IP in its access programs has driven down the price of ARV drugs and expanded the number of patients treated.
Tenofovir disoproxil fumarate is a prodrug of tenofovir in that it improves its bioavailability or uptake by the body. “The problem with tenofovir is that you can’t administer it orally because it won’t go through the gut. It has to be injected, and injectables are off the table in HIV. By prodrugging tenofovir with disoproxil fumarate you can take it as a pill and, because it targets the lymphatic system more directly, it is significantly more potent than tenofovir. We actually overcame a lot of scientific hurdles to develop it,” he observes, “and in doing so we delivered a therapy, Viread, that has literally saved millions of lives. Would it have been a better outcome to signal to capital markets that nobody should invest in improving tenofovir? Unfortunately, when a patent office declares a blanket policy that so-called ‘incremental innovation’ is not patentable, that’s exactly the signal they are sending.”

Another challenge facing Gilead is the reality of transparent and tiered pricing. Similar to a progressive tax code – where wealthier citizens pay a higher percentage of income in taxes than the middle class, and the middle class pays a higher rate than the poor – some wealthy countries try to claim poverty to qualify for lower rates. “All countries want the lowest possible price, but we have to agree that there is a difference in what China or Brazil should pay and what Haiti or Lesotho should pay.”

Ensuring the access programs remain a financially viable proposition for its licensing partners is a priority for Gilead. “If profit margins are squeezed too much, Indian generic companies will start to lose interest, as was the case in producing generic versions of the antifungal, amphotericin B,” Mr. Alton observes. Gilead is looking for new ways to incentivize its generic partners by, for example, adding selected semi-exclusive markets – where generic competition is less fierce – to its licensing agreements with them. This offers them a chance to discount Gilead’s access price and “make a little more money,” Mr. Alton explains. “Our hope is that this will give our Indian partners the viability they want, but it’s still experimental.” Longer-term contracting of drugs by countries would also help address this problem by enabling generic companies to fine-tune production schedules.

FUTURE OBJECTIVES

While much has been achieved, changing the course of HIV infection still remains a daunting challenge. Mr. Alton is clear that “a lot still needs to be done.” Current treatment guidelines, he explains, significantly underestimate the number of HIV treatment-eligible people in the developing world. While there are limits to how far the cost of Gilead’s generic treatments can fall, there is scope for optimism as safer, more effective and better tolerated drugs come on stream, such as Gilead’s new prodrug of tenofovir – 7340 – which could further reduce prices.

Greater emphasis on early treatment is also needed, he notes, to stem HIV infection rates in light of the recent understanding that when the viral load of HIV patients is undetectable “it becomes incredibly difficult, if not impossible, to transmit the virus.” Treating patients to prevent further infection is essential “if we want to change the course of HIV.” A medically-driven and more open discussion about how much money is being spent in the developing world on HIV and whether it is being spent in the right way is another “must” going forward, Mr. Alton notes.

While Gilead’s access initiatives “are not perfect,” and continue to evolve, they are without doubt “a step in the right direction,” Mr. Alton hopes that “as people see it is not hurting the commercial side of our business, we will see more companies following suit.” The good news is that, in addition to expanding access to affordable HIV treatments, Gilead’s innovative access programs are already encouraging other companies and entities such as the MPP to adopt similar approaches.
US COURTS grapple with patent-eligible subject matter

By Susie S. Cheng, Ph.D., J.D., partner at Leason Ellis LLP-Intellectual Property Attorneys, USA.
Over the past few years, patent-eligible subject matter has become one of the most closely watched areas of patent law in the United States. On March 20, 2012, the US Supreme Court issued its decision in Mayo v. Prometheus, 132 S. Ct. 1289 (2012) (“Mayo”), holding that process claims broadly directed to a natural bodily response to a drug are not patent-eligible under 35 U.S.C. §101. Mayo not only pronounced the Supreme Court’s guidance for patenting pharmaceutical process inventions, it also raised questions with regard to patent preemption. Shortly after Mayo, the Supreme Court remanded Association for Molecular Pathology v. U.S. Patent and Trademark Office (“Myriad”), on whether isolated DNA molecules are patentable subject matter, to the United States Court of Appeals for the Federal Circuit (“Federal Circuit”). The Federal Circuit’s recent decision in Myriad thus sheds some light on how Mayo is judicially interpreted and applied.

35 U.S.C. §101 broadly defines patent-eligible subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” The US courts have long recognized three judicially-created exceptions for patent-eligible subject matter, namely “laws of nature, natural phenomena, and abstract ideas” as in, for example, Diamond v. Diehr, 450 U.S. 175, 185 (1981). The development of personalized medicine and therapeutic innovation, however, has renewed interest in understanding which pharmaceutical and biotechnology inventions are patent-eligible.

THE MAYO DECISION

The patent claims at issue in Mayo are directed to a method for optimizing therapeutic efficacy for treating a disorder by administering a drug to a patient and monitoring the patient’s metabolites to determine the best drug dosage. The method can be summarized in three steps: (a) administering a drug to a subject, (b) determining the levels of the drug’s metabolites in the subject’s red blood cells, and (c) comparing the measured metabolite levels to predetermined metabolite levels, to either increase or decrease the drug dosage in order to minimize toxicity and maximize treatment efficiency. See Mayo, 132 S. Ct. at 1295-96.

The Supreme Court first identified that the patent claims set forth laws of nature, namely, the correlations between metabolite levels and likely harm or ineffectiveness of a dosage (Id. at 1296). The Court then concluded that the claimed three steps, alone or in combination, were insufficient to transform unpatentable natural correlations into a patentable process (Id. at 1297-98). Specifically, the three steps are “well-understood, routine, conventional activity previously engaged in by researchers in the field” (Id. at 1298). Because the claimed processes lack any “additional features that provide practical assurance”, the claims are a “genuine application of laws of nature” (Id.). In fact, the Mayo Court has invoked the patentability sections of the Patent Act, namely novelty (§102) and inventiveness (§103), in determining whether the claimed subject matter satisfies the patent-eligibility requirement in §101. In other words, the Court’s analysis of whether the subject matter is patent-eligible hinges on whether the additional steps are novel and inventive – meaning whether they are patentable.

Relying on the precedents – Diamond v. Diehr, 450 U.S. 175 (1981) and Parker v. Flook, 437 U.S. 854 (1978) – the Court stated that the patent claims presented in the Mayo case are weaker than Diehr’s patent-eligible claim, where the additional steps of the process integrated the equation into the process as a whole (Id. at 1299). The Court also determined that the patent claims are no stronger than Flook’s unpatentable claim, which adds nothing specific to the laws of nature (Id. at 1299). Notably, all scientific inventions are based on and utilize some laws of nature and natural phenomena. The Mayo Court stated that abstract and broad claims would preempt or tie up “the basic tools of science and technological work” (Id. at 1301). According to the Court’s policy argument, if the patent claims were upheld, it would threaten the development of more refined treatment recommendations that combine the underlying correlations with later discoveries (Id. at 1302).

FEDERAL CIRCUIT’S RESPONSE TO MAYO IN MYRIAD GENE PATENT CASE

Perhaps equally as important as the Supreme Court’s opinion in Mayo is its impact on subsequent cases and how the Federal Circuit interprets and applies the Mayo decision. In Myriad, the Supreme Court had granted certiorari (legal review), but vacated the judgment and remanded the case to the Federal Circuit for further consideration in light of Mayo.

At the outset in Myriad, the Federal Circuit devoted several paragraphs to stating what the appeal was not about. By doing so, many policy arguments raised in Mayo were circumvented. Most important, the Federal Circuit said that the appeal was not about whether the claims at issue were novel under 35 U.S.C. §102, non-obvious under 35 U.S.C. §103 or that the patent disclosure was adequate in supporting particular claims under 35 U.S.C. §112. The Federal Circuit plainly stated that the issue was patent-eligibility, not patentability. This approach clearly separates, as it should, patent-eligibility from patentability.

The Federal Circuit, in its remedial ruling, frames the question as to whether: (1) the composition of matter claims in relation to the isolated BRCA DNA molecule (BRCA1 and BRCA2 are breast cancer susceptibility genes type 1 and type 2, respectively); (2) the method claims for analyzing and comparing DNA sequences; and (3) the process claims for screening potential cancer therapeutics involving growing a transformed host cell, constitute patent-eligible subject matter under 35 U.S.C. §101. Distinguishing this from the Mayo case, the Court held that both the composition and process claims are patent-eligible. The Court, however, found that the method claims are not patent-eligible.
With regard to the composition of matter claims drawn to isolated DNA molecules, two points are notable from the Myriad decision. First, the Mayo decision applies to cases involving method claims. As the claims reviewed by the Supreme Court in Mayo are not directed to composition of matter, Mayo does not create a controlling precedent. Instead, the Supreme Court’s decisions in Diamond v. Chakrabarty 447 U.S. 303 (1979) and Funk Brothers Seed Co. v. Kalo Inoculant Co. 333 U.S. 127 (1948) are controlling precedents that set out the primary framework for determining the patent-eligibility of compositions of matter, including isolated DNA molecules. The Federal Circuit stated that isolated DNA molecules are not found in nature, but are obtained in the laboratory, are man-made and the product of human ingenuity. While the Federal Circuit recognized that isolated DNA molecules are prepared from products of nature, the same is true of every other “composition of matter”; they are nevertheless different from natural materials. The Federal Circuit thus reiterated that it is the activity of reducing a portion of nature to concrete form that the patent laws seek to encourage and protect.

Second, the Federal Circuit sets forth its arguments in response to the preemption concern raised in Mayo, namely that permitting patents on a particular subject matter would prevent use by others of a law of nature. The Federal Circuit took the view that permitting patents on isolated genes does not preempt a law of nature, since a composition of matter is not a law of nature. The Court further recognized that “a limited preemption is inherent in every patent: the right to exclude for a limited period of time.” In addition, the Federal Circuit dismissed the preemption concerns in the context of scientific research. According to the Federal Circuit, “patents are rarely enforced against scientific research, even during their terms.”

Turning to Myriad’s method claims for analyzing and comparing certain DNA sequences, the Federal Circuit reaffirmed its prior ruling that such diagnostic methods claim natural laws and are not eligible for a patent. The Federal Circuit reasoned that these method claims merely recite the mental steps of comparing two DNA sequences, which is the entire process claimed. As such, it is indistinguishable from the claim reciting a diagnostic method in Mayo, and is thus patent-ineligible.

Finally, the Federal Circuit ruled that a method claim for screening potential cancer therapeutics via changes in cell growth rates of transformed cells is patent-eligible. Since the cells are man-made and not naturally occurring, the claim thus includes more than the abstract mental step of looking at two numbers and “comparing” two host cells’ growth rates. As such, it does not simply apply a law of nature. In other words, the transformed, man-made nature of the underlying cells in this type of claim makes it patent-eligible.

The Federal Circuit has therefore not expanded the scope of the Supreme Court’s standard for patent-eligibility for the moment. However, it is expected that the legal standards for patent-eligibility in the pharmaceutical and biotechnology fields will continue to evolve. Patent practitioners and legal scholars eagerly await further developments in this area of patent law.
Disposing of counterfeit goods: UNSEEN CHALLENGES

By Judith Soentgen, Building Respect for Intellectual Property Division, WIPO

The escalation of counterfeiting and piracy and the increasing effectiveness of customs authorities in detecting and confiscating intellectual property (IP) infringing products are creating added logistical and environmental dimensions to the multiple challenges associated with combating counterfeiting and piracy. In 2011, customs authorities in the European Union (EU) alone, seized some 115 million items (a 15 percent increase on goods seized in 2010) ranging from sunglasses, bags, and shoes, to medicines, electronic devices, batteries, refrigerants and pesticides. Over 75 percent of these goods were destroyed.

There is increasing recognition of the need to dispose of these goods in a safe and environmentally-sensitive way. This can be a costly and technically complex undertaking. Minimizing the environmental impact of disposal requires specialized facilities, expertise and high levels of stakeholder collaboration. This article considers some of the more innovative and cost-effective solutions being adopted to tackle this complex problem.
DImenSIonS of THe CHALLenGe

One of the key objectives in disposing of seized goods is to ensure they are removed from all channels of commerce. While originally conceived as a means to protect private IP rights, increasingly, concerns about the social and environmental impact of these goods are coming to the fore. “Safe, secure disposal and storage of these goods is critical to ensure the environmental risks are mitigated and that harmful goods are disposed of in a manner that prevents diversion,” observes David Blakemore, of the IP Rights (IPR) Business Partnership, a forum for public-private sector debate on issues relating to combating IP infringements. Achieving this objective is an increasingly costly and technically complex undertaking.

THe InTernATIonAL LeGAL frAmeWorK

Minimum international requirements for the disposal of IP-infringing goods are outlined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), administered by the World Trade Organization (WTO). Article 46 of the Agreement states that IP-infringing goods should be “disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed.” It further states that “the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.”

Current disposal options include recycling, open air burning, shredding, crushing, burying in landfill sites and donation to charities. The methods adopted, however, depend on the nature of the goods requiring disposal as well as the availability of appropriate disposal facilities.

reCyCLInG

While not all IP-infringing goods are readily recyclable – especially those containing toxic substances – some goods can be dismantled and reused.

The European anti-counterfeiting network, REACT, a non-profit, right holders’ organization, for example, recycles some 95 percent of all counterfeit goods seized in the Netherlands. REACT offers its 185 plus member companies a practical and cost-effective solution for the disposal of counterfeit goods. Together with the national mental health authority, it co-owns a recycling facility in the Netherlands where goods are sorted, dismantled and processed for recycling.

Once the necessary legal processes have been finalized and Dutch customs approve the destruction of seized goods, REACT transports them to its recycling facility where they are sorted, dismantled and/or shredded. The remaining materials – such as polycarbonate granules derived from shredding pirated DVD/CDs – are sold on to specialist recycling outfits and used to produce a range of goods such as furniture, clothing, shopping bags or even construction materials for sports facilities and playgrounds.

This approach offers multiple advantages. “The facility offers a valuable means of mitigating negative environmental consequences while complying with the necessary requirement to ensure that the counterfeit products do not enter the channels of commerce,” notes REACT director Ronald Brohm. It also offers employment to a large number of socially disadvantaged people and supports their reintegration into society. “Such an outcome requires close coordination and cooperation between Dutch customs, member companies and social agencies”, Mr. Brohm observes, noting that “React will be looking elsewhere for similar opportunities to replicate the success that we and our partners have achieved in the Netherlands.”

DONATIONS

Another imaginative and environmentally benign method of disposal involves the donation of IP-infringing goods to social welfare bodies. After consultation with right holders, customs authorities in China, the Philippines and the UK frequently supply charities with IP-infringing goods. In the UK, for example, infringing clothing and footwear collected by the registered charity, “His Church”, are de-branded, altered, re-marked with the charity’s “HIS” brand and used for humanitarian purposes.

— Breakdown of results by cases

Breakdown of results by cases handled by European Customs:

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According to the Report on EU Customs Enforcement of Intellectual Property Rights, in 2011, over 77 percent of IP-infringing goods confiscated by European customs authorities were destroyed. The bulk (97%) of products confiscated were suspected of infringing a European Community or national trademark (http://tinyurl.com/d2vqk4).
This approach, however, is feasible only when steps are taken to ensure the goods involved are not sub-standard, defective, dangerous or hazardous. Only after rigorous testing to ensure compliance with health and safety standards, are infringing goods donated to social welfare organizations.

Steps also need to be taken, in line with the TRIPS Agreement, to safeguard the rights of IP owners, particularly in terms of avoiding any harm to their reputation, and preventing the return of IP-infringing goods to the marketplace. It is not enough simply to remove a trademark that has been unlawfully affixed to a product. A variety of creative solutions are being adopted around the world. In the Republic of Korea, for example, customs authorities invited volunteers to alter counterfeit sneakers by decorating them with drawings. The redesigned shoes were then donated to orphanages.

**REGULATED INCINERATION AND LANDFILL**

Controlled incineration or use of officially registered landfill sites are other common methods of disposal. High-profile public ceremonies to destroy infringing goods are helpful in shaping public opinion and building respect for IP. The Thai authorities, for example, regularly organize destruction ceremonies. At a recent event in Phuket some 80,000 items with a street value of over 182 million baht (US$5.9 million) were destroyed, attracting widespread public and media attention. These methods, however, require careful management and adherence to environmental standards.

**WIPO’s Advisory Committee on Enforcement**

Established by WIPO member states in 2002, the mandate of the Advisory Committee on Enforcement (ACE) focuses on technical assistance and coordination with relevant stakeholders to improve capacity to combat counterfeiting and piracy. It does not have a mandate to set norms. The Committee also promotes information exchange and public education activities to build respect for IP.

The ACE approaches IP enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that “the protection and enforcement of IP rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”, in accordance with Article 7 of the TRIPS Agreement, as outlined in the WIPO Development Agenda (Recommendation 45).
HAZARDOUS WASTE

Mitigating the environmental impact of the disposal of counterfeit goods containing toxic elements poses particular challenges. The composition of certain counterfeit electronic devices is often not known, making it very difficult to determine the best means of disposal. Similarly, the disposal of counterfeit chemicals and pesticides that present serious environmental and health risks, can be costly and technically complex. While high temperature incineration is common for disposing of these toxic substances, this can generate air pollution and hazardous waste. Moreover, many countries do not have the necessary infrastructure or technical know-how to dispose of these substances safely.

While transporting hazardous IP-infringing goods to countries with appropriate disposal facilities might seem an obvious solution, this can be impeded or even prevented by national or regional legislation. Transporting these goods across borders requires compliance with multi-lateral environmental agreements, such as the Montreal Protocol on Substances that Deplete the Ozone Layer and the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, as well as compliance with customs regulations.

In this respect, awareness-raising among policy makers is essential in creating an enabling legal and regulatory environment to open the way for greater cooperation between countries. Policymakers in Europe, for example, have submitted proposals to allow for the movement of goods destined for destruction between different countries within the customs territory of the EU under the supervision of customs authorities. These have yet to be adopted.

The technical difficulties associated with the environmentally-sound disposal of infringing goods containing harmful substances and hazardous waste, underline the importance of strengthening national legal frameworks on waste management and developing efficient and timely legal processes for the safe and efficient disposal of IP-infringing goods. They also agreed that awareness-raising among policymakers, the general public and right holders was an essential part of policy development in this area.

As the disposal landscape continues to evolve, the long-term objective when disposing of IP-infringing goods is to:

- reduce the production and demand for infringing goods through more expansive and effective public education and awareness campaigns;
- reuse all IP-infringing goods that are certified as safe to donate; and
- recycle everything else.

The environmentally-sound disposal of confiscated IP-infringing goods is becoming a priority for many countries. Tackling this complex challenge in a timely and efficient manner will go a long way in minimizing the costs and potential environmental harm associated with bottlenecks in the storage and disposal of IP-infringing goods.

THE WAY FORWARD

Amid growing interest in finding efficient, cost-effective and environmentally friendly methods of disposal, WIPO is working with its international partners, including the United Nations Environment Programme (UNEP), and its member states to promote a clearer understanding of the dimensions of the challenge. In July 2012, in cooperation the Government of Thailand and UNEP, WIPO organized a Regional Workshop on the Disposal of Counterfeit Goods for the Judiciary, Law Enforcement Officials and Environmental Officers. “The Workshop was an eye-opener and was extremely helpful in enabling me to grasp the serious impact that counterfeit and IP-infringing goods in general can have on the environment” observed Mr. Tohpong Smiti of the Department of Intellectual Property, Thailand.

The event brought together officials from Cambodia, Malaysia, the Philippines, Thailand and Viet Nam and was an important first step in fostering greater regional cooperation and in developing a consistent approach to and guidance in tackling this complex issue.

In the face of the daunting logistical challenges associated with the environmentally-sound disposal of counterfeit goods, participants underlined the importance of strengthening national legal frameworks on waste management and developing efficient and timely processes for the safe and efficient disposal of IP-infringing goods. They also agreed that awareness-raising among policymakers, the general public and right holders was an essential part of policy development in this area.

The growing trade in IPR-infringing products now so significantly increases the risk that we must collectively innovate to protect the global environment and our fellow citizens,” observes David Blakemore. “The public and private sector must examine their existing communication, collaboration and information sharing protocols to determine if they are adequate at both the national and international level. This will provide us with the best chance to ensure that these type[s] of products are detected with certainty in global trade,” he adds.
Mitigating the environmental impact of the disposal of counterfeit goods containing toxic elements can be costly and technically complex.
COLLABORATION in intellectual property: An Overview


Over the past two decades there has been an explosion in the number of patent awards across a wide variety of technologies, and a dramatic increase in the volume of patent litigation between rivals. Numerous commentators have suggested that this proliferation of patent rights has socially detrimental consequences insofar as multiple, overlapping intellectual property (IP) rights create “patent thickets” which make it expensive for manufacturers to commercialize innovative products and difficult for inventors to extend the frontiers of technology. Knowledge-sharing organizations, such as patent pools, alliances and standard-setting organizations – where owners of IP share patent rights with each other and third parties – have been proposed as a way for firms to work around the problem of patent thickets. This article explores the merits of knowledge-sharing organizations, and outlines a number of policy considerations that may serve to eliminate some of the tensions that can arise from such IP-focused collaborations.

Evidence suggests that companies are recognizing the benefits of participating in IP collaborations. In 2001, for example, sales of devices based in whole or in part on pooled patents were estimated to be at least US$100 billion. While the information and communication technologies (ICT) industry, broadly defined, has accounted for the majority of patent pools over the last 20 years, there are indications of more widespread interest in such arrangements. The biomedical research community, for example, has expressed a keen interest in the development of patent pools for biomarkers for cancer, HIV/AIDS and severe acute respiratory syndrome (SARS), as well as for biotechnologies applied to agriculture and animal cloning.

We may well be returning to the days of the early 20th century when many (if not most) important manufacturing industries had a patent pooling arrangement. At that time an extremely laissez-faire approach prevailed, as reflected in the 1902 US Supreme Court ruling in Bement v. National Harrow Co. (186 U.S. 70), which stated that “the general rule is absolute freedom in the use or sale of rights under the patent laws of the United States.”

The more stringent regulatory environment of the mid-20th century, which viewed patent pools with outright hostility, has, however, given way to a more favorable stance in recent years. Although patent pools are no longer frowned upon by competition authorities as collusive agreements among potential competitors, they continue to raise a number of concerns. These need to be addressed if patent pools and similar arrangements are to continue to be adopted by the business community and viewed favorably by regulators as an effective means of promoting technological innovation.
The ICT industry dominates the recent wave of patent pools

Number of patent pools by industry

Source: Updated from Lerner et al. (2007).
Note: Based on information for 75 documented pools.

Aligned objectives and conflicts of interest in R&D alliances

<table>
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<tr>
<th>Balanced objectives</th>
<th>Conflicts of interest</th>
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| **Among producers of technologies** | • Sharing experiences  
• Spreading costs  
• Spreading development risk  
• Coordinating the production of complementary products  
| • Free riding  
• Risk shifting and moral hazard  
• Holdup risk |
| **Between technology producers and consumers** | • Cost reduction  
• Ensuring compatibility among products  
| • Higher prices/less variety due to market power  
• Possible collusion to slow introduction of new technologies |
ADVANTAGES OF COLLABORATION

Patent pools present compelling reasons for firms to cooperate as they can offer attractive “complementaries”. For example, it may be far more efficient for multiple firms – each working to its own strengths – to work together to produce a complex technology. This has been particularly true within the ICT industry, where many different firms develop complementary and interoperable technologies. Take, for example, the respective roles of Dell, Intel and Microsoft in the sphere of personal computing, or Apple and its iPhone application developers. Collaborating with developers of such technologies can help coordinate investment schedules and promote interoperability in new product releases.

More generally, acquiring the foundational knowledge needed to produce cutting-edge technologies is a costly affair. Taking advantage of the experience of others can be much cheaper than gaining such experience firsthand. Collaborating with another firm can be a way to leverage its experience without locking in to a commitment to build up the required knowledge internally. This is a particularly useful option when exploring new markets, geographies or technologies.

Teaming up to divide effort can also provide efficiency gains where two firms want to explore the same area of technology. Cost sharing is frequently cited as an important reason for joining forces. Investments in research and development (R&D) – the cost of labs, instrumentation, testing equipment and technical specialists – can be substantial. In some industries, such as those producing semiconductors or telecommunications equipment, the cost of a single R&D project can be beyond the reach of most companies. In more typical smaller-scale R&D operations, effective facilities not only require lab equipment but also ancillary services such as administrative support, staff to maintain specialized equipment or hazardous materials and testing technicians. Collaborating with a player that has similar needs helps spread these costs. It also allows firms to share development risks and undertake projects that might otherwise be considered too risky.

These collaborations can lead to complex strategic games. Joint development of complementary assets can provide mutual benefits, but partners may also shape technological development in a way that locks in their technologies to the exclusion of other players. Strategic maneuvers to embed switching costs (i.e., the cost to the consumer of switching to an alternative technology) also represent a loss in social welfare, since consumers may be offered an inferior technology.

Monitoring a business partner’s behavior can be difficult if not impossible. The recent lawsuits between Apple and Samsung, a key supplier of Apple’s processor chips (the two companies have also reportedly collaborated on other products) provide a cautionary tale about the pitfalls of contractual joint collaborations and the disputes that can arise between market rivals operating within a complex strategic context.

A THOUGHT FOR POLICYMAKERS

IP rights affect collaboration and competition in a complex way. The wealth of recent studies on this subject seems to generate more questions than answers. What is clear, however, is that the circumstances surrounding individual collaborative arrangements can have a dramatic effect on whether they have a positive or negative impact on the collective welfare.

The clear-cut lessons that have emerged from research and experience, though few in number, can, nevertheless, help policymakers map the major dynamics at work. While the devil is often in the details, there are a number of areas on which policymakers can focus their attention.

MANDATORY INDEPENDENT LICENSING

One of the key lessons drawn from the economics literature is the importance of requiring patent pools to engage in independent licensing. Such an obligation makes it possible for any pool member to license its patent outside the pool.

The option to license patents independently outside the pool or alliance can work in the public interest in four ways:

- It puts a ceiling on the fees that the pool can charge, insofar as the cooperation inherent in a pool avoids royalty stacking – the separate payment of royalties on each patented technological component – which can result in consumers paying higher prices.

- Patents may have alternative uses outside the patent pool. Independent licensing encourages alternative applications of multiuse patented technologies rather than restricting them to pool-related licensing.

- Independent licensing reduces incentives for “socially wasteful” inventive efforts. Consider, for example, the following scenario: Inventor A is a member of a patent
Independent licensing can serve as a screening device for policymakers to separate anticompetitive pools with duplicative patents from beneficial pools comprising complementary patents. In anticompetitive pools that do not include provisions for independent licensing, the freedom of members to license their technology independently would break the pool’s ability to fix prices above the competitive rate. Such provisions, however, do not negatively impact pools comprising complementary patents since external licensing of any component is either not valuable without the remaining complements or occurs in a market that does not compete with the pool.

Mandatory independent licensing provisions may prove to be valuable in allowing regulators to “select out” harmful pools before they come into existence. In a more limited application, the absence of such terms can alert regulators to collaborations that may harbor anticompetitive motivations.

**ADVANTAGEOUS POLICY OPTIONS**

Rather than focusing solely on regulating harmful, anticompetitive alliances, there is much to be gained from actively encouraging socially beneficial collaborations. There are instances in which regulatory authorities treat publicly-spirited IP collaborations favorably – in France, for example. Similarly, in Germany and the UK patent renewal fees may be reduced in exchange for making patents available for licensing.

Beyond these measures, regulatory agencies could consider granting temporary safe-harbor status to firms that wish to explore the feasibility of collaborating. It is difficult to estimate the number of potentially fruitful collaborations that go unexplored because of the fear of a negative regulatory reaction. Creating conditions in which potential partners can discuss terms more openly may promote increased collaborative activity.

Historically, US regulators have taken (and continue to take) a strong stance against any discussion of pricing among standard-setting organizations. This unequivocal prohibition makes any discussion of price per se illegal. This, in turn, makes it difficult for potential collaborators to assess the viability of partnering. A great deal of time is wasted in avoiding discussion of the topic directly, even though all collaborators will ultimately have to agree on the matter in order to form a pool.

Although regulators’ preference for clear rules is understandable, finding ways to provide firms with a safe harbor to explore the merits of collaborating may encourage more beneficial alliances without dismantling the rules for prosecuting harmful ones. In particular, allowing firms greater flexibility to commit to caps (not floors) on patent royalty rates as part of the standardization process could prove highly beneficial.

**FURTHER RESEARCH NEEDED**

A number of additional questions in relation to standards need further scrutiny. The link between standards and patent pools arises from the fact that many standards are based on complementary technologies often developed by different firms. As suggested in *Standards and Public Policy* by Greenstein and Stang (2007), key questions include:

- Under which circumstances should governments consider intervening in market processes for selecting standards?
- How well do non-market mechanisms perform?
- What trade-offs do policymakers face when choosing standards or shaping the legal restrictions faced by participants in standard bodies?

Further enquiry into IP collaborations more generally is also warranted. We need to ask, for example, whether joint R&D efforts are underutilized? Are there social benefits in encouraging their use, or are institutions such as universities more effective intermediaries for diffusing knowledge? We also need to ask how specific institutional structures and decision-making rules affect the speed and quality of standard-setting groups as well as how ongoing patent reform in the US and Europe will affect incentives to share IP and the effectiveness of these collaborations.

IP collaborations represent both a regulatory challenge and a fertile area for research. Improved understanding of the economic forces at work will provide better guidance to those seeking to balance competition and cooperation in the quest for innovation. Further investigation of specific institutions, their roles and their decision-making processes will be critical to advancing our understanding of the questions raised here.