



IPO COMMITTEE NEWSLETTER

December 2011

Written by Members of the IPO Patent Law and Practice (International) Committee

Chair: Larry Welch, Eli Lilly
Vice Chair: Samson Helfgott, Katten Muchin Rosenman LLP
Board Liaison: Daniel J. Staudt, Siemens

With contributions from the European Practice Committee

Chair: Filip DeCorte, Cargill
Vice Chair: Jean-Jacques Canonici, Procter & Gamble
Vice Chair: Hans Prins, Bird & Bird

and from the Asian Practice Committee

Chair: Edward Blocker, Koninklijke Philips Electronics
Vice Chair: Eugene Chang, Willkie Farr & Gallagher, LLP
Vice Chair: Kevin Luo, Microsoft Corp.
Vice Chair: Christopher E. Chalsen, Milbank, Tweed, Hadley & McCloy, LLP

CONTENTS

Experience with Compulsory Licensing of Patents in Japan

Matthew P. Fitzpatrick, Procter & Gamble, United States

Europe's Registered Community Design Right. Early Learnings From Apple vs. Samsung

Jean-Jacques Canonici, N.V. Procter & Gamble Services Company, S.A.

Star Wars Stormtrooper Helmets Not Copyrightable Under British Law, But Infringement Of U.S. Copyright is Justiciable

John Richards, Ladas & Parry LLP, New York, NY

European Court of Justice Decision on Patentability of Stem Cell Related Inventions

John Richards, Ladas & Parry LLP, New York, NY

Federal Circuit Rules That Isolated DNA Sequences Represent Patent-Eligible Subject Matter

Robert Smyth, Morgan, Lewis & Bockius, LLP, Washington, D.C.

Disclosure of Prior Art: Duty Free in the Canadian Patent Office?

Falon Leach, Bereskin & Parr, LLP, Toronto, Ontario, Canada

Innovation Patents in Australia

Michael J. Houlihan, Houlihan², Victoria, Australia

The Canadian Patent Promise: A Concern for Pharmaceutical Innovators?

Arvie Anderson and Lawrence Welch, Eli Lilly and Company

This paper was created by the authors for the Intellectual Property Owners Association all of whom are members of the Patent Law and Practice (International) Committee, with contributions by the European and Asian Practice Committees, to provide background to IPO members. It should not be construed as providing legal advice or as representing the views of IPO.

EXPERIENCE WITH COMPULSORY LICENSING OF PATENTS IN JAPAN

Matthew P. Fitzpatrick
Proctor & Gamble
United States

Introduction

In recent decades, intellectual property in general and patents in particular have taken on increasing importance to the development and functioning of the global economy. As actors in all aspects of commerce come to appreciate the substantial role patents play in the functioning of the world's economy, business, and markets, it comes as little surprise that patents are increasingly being seen as subject to regulation, control, and correction of suspected "market failure" that other economically significant assets have long been exposed to. In recent years the propriety of and circumstances under which patents may and should be subject to compulsory licensing has been a global hot topic.

The debate about the proper role of patents rages on in a world now pre-occupied with the overall state of the world's economies and financial systems. Many thought leaders see patents as either hostile generally, or in specific circumstances, the most effective and beneficial development of various sectors of the economy. Some areas, such as health care including pharmaceutical compositions, have come to be seen by many as essential facilities or basic human rights. This view is often invoked to justify special regulations or exemptions from traditional patent expectations and practices. Others make the case that a patent system generally designed in the earliest days

of the industrial revolution is ill suited to the realities of certain technologies, sectors, or industries in the modern economy. In particular, the existence of patents granted to so called "non-practicing entities" is often cited as a situation requiring government intervention by those who see a key role of patents as to facilitate the actual introduction of technology to market in exchange for the patent right. Some would create a system with specialized or differing rules tailored to the supposed differences these realities create. Others propose a variety of flexible tools, including compulsory licensing, to remedy the perceived deficiencies with patents achieving their proper and intended purposes.

This paper will not attempt to analyze all of the rationales given for or against compulsory licensing. Nor is it an attempt to put forth a policy position for what the ideal compulsory licensing should be in a given jurisdiction. Rather, this paper will attempt to provide an up to date overview of the legal and experiential framework on the topic in Japan. This paper considers situations in which the government may grant a (typically) non-exclusive license to a private third-party in exchange for a royalty also set by the government. Also included within the scope of this paper is the refusal, for whatever reason, of a court to grant prospective injunctive relief to a patent owner once an infringer has been adjudicated liable for infringement of that owner's patent rights.

Provisions for Compulsory Licensing in the Japan Patent Act

Japan is a Paris Convention member state and a WTO member state. Both the Paris Convention and the WTO TRIPS Agreement explicitly

authorize member states to provide for compulsory licensing in national law with certain conditions and procedural safeguards.

The Japanese Patent Act (JPA) has long provided for a detailed arbitration system for reviewing and granting requests for compulsory licenses.¹ The system has been revised several times over the years with the most recent provisions detailing the procedure and the conditions being codified in the JPA at Sections 83-94. The Japanese Patent Act provides three basic situations in which a compulsory license may be requested and granted. These are for failure to work, to remedy a case of “blocking patents,”² and for the sake of the public interest.

When a patented invention has not been “sufficiently and continuously” worked for three years or longer and four years have elapsed from the filing date of the patent application, a person intending to work the patent may request that the patentee discuss granting a non-exclusive license to him. While the language is expressed in terms of “request consultations”, in reality, the person seeking the license can force negotiations with the non-practicing patent owner or have them declared to be deemed to have failed. In the event agreement is not reached or if consultations are not possible, the person intending to work the invention may then request an Arbitration Decision from Director-General of the Patent Office in accordance with the legislated procedures. The procedures, including provisions for appeal and review, are set out in the Act in detail

¹ See, e.g., JPA (1909), Article 47.1.

² This section of the JPA is typically translated into English as “award granting non-exclusive license to work own patented invention” but the meaning involves so called basic and improvement patents situations.

and incorporate at least all of the procedural and substantive restrictions set out in the Paris Convention and TRIPS Agreement on such compulsory licenses.

Article 92 of the Japan Patent Act addresses the situation of a request for a compulsory license in the event of a “blocking patent” situation. All of the basic procedures of the Arbitration system referred to above also apply to proceedings for a compulsory license in the blocking patent situation. Article 93 adds additional requirements and limitations, tracking the requirements of TRIPS Article 31(1) on the subject. As required by TRIPS, a compulsory license is not to be granted in a dominated patent situation unless the invention claimed “involves an important technical advance of considerable economic significance” compared to the invention claimed in the basic patent. The JPA provides, however, that the corresponding test³ is applied in both directions.

Article 93 of the JPA provides that when a patented invention is “particularly necessary in the public interest” a person intending to work the patent may compel negotiations with the patent owner for a license. If no agreement is reached, the Minister of Economy, Trade and Industry may be petitioned for an arbitration decision following the same basic procedure as above.

Actual Usage and Experiences with Arbitration System

The JPO reports that 23 requests in total have been submitted for compulsory licenses of various types

³ Under the JPA, a compulsory license will not be granted if the grant of such license to one patent holder would “unduly injure” the rights of the other. JPA, Article 92, Section 5.

of patent rights (invention patents, utility models, and design rights).⁴ Of these, 9 were predicated on failure to work and 14 were instances of blocking patents. All 23 requests were withdrawn before reaching an arbitration decision. There is, therefore, no instance of Japan having granted a compulsory license despite detailed provisions and procedures in the law for doing so.

Practitioners, academics, and commentators typically offer several reasons as to why Japan has never granted a compulsory license under its patent law. While it is, of course, impossible to know for sure the reasons behind forbearance to act, the commonly proffered reasons will be discussed in turn.

Perhaps the most often-cited reason why a compulsory license has never been granted in Japan is that the very threat (i.e. the legal provisions allowing for them) encourage parties to settle “voluntarily” rather than have the government both grant a license and determine its terms. It is impossible to know how strong this “voluntarily coerced” agreement phenomenon might be, but the theory is popular.

As part of a series of discussions involving bi-lateral agreements on patents, the United States and Japan agreed not to engage in arbitration to grant compulsory licenses. The two exceptions to the agreement not to grant compulsory licenses are to remedy practices found (judicially or administratively) to be anti-competitive or for public, non-commercial uses (e.g. eminent domain).⁵ This agreement was

reached in 1994. But, Japan has not modified its Patent Act to reflect this agreement. The officially reported reason is that the Patent Act allows for, but does require, any grant of a compulsory license. Therefore, there is no direct conflict between this agreement and the Patent Act. Presumably, no party would have standing to enforce this agreement, nor is there a mechanism to do so. It is, in that sense, non-binding on Japan. Nevertheless, many observers expect Japan will be very reluctant to grant a compulsory license as long as the United States does not do so. There is also a belief among commentators in Japan that compulsory license grants are not generally necessary in highly-developed nations with well-functioning patent systems. These observers opine that a rather significant and pervasive market failure widely affecting an important industry would need to exist before such a grant becomes likely.

Refusal of Injunctive Relief for Infringement

Article 100 of the Japan Patent Act gives a patent holder the right to seek an injunction against infringers. The Act itself provides no other conditions or circumstances conditioning the grant of such an injunction. As a result, when a court finds infringement, an injunction (equivalent to a permanent injunction in the United States) is granted essentially as an automatic matter.

While the Patent Act does not qualify or otherwise limit the right to an injunction for infringement, the Japan Patent Act is a specific statute

⁴ JPO Manual on Arbitration System.

⁵ There is some disagreement among commentators as to whether this US-Japan agreement is general with the two exceptions noted, or if it only applies to compulsory

licenses in the blocking patent situation. The majority view is that it is a general agreement as characterized here.

coming under the general Japanese Civil Code (JCC). Article 1(3) of the JCC provides generally that in all exercises of rights “no abuse of rights is permitted.” We turn then to situations in which a Japanese court has or might find granting of a permanent injunction to be an abuse of the right, and refuses to do so on that basis. This is the only statutorily available basis to the Japanese civil-law courts to ground refusal to grant an injunction.

The general theory of “abuse of rights” requires the court to consider the interests of the plaintiff, the defendant, and the public on a case-by-case basis.⁶ The two factors to be considered by the court are:

- The legitimacy of the relief sought, and
- The potential benefit and potential loss for each party should the injunction be issued or refused.

In the specific case of patent infringement, the alleged infringer would have the burden of proof to show that issuing an injunction would be an abuse of rights applying the factors above.

The leading case in Japan in which an abuse of the patent right was found by the Supreme Court is the *Fujitsu* case.⁷ In this case the Supreme Court upheld the decision of the District Court to refuse to grant an injunction. Importantly, however, both the District Court and the Supreme Court noted that the patent was likely invalid. The term “likely invalid” is used because

⁶ Kazuo Shinomiya & Yoshihisa Nomi, *Minpo Sosoku* Seventh Edition 17 (7th ed. 2005).

⁷ *Texas Instruments v. Fujitsu Ltd.*, 54 Saiko Saibansho Minji Hanreishu 04, 1368 (Sup. Ct. 2000)

Japan is a civil-law country. Under the JPA, only the Japanese Patent Office may officially declare a patent invalid in an invalidity trial. Prior to *Fujitsu*, the general practice in Japanese courts was to stay proceedings until a final determination was made by the JPO in an invalidity trial. *Fujitsu* stands for the proposition that courts may evaluate the validity of patents on their own. While the court does not have authority officially to declare the patent to be invalid, the Supreme Court has confirmed that granting of an injunction on a patent “likely” to be held invalid would be an abuse of the right as defined in the JCC. The use of the term “likely” here should be read as a judicial finding of invalidity. While only the JPO can officially declare a patent invalid, the court, by refusing to enforce it, effectively has found the patent invalid. Such a “finding” of invalidity by one court is not binding on other courts even with respect to the same patent, however.⁸

Post-*Fujitsu*, many courts refused to issue injunctions for “infringed” patents. In fact, the decision in *Fujitsu* led to amendment of the Patent Act. Article 104-3(1) of the Patent Act now provides that where, in litigation concerning infringement of a patent right, the patent is recognized as one that should be invalidated by a trial for invalidation, the rights of the patentee may not be exercised against a third party. This effectively codifies the *Fujitsu* holding letting courts take patent validity into account at trial as a defense, but leaving formal authority of invalidity declarations solely with the JPO. In no case, however, has an injunction been refused for a patent the court would have found to be valid were it the arbiter of patent validity.

⁸ Unless, of course, this finding has been affirmed or made by the Supreme Court.

It is safe to say that Japan basically follows the pre-eBay⁹ practice in the United States of “automatic” injunction grants following a finding of infringement of a patent the court does not deem invalid. There are some signs, however, that this situation may be changing. One very prominent case is *Ichitaro*. The Tokyo District Court held that JustSystem Corp. infringed a software patent, on a technique to display online help, owned by Matsushita Electronic Industrial Co. (the parent company of Panasonic).¹⁰ In this case, Matsushita was a non-practicing entity¹¹ and the JustSystem products, “Ichitaro” word-processing software and “Hanako” graphics software were extremely popular and well-used in Japan at the time. Following the finding of infringement, the court issued an injunction in accordance with standard practice. On appeal, the Intellectual Property High Court reversed the District Court Decision finding the patent should be invalid as lacking inventive step and holding that allowing its enforcement would be an abuse of the right. Nevertheless, the first-instance finding of infringement and grant of injunction to a non-practicing party on widely used and popular software prompted substantial public commentary and led to action by the JPO.

In 2006, the JPO issued “General Rules on Software Related Intellectual Property” for the purpose of clarifying what acts would constitute “abuse of the right” in enforcing patents directed to computer software. These

guidelines¹² provide that exercise of patent rights in the following situations may constitute abuse of the right:

- In the case that the exercise of the patent right shows wrongfulness, such as purposefulness of offense, in light of the subjectivity of the person who did the exercise of the patent right;
- In the case that the exercise of the patent right shows wrongfulness, such as forcing the opponent party to suffer an unreasonable loss, in light of the acts; or
- In the case that the exercise of the patent right puts the opponent party and the public at much more disadvantage than advantage the person who did the exercise of the patent right obtained.

These guidelines are not binding legal authority on the courts and no court has yet found enforcement of a valid patent to be an abuse of the right. In any event, they do represent the views of the ministry charged with responsibility for the patent system. And it is significant that the JPO view is that abuse of the right could be easier to show in the case where the patent owner does not practice the patent, at least in the context of software. It is also interesting to note that the factors incorporate some of the flexibility and balancing of interests that the United States Supreme Court has held is mandatory under *eBay* before an injunction can issue.

⁹ *eBay, Inc. v. MercExchange L.L.C.*, 547 U.S. 388 (2006).

¹⁰ *Matsushita Electric Industrial Co. v. JustSystem Corp.*, Heisei 16 wa 16732 (Tokyo Dist. Ct. Feb. 1, 2005).

¹¹ At least with respect to the patented technology.

¹² See General Rules on Software-related Intellectual Property http://search.e-gov.go.jp/servlet/Public?ANKEN_TYPE=3&CLASSNAME=Pcm1090&KID=595206007&%20OBJCD=&GROUP (Last visited August 3, 2011), Japanese translated by MultiLing.

The training of judges in Japan is that more specific statutes should be applied in most cases and general statutes should be applied only as a last resort in extreme cases. As has already been stated, any court finding enforcement of a valid and infringed patent to be an abuse of the right would be the first to do so. Given the natural reluctance of courts in Japan to resort to general statutes and the hesitancy to be the first court to make such a significant break with common practice, many observers find it unlikely that Japan will depart from its near automatic grant of permanent injunctions following a finding of infringement of a valid patent.

Conclusion

The Japan Patent Office and the United States Patent and Trademark Office each take a rather different approach to compulsory licensing in their respective national law. The United States makes no mention of compulsory licensing in its patent act, but permits it as other legal considerations warrant (such as in the antitrust remedy context). Japan, by contrast, makes extensive provision for compulsory licenses in a much wider variety of circumstances. Interestingly, however, if anything the actual practice in the two countries is the reverse of this relationship. As has been noted, Japan has not in fact granted any compulsory licenses despite the various mechanisms to do so. Following the *eBay* decision, the United States has several examples where courts have refused to grant injunctive relief following a finding of liability for infringement. The U.S. is also more active than Japan in the use of compulsory licensing and similar techniques in antitrust matters.

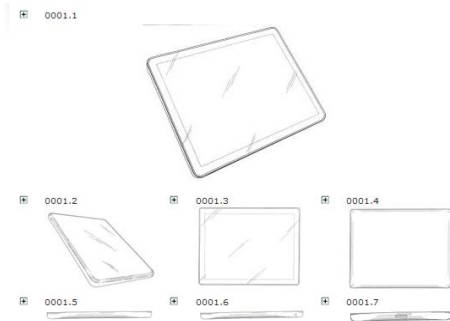
As the post-*Ichitaro* action by the JPO highlights, high profile cases often

lead to action on the part of governments and can be an impetus for change. Japan's neighbors, particularly China, are rapidly developing their own body of experience with IP law in which compulsory licensing may play a more active role. This reality combined with the yet to be determined full impact of the *eBay* decision in the United States may exert influence on the development of the law in Japan in the direction of more willingness to employ compulsory licenses. While these trends bear watching, the prevailing view among observers in Japan is that the current system (both as written and as applied) is functioning well. The expectation is that any changes to the current practice in Japan are likely to be incremental and cautious.

Japan is currently finalizing a series of changes to its Patent Act. These changes are designed to update certain provisions of the law to reflect the rise and importance to the economy of "open innovation" or other forms of R&D partnerships. These changes do not touch the compulsory licensing regime in Japan at all. This is at least one data point supporting the notion that even as Japan looks to keep its system up to date and relevant in a changing economy, the view that the current compulsory licensing system is functioning well and as intended, is still the predominant one.

EUROPE'S REGISTERED COMMUNITY DESIGN RIGHT. EARLY LEARNINGS FROM APPLE VS. SAMSUNG

Jean-Jacques Canonici
Procter & Gamble
Belgium



This past summer in Northern Europe a decision by the Düsseldorf Landgericht Court rocked the electronics industry and the public at large. On August 9, an *ex parte* preliminary injunction forced Samsung to interrupt the launch of its Galaxy Tab 10.1 across the EU, but for the NL. Only a few days later, on August 16, the Court amended the ruling following a petition by Samsung and limited the impact of the preliminary injunction to Germany.

This was the result of a suit brought by Apple for infringement by Samsung's Galaxy Tab 10.1 line of Apple's Registered Community Design 000187607-0001 (hereinafter the RCD) covering its iPad devices. It also signaled a new episode of the global IP war between Apple and Samsung, started by Apple in the US in April 2011.

On August 24, the Civil Court of The Hague issued a judgment in summary proceedings after Apple sued Samsung in NL for infringement of several of Apple's European Patents and the RCD. Although the Judge

found that Samsung's Smartphone's Galaxy S, SII and Ace infringed Apple's EP 2 059 868, he ruled that Samsung's Galaxy Tab 10.1 and 10.1.v did not infringe Apple's RCD. Apple appealed the decision of The Hague Court as regards the RCD and an appeal hearing is scheduled for December 15.

On September 9, the Düsseldorf Landgericht Court, after having heard the parties, including Samsung's invalidity and non-infringement case, confirmed the validity of the RCD and its infringement by Samsung's Galaxy Tab 10.1. Samsung thus remains enjoined from selling its Galaxy Tab 10.1 in Germany. The September 9 decision has been appealed by Samsung and the case will be heard and decided on December 20 by the Oberlandgericht Court in Düsseldorf.

The first-instance decisions in the preliminary proceedings in Düsseldorf and The Hague on the present case are particularly rich in the legal aspects addressed. Only two have been selected for this article, but reading the decisions will reveal other interesting legal aspects.

1. Registered Community Designs, some background.

The Registered Community Design right was created by European Council Regulation 6/2002 of 12 December 2001 (hereinafter the Regulation), which entered into force in 2003, and was complemented by European Directive 98/71/EC harmonizing EU member states Design laws with the Regulation. Like Community Trade Marks, Registered Community Designs constitute a unitary IP right valid across the whole territory of the EU. RCDs are granted by the OHIM in Alicante, which also grants

Community Trade Marks. OHIM does not perform a substantive examination, but granted RCDs are open to invalidity proceedings by 3rd parties. Such proceedings are handled at the first and second instance by OHIM, and can then be taken to the General Court of the EU (formerly the Court of First Instance).

Jurisdiction for infringement cases is entrusted to designated Community Design Courts, established in each EU Member State.

The Regulation created substantive Community Design Law and contains all provisions relative to validity, scope of protection, and jurisdiction relevant to Community Designs.

2. The Jurisdiction issue vs. Samsung Parent Company as decided by the Dusseldorf Court.

This is the first point of interest in this case, and it is of particular relevance to defendants or plaintiffs not headquartered in the EU but who are involved in a RCD case.

The case was filed against both the Samsung German subsidiary and the Samsung parent Korean company. In its September 9 judgment, the Dusseldorf Court confirmed the revised *ex parte* ruling of August 9, and declared the Court could not issue a pan-European injunction vs. Samsung Parent Company because it did not have jurisdiction to grant such a measure, under Article 82 (1) of the Regulation.

Article 82 (1) states: “*Subject to the provisions of this Regulation and to any provisions of the Convention on Jurisdiction and Enforcement*

applicable by virtue of Article 79, proceedings (...) shall be brought in the courts of the Member State in which the defendant is domiciled or, if he is not domiciled in any of the Member States, in any Member State in which he has an establishment.”.

Article 83 (1) further stipulates that: “*A Community design court whose jurisdiction is based on Article 82 (1), (...) shall have jurisdiction in respect of acts of infringement committed or threatened within the territory of any of the Member States”.*

In contrast, Article 82 (5) says: “*Proceedings (...) may also be brought in the courts of the Member State in which the act of infringement has been committed or threatened” and Art 83 (2) stipulates “A Community Design court whose jurisdiction is based on Article 82 (5) shall have jurisdiction only in respect of acts of infringement committed or threatened within the territory of the Member State in which that court is situated”.*

The Court was thus entitled to issue an injunction against the German subsidiary, with effect across the whole EU, except NL in the present case (only because a parallel case was pending based on the same right in NL). But, the Court did not have jurisdiction to grant a pan European injunction against the Samsung patent company, which is not domiciled in Germany. Apple was initially successful in arguing that the German subsidiary was actually “a branch office” of the parent company, equating to a domicile within the meaning of Art 82 (1). The Dusseldorf Court, however, decided that the subsidiary did not qualify as a branch office, relying on the requirements laid out in the European Convention on Court Jurisdiction and Execution of

Court Decisions in Civil and Commercial Matters. To qualify as a branch office, a Company must have an independent management and must be seen by 3rd parties as sole partner, not needing to involve the parent company.

The Court found that Samsung German subsidiary did not have a separate management vs. the parent Company, and through its identity was clearly signaling to 3rd parties that it was a subsidiary of the Parent Company.

Interestingly the Court noticed that the plaintiff, Apple, may have tried to obtain a pan-European injunction by arguing that they had a branch office in Germany. But since Apple did not select this approach, we do not know if they would have succeeded.

3. The degree of freedom of the designer as construed by the Dusseldorf and The Hague Courts

The notion of degree of freedom of the designer is instrumental under Community Design Law, in both validity and infringement analysis. Article 6.2 of Regulation 6/2002 stipulates that “*in assessing individual character, the degree of freedom of the designer in developing the design shall be taken into consideration*”. Article 10.2 of the Regulation says “*in assessing the scope of protection the degree of freedom of the designer in developing his design shall be taken into consideration*”.

Indeed, numerous OHIM as well as national Court decisions, have enshrined the principle that the larger the degree of freedom, the more differences will be required to create a

different overall impression on the informed user (and vice versa)

However, as the EU Court of Justice Advocate General Mengozzi put it in his opinion dated 12 May 2011, in the PepsiCo vs. OHIM case before the Court of Justice of the EU: “Design freedom facts are a crucial aspect of the Community Rules on Design, yet the Regulation does not give sufficient clarity as to the definition of the degree of freedom.”

The present decisions perfectly illustrate how differently the notion can be construed, yet they also highlight the criticality of this factor in the scope of protection assessment. The difference of analysis of the factor by the respective judges, was the direct cause for the diverging judgments: The Court of The Hague concluded no infringement and the Dusseldorf Court found infringement of Apple’s Community Design by Samsung’s Galaxy 10.1 tab.

The Court of The Hague judgment first illustrates a certain overlap between the notion of design freedom and the exception of technical function embodied in Article 8.1 of the Regulation, namely “*A community design shall not subsist in features of appearance of a product which are solely dictated by its technical function.*”

The Court said that the minimalistic exterior design of the Apple device was merely due to a trend in the market present at the time of filing of the RCD. The Court equated the “minimalistic” qualification to the selection of features dictated by technology and ergonomics, applying such a reasoning to, e.g., the rounded corners and the continuous “glass” touch panel of the

Apple device. Quoting the Judge, “protecting a minimalistic design would deprive competition from access to a product configuration dictated by market needs”, adding that “this competitive advantage is unjustifiable because it is not so much the result of design work, as coming from the fact the respective design rights holder was the first to be able to register the tight (minimalistic) exterior of a new product segment. Consequently, the protection cannot be broad and must be limited to the elements of the design not being considered as dictated by constraints”.

With such an approach, the Judge could only conclude no infringement, since the comparison was driven to details of the RCD and the Samsung device, and not from the “overall impression” analysis on which the assessment of individual character is based, according to Article 6 of the Regulation.

The Dusseldorf Court reached a radically different conclusion, yet also casted its arguments on design freedom under the umbrella of Article 8.1 of the Regulation. Actually, referring to the Judgment in The Hague, the Dusseldorf Court affirmed that “minimal is certainly not a technical consideration” and concluded that “it is especially the combination of a minimalistic designed front side with a smooth back side and a housing from which sharp corners, edges and protruding or decorative elements are avoided, which forms the basis for the design effort, and this is not merely a technically necessary arrangement”.

The Court actually relied on the prior art cited by the parties to conclude that at the time of filing of the RCD other designs were possible, without compromising the technical

function of the device. Such an approach is, in my view, more keen to a degree of freedom analysis.

But the Dusseldorf Court actually made still another interpretation of the notion of design freedom, concluding that there was wide freedom, because at the time of filing of the RCD, a wealth of styles for similar devices was available, all remote from the distinctive, minimalistic design protected by Apple.

This in my view is not design freedom *per-se*, but merely a consequence of the wide freedom of design, which is dictated by technical constraints imposed on the designer and not by the *design corpus* available at the filing date of the RCD.

Advocate General Mengozzi in the above-referred opinion dated 12 May 2011, did give his view of what freedom of the designer should entail, and in particular what type of constraints on the designer are intended. The Advocate General laid out two possible approaches, one of strict functional nature, *i.e.* the features which the goods to which the design relates must possess if they are to fulfill their function; the other reflecting a broader interpretation, which would require any “standard” feature that the market expects. And, he made a clear choice: only the strictly functional approach should be used since accepting that market expectations be taken into account would be at odds with the very aim of the design protection system.

The CJEU issued its judgment on the case (the very first in Community Design law) on October 20, 2011. But as anticipated by the Advocate General, it did not rule on the definition of degree of freedom of the

designer, which was not *per-se* a matter of dispute.

4. Comments

It will be very interesting to watch how the two cases will evolve in the Netherlands and Germany, starting with the upcoming appeal hearings of respectively December 15 and 20. It is difficult to predict which legal arguments will dominate the appeal decisions and what the outcome will be. Notwithstanding, my personal opinion as to the aspects discussed in this article is as follows:

The clarification on jurisdiction of Community Design Courts in respect of defendants (or plaintiffs) domiciled outside the EU is a useful one, and the argumentation relative to branch offices, an interesting one. I find it difficult to foresee however, how European subsidiaries of Companies domiciled outside the EU, could ever qualify as branch offices within the definition referred to by the Dusseldorf Court. Hence, I would give very little chance for the Landgericht decision to be overturned in appeal on this particular aspect.

The position taken by the Judge in The Hague Court on the type of constraints which determine degree of freedom of the designer is in my opinion not sustainable, particularly in view of the Opinion of the Advocate General of the CJEU discussed above. The approach taken by the Dusseldorf Court, in contrast, is compatible with the A.G.'s opinion, and in my view the correct one. I would thus hope that the Judgment in appeal in The Hague Court, will reverse the first instance decision on this point, and that the Appeal Court in Dusseldorf will uphold the Court of first instance reasoning. To which degree such

positions on the degree of freedom of the designer will influence the final determination of overall impression, as judged by the informed user, remains to be seen.

No matter how these cases evolve, these first instance decisions have already, in my view, given significant basis for continued clarification of some key aspects of Community Design law.

And, last but not least, the Dusseldorf Court decision for sure, has brought another tangible signal to the global user's community that Design Rights in the EU constitute an IP right, which increasingly will need to be accounted for.

STAR WARS STORMTROOPER HELMETS NOT COPYRIGHTABLE UNDER BRITISH LAW, BUT INFRINGEMENT OF U.S. COPYRIGHT IS JUSTICIABLE

John Richards
Ladas & Parry LLP
New York, NY

Introduction

On July 27, 2011, in **Lucasfilm Ltd v. Ainsworth** the United Kingdom Supreme Court (which took over the judicial functions of the House of Lords in October 2009) in a joint judgment by Lords Walker and Collins delivered a judgment defeating a bid by George Lucas' company ("Lucasfilm") to stop unauthorized manufacture and sale of the iconic Imperial Stormtrooper helmets used in the 1977 Star Wars film later renamed "Star Wars Episode IV – A New Hope". However, the Court did hold

that Lucasfilm had the right to enforce its U.S. copyright in the English courts.

The copyright infringement suit was brought by Lucasfilm and others against Andrew Ainsworth. George Lucas conceived the film's story-line and characters, including the Imperial Stormtroopers, whose "fascist white-armored suits" were given visual expression in drawings by Ralph McQuarrie, and first produced as 3-D models by Andrew Ainsworth, the defendant in this case. Lucasfilm owns the copyrights in the artistic works created for the Star Wars films, which has produced successful licensing revenues over the years. In 2004 Ainsworth started making the Stormtrooper helmet and armor and sold them in the U.S. in the value between \$8,000 and \$30,000.

Lucasfilm obtained a default judgment against Ainsworth for breach of copyright in the U.S. District Court for the Central District of California in 2006 for \$10 million of compensatory damages and a further \$10 million of punitive damages. The California judgment could not be enforced since Ainsworth, a resident of the U.K., held no assets in the U.S. Therefore Lucasfilm moved the battle to the U.K., and commenced proceedings in the Chancery Division of the English High Court.

Three main issues arose: 1) could the California judgment be enforced in England; 2) was there infringement of copyright under British law and 3) if not was infringement of U.S. copyright justiciable in England.

Possible Enforcement of the California Judgment

The first of these issues was disposed of at first instance and not appealed. The trial judge, Mann J., rejected the claims for enforcement of the California judgment. Judgments of American courts are enforceable in England under common law, subject to a limitation imposed by the Protection of Trading Interests Act that precludes recovery awards for multiple damages. The basic common law rule is that

where a court of competent jurisdiction has adjudicated a certain sum to be due from one person to another, a legal obligation arises to pay that sum, on which an action for debt to enforce the judgment may be obtained.

However, the definition "court of competent jurisdiction" is to be determined by the rules of English private international law which makes its own determination of whether a court making an award is one of "competent jurisdiction". These require a much greater degree of contact between the person against whom a judgment is made with the country whose court makes the judgment in question than is required for exercise of personal jurisdiction under the long arm statutes of most states in the United States. In the present case, these requirements were found not to have been met. Consequently, the judgment of the California court was not enforceable in England.

Was there Infringement of British Copyright?

British law on intellectual property protection for three dimensional

objects is complex, but for the most part governed by the Copyright, Designs and Patents Act 1988 (“the 1988 Act”). Under section 1(1) copyright covers original literary, dramatic, musical, artistic works, and films, etc. Under section 4(1), for copyright purposes, “artistic works means”:

- “(a) a graphic work, photograph, sculpture or collage, irrespective of artistic quality,
- (b) a work of architecture being a building or a model for a building, or
- (c) a work of artistic craftsmanship.”

By section 4(2) “sculpture” includes a cast or model made for purposes of sculpture.

However, under Section 52 of the 1988 Act, copyright which exists in an artistic work which is used as a model for copies made by an industrial process is limited so that, once a 25 year period from the end of the calendar year in which such articles are first marketed, the work may be copied by making articles of any description without infringing copyright in the work.

Furthermore, under Section 51 of the 1988 Act, it is not an infringement of copyright in a design document for anything other than an artistic work or a typeface to make an article to the design or to copy an article made to the design. Finally, design rights exist independently of copyright, and focus more on the shape, configuration and construction of a product. UK’s unregistered design right protection, provided for by Part III of the 1988 Act, gives protection to certain designs that are used in the production of both

functional and artistic articles for a period of up to 15 years (See sections 213 and 216).

Since more than 15 years had elapsed since the designs in question were first created and used (therefore the design right has expired), the question of whether the helmets were copyright-protected “artistic works” under section 4(1) of the 1988 Act became the major issue under British law and gave impetus to the alternative approach of seeking to enforce U.S. copyright law in England if the plaintiffs failed in their attempts under the British statute.

In the trial court, Mann J. dismissed the claims for infringement of British copyright law, holding that original 3-D versions of the helmet made by Ainsworth from McQuarrie’s drawings was not a work of “sculpture” under section 4(1) of the 1988 Act, nor a work of “artistic craftsmanship”.

The issue of whether the helmets were sculptures was appealed up to the Supreme Court. The decision on artistic craftsmanship was not appealed and so it is worth noting that Mann J’s reasoning was that prior case law required that the work had to be both “artistic” and a work of “craftsmanship.” In the present case even though the helmets might be works of “craftsmanship” they were not in themselves “artistic”. The judge extracted from the complex prior case law the principle that to meet the requirement of being “artistic”, the author had to have intended to produce something having aesthetic appeal.

After an exhaustive analysis of the complicated history of the interrelationship of design and copyright laws in the United Kingdom, the Court of Appeal agreed with Mann J that the helmet was not a work of “sculpture”.

The Copyright Issue Before the Supreme Court

The key question was “were the helmets sculptures”?

The Supreme Court agreed with the Court of Appeal that investigation into the relationship between design and copyright laws was of “little or no assistance as to the meaning of ‘sculpture’ in the 1988 Act.”

As a result, in the Supreme Court Lords Walker and Collins discussed the “sculpture” issue extensively. As noted above, the statute provides that if a work qualifies as “sculpture” its artistic quality is irrelevant.

Lucasfilm contended before the Supreme Court that the helmets were “sculptures”, and so protected under the 1988 Act, because it had no practical function at all. They argued:

“The Stormtroopers’ helmets and armour did not exist in order to keep their wearers warm or decent or to protect them from injury in an inter-planetary war. Their sole purpose was to make a visual impression on the filmgoer. They are therefore artistic works.”

To determine the meaning of “sculpture”, the Supreme Court looked at the case law, including that of other Commonwealth countries. In **Wham-O** the Court of Appeal of New Zealand held that the wooden model of a Frisbee made by hand, but not the molds and final products that had been made industrially was a sculpture under the 1988 Act. In the English **Breville** case the Court of Appeal had held that plaster shapes made for the production of die-cast molds of the sandwich toasters were not protected by copyright. The Court had emphasized the molds lack of “artistic expression”. Similarly, a claim to artistic copyright in molds used for making cartridges used in conjunction with flow mixers was rejected in **Metix**.

Both Mann J. of the trial court and the Court of Appeal had taken the view that since the helmet and the armor are still “recognizable as such” and used as helmet and armor in the film, therefore their “utilitarian” purposes were as “costume and prop”. The Supreme Court agreed with the lower courts on this point, holding that the helmet is not a “sculpture” within the meaning of the 1988 Act, by stating that:

“[I]t was the Star Wars film that was the work of art that Mr Lucas and his companies created. The helmet was utilitarian in the sense that it was an element in the process of production of the film.”

The Supreme Court analogized the Stormtroopers’ helmet to a 20th century military helmet used in a film, finding that the latter would not qualify as sculpture, “however great its

contribution to the artistic effect of the finished film”.

The Supreme Court noted that the British scheme of copyright protection applicable to this case accorded fullest protection to artistic works of art (sculpture and works of artistic craftsmanship), followed by works with “eye appeal”, and the third level is under Part III of the 1988 Act that accords a modest level of protection (by design right protection) to purely functional objects, like the exhaust system of a car. Although the helmet could be arguably protected on the second or the third level, since Lucasfilm claimed only that the helmet qualified as “sculpture” under the 1988 Act, the Supreme Court’s denial of its “sculpture” status gave defendant Ainsworth a defense under section 51 to any infringement claim based on Ralph McQuarrie’s original drawings since such drawings had already been used as “design documents” for production of articles based on them.

Justiciability in England of a Claim under U.S. Copyright Law

Mann J. at trial had held that the U.S. copyright claims were justiciable and that U.S. copyright had been infringed by Ainsworth, even though the U.S. judgment was unenforceable for lack of personal jurisdiction over Ainsworth. The Court of Appeal reversed Mann J’s decision, holding that enforcement of a foreign copyright did not fall within the ambit of two old common law rules relating to the ability of English courts to try actions based on property or act abroad.

Traditionally, there have been two major impediments to trying to enforce foreign intellectual property rights in England. The first is an extension of the view that only the courts of a country where real property is situated should decide ownership of that property (with an exception where the court has an equitable jurisdiction over the parties as in the case of *Penn v. Lord Baltimore* which led to the drawing of the Mason-Dixon Line). The real property rule has come to be known as the **Rule in the British South Africa Co. v. Companhia de Moçambique** (1893) (“the Moçambique case”). The second traditional rule was the so-called “double actionability rule”, which held that torts committed outside England were only justiciable in England if they were unlawful both in the country where perpetrated and in England. Since infringing a foreign IP right was not unlawful in England, it followed that an action could not be brought in the English courts with respect to that infringement.

The Court of Appeal held that the traditional common law rule in the Moçambique case had no jurisdiction to entertain an action for the determination of title to, or the right of possession of, foreign land, or the recovery of damages for trespass to such land, applies to claims for infringement of foreign copyright, and therefore, the U.S. copyright infringement is not justiciable in an English court.

In reversing the Court of Appeal on the justiciability issue, the Supreme Court concluded that, provided there is personal jurisdiction over the defendant (which there is, since Ainsworth lives in England), an English court does have jurisdiction to

try a claim for infringement of copyright in a foreign country even if outside E.U. in breach of that country's copyright law. (The position within the EU is governed by EU regulations). In effect, the Supreme Court limited the Moçambique rule relied upon by the Court of Appeal, explaining that the departure from the rule was accomplished by section 30(1) of the Civil Jurisdiction and Judgments Act 1982 ("the 1982 Act"), which provides that with respect to actions relating to property outside the EU (where other rules apply):

"The jurisdiction of any court in England ... to entertain proceedings for trespass to, or any other tort affecting, immovable property [i.e., land] shall extend to cases in which the property in question is situated outside that part of the United Kingdom unless the proceedings are principally concerned with a question of the title to, or the right to possession of, that property."

As a consequence, the Moçambique rule can only apply "where a question of title is involved." Therefore, the Court of Appeal erred in applying the Moçambique rule in claims for infringement of foreign copyrights. The Court noted:

"It is possible to see how the rationale of the Moçambique rule can be applied to patents, at any rate where questions of validity are involved. ... But it is very difficult to see how it could apply to copyright."

As to the "double actionability rule", after pointing out there is no European public policy against litigation of foreign intellectual property rights, the Supreme Court noted that following the enactment of the Private International Law (Miscellaneous Provisions) Act 1995,

"The general rule is that the applicable law is the law of the country in which the events constituting the tort or edict in question occur."

Hence in this case where the defendant was within the jurisdiction of the English court and there was no other reason why the action should not be brought in England, the reasons given by the Court of Appeal for declining jurisdiction did not apply.

The Supreme Court further considered whether the "act of state" doctrine might be a reason to decline jurisdiction in the case of foreign copyright infringement, but held that it did not. The court noted:

"[I]n England the foreign act of state doctrine has not been applied to any acts other than foreign legislation or governmental acts of officials such as requisition, and it should not today be regarded as an impediment to an action for infringement of foreign intellectual property rights, even if validity of a grant is in issue, simply because the action calls into question the decision of a foreign official."

In conclusion, the Supreme Court held that:

“There is no room for the application of the act of state doctrine in relation to copyright in this case, even if ... actions of officials involved with registration and grant of intellectual property rights were acts of state.”

Conclusion

These rulings reflect the modern trend in favor of the enforcement of foreign intellectual property rights. The Supreme Court further held that although there is no international regime for the mutual recognition of copyright jurisdiction and copyright judgment, “this is no reason for the English court refusing to take jurisdiction over an English defendant in a claim for breach of foreign copyright”.

The ruling means that Ainsworth can continue to make and sell the helmets in the U.K. (because they are not copyright protected in the U.K. as “sculptures” within the meaning of the 1988 Act), but not export them to the U.S. in violation of U.S. copyright law.

EUROPEAN COURT OF JUSTICE DECISION ON PATENTABILITY OF STEM CELL RELATED INVENTIONS

John Richards
Ladas & Parry LLP
New York, NY

The European Patent Convention prohibits the grant of patents on inventions whose commercial exploitation would be contrary to

“*ordre public*” or to morality.¹ There is a corresponding provision in Article 2 of the German national patent law.

Cases such as the Harvard oncomouse case and patenting of genetic material raised concerns as to the proper scope of this provision and in 1998, the EU finally adopted a directive requiring that its member states harmonize their laws relating to the patenting of biotechnological inventions.² Among its provisions was one that certain inventions are excluded from patentability on the basis that they infringe prohibitions on patents for inventions whose exploitation is contrary to *ordre public* or morality. One of these is inventions involving “use of human embryos for industrial or commercial purposes.” This provision was incorporated in to the German Patent Act as Article 2(1)(3). The European Patent Organization also amended its rules to include a similar provision.

The meaning of this prohibition on patenting of inventions involving use of human embryos came before the Court of Justice of the European Union in the case of *Oliver Brüstle v. Greenpeace e. V.* Mr. Brüstle had obtained a German patent for isolated and purified neural precursor cells for treatment of neural defects. Such cells are apparently only available from cerebral tissues of human embryos. Greenpeace sought invalidation of the patent on the ground that the invention

¹ There was a change of wording with the adoption of EPC 2000, previously the prohibition was on patenting inventions whose “publication or exploitation” would be contrary to *ordre public* or morality. The change was for conformity with Article 27(2) of TRIPS. Consistent with Article 4 *quarter* of the Paris Convention, it is specifically provided that something shall not be treated as being unpatentable “merely because it is prohibited by law or regulation in some or all of the Contracting States”.

² Directive 98/44.

claimed involved use of human embryos for industrial or commercial purposes. The German Patent Court agreed. Mr Brustle appealed to the German Supreme Court which referred the following questions to the Court of Justice of the European Union:

1. What is meant by the term “human embryos” in the Directive?

(a) Does it include all stages of the development of human life, beginning with the fertilization of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

– unfertilized human ova into which a cell nucleus from a mature human cell has been transplanted;

– unfertilized human ova whose division and further development have been stimulated by parthenogenesis?

(c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression “uses of human embryos for industrial or commercial purposes”? Does it include any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching:

– because the patent concerns a product whose production necessitates the prior destruction of human embryos,

– or because the patent concerns a process for which such a product is needed as base material?

The questions were answered by the Grand Chamber³ of the Court of Justice as follows:

1. Any human ovum after fertilization, any non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo.’

2. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in the Directive also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable.

3. The Directive excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

³ Because there are now 27 judges in the Court of Justice of the European Union (one for each member state), the court no longer sits *en banc* with all judges participating and the largest bench of judges to sit on a case is 13 sitting as a “grand chamber” as was done in this case.

It was left to the German Supreme Court to decide whether “in the light of scientific developments, a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ within the terms of the definition given above.”

In reaching its decision on the first question, the Court first noted that it should not be influenced by national laws relating to use of stem cells nor by questions of morality and culture where there were differences between member states, but by the wording of the Directive itself. In doing this the Court noted that elsewhere in the Directive it was provided that the human body at the various stages of its formation and development cannot constitute a patentable invention and that specific prohibitions on the grant of patents on the grant of patents because the exploitation of the inventions would be contrary to *ordre public* or morality applied to processes for cloning human beings, processes for modifying the germ line genetic identity of human beings as well as uses of human embryos for industrial or commercial purposes. The Court noted that the purpose of these prohibitions was to prevent the grant of patents for processes the use of which would offend against human dignity. From this the Court reasoned that it followed that the concept of ‘human embryo’ in Directive must be understood in a wide sense.

The Court concluded:

Accordingly, any human ovum must, as soon as fertilized, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of ... the Directive, since that fertilization is such as to

commence the process of development of a human being.

That classification must also apply to a non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis. Although those organisms have not, strictly speaking, been the object of fertilization, due to the effect of the technique used to obtain them they are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilization of an ovum can do so.

As regards stem cells obtained from a human embryo at the blastocyst stage, it is for the referring court to ascertain, in the light of scientific developments, whether they are capable of commencing the process of development of a human being and, therefore, are included within the concept of ‘human embryo’ within the meaning and for the purposes of the application of the Directive.

On the second question as to what constituted use of an embryo for industrial or commercial purposes, the Court reasoned that scientific research that “can access the protection of patent law, ... implies, in principle, its industrial or commercial application.” In the court’s view, only use for therapeutic or diagnostic purposes which are applied to the human

embryo and are useful to it are patentable.

The Court noted that this conclusion was consistent with that the EPO Enlarged Board of Appeal decision in the WARF case mentioned below.

On the third question the Court reasoned that there is use of human embryos within the meaning of the Directive because where there was an implied destruction of human embryos to produce the cells, “[n]ot to include in the scope of the exclusion from patentability technical teaching claimed, on the ground that it does not refer to the use, implying their prior destruction, of human embryos would make the provision concerned redundant by allowing a patent applicant to avoid its application by skillful drafting of the claim.

Previously the Enlarged Board of Appeal of the European Patent Office he In its decision of November 25, 2008⁴, the Enlarged Board of Appeal held that claims to a cell culture containing primate embryonic stem cells having certain properties were not patentable in view of Rule 28. At the time of filing of the application, such a culture could only have been obtained by destruction of embryos. The fact that destruction of the embryos was not a feature of the claims was not relevant. The fact that after the filing date techniques that could obtain embryonic stem cells without destroying the embryo did not help either. Patentability had to be decided as of the filing date. Nor was it relevant that the intention was to use the culture for research. The Board held:

⁴G2/06 [2009] OJ EPO 306.

Making the claimed product remains commercial or industrial exploitation of the invention even when there is an intention to use that product for further research.

**FEDERAL CIRCUIT RULES
THAT ISOLATED DNA
SEQUENCES REPRESENT
PATENT-ELIGIBLE SUBJECT
MATTER**

Robert Smyth
Morgan, Lewis & Bockius, LLP
Washington, D.C.

In a recent decision, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office et al.*, No. 2010-1406 (Fed. Cir. July 29, 2011), the Federal Circuit held that isolated DNA sequences are patent-eligible subject matter under 35 U.S.C. § 101 (Section 101).

Background

On May 12, 2009, the American Civil Liberties Union (ACLU), on behalf of several medical associations, advocacy organizations, physicians, researchers, and individuals, filed a declaratory judgment lawsuit, naming the U.S. Patent and Trademark Office (USPTO) and Myriad Genetics, Inc. (Myriad) among the defendants. The ACLU challenged the validity and constitutionality of Myriad’s BRCA1/2 breast cancer gene patents.

Myriad’s patents, however, are not unusual or unique in view of present USPTO rules and practice and the courts’ legal precedents. The USPTO has taken the position that isolated and purified genes are chemical compounds, albeit complex ones, and

thus qualify for potential patenting as compositions of matter. Thus, the position of the USPTO has been that, although a naturally occurring product (as it exists in nature) cannot be patented, naturally occurring products that have been isolated and purified should be patent-eligible subject matter. For this reason, since 1975, the USPTO has issued more than 15,000 patents with claims containing the word “gene” and current estimates are that approximately 50,000 gene patents have been issued over the years.

Accordingly, in challenging the validity of Myriad’s gene patents, the ACLU attacked the legality of at least a significant part of all issued gene patents. Specifically, the ACLU disagreed with current USPTO practice and the courts’ precedents by stating in its declaratory judgment complaint that “[e]very person’s body contains human genes, passed down to each individual from his or her parents. These genes determine, in part, the structure and function of every human body. This case challenges the legality and constitutionality of granting patents over this most basic element of every person’s individuality.”

District Court Ruling

On March 29, 2010, the U.S. District Court for the Southern District of New York ruled in favor of the ACLU and held that Myriad’s claims reciting isolated BRCA1/2 breast cancer genes were invalid.

Section 101 of the U.S. Patent Law defines the categories of statutory subject matter as “any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof.” As the U.S. Supreme Court has noted, the terms in Section 101 reciting

“manufacture” and “composition of matter,” modified by the comprehensive “any,” are “expansive terms,” and “the language of Section 101 is extremely broad.” Specifically, the Supreme Court previously interpreted Section 101 broadly to include “anything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303,309 (1980). The broad reading of Section 101, however, has a limit. In interpreting Section 101, the Supreme Court has recognized three narrow categories of subject matter that fall outside the scope of Section 101: “laws of nature, physical phenomena, and abstract ideas.” *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010). In his opinion, district court judge Robert W. Sweet reasoned that Myriad’s challenged claims encompass patent-ineligible subject matter because the underlying BRCA genes exist in nature and thus are part of the laws of nature, which are not patentable.

Federal Circuit Decision

On appeal, the Federal Circuit reversed Judge Sweet’s decision and ruled that isolated DNA sequences are patent-eligible subject matter under Section 101. In reviewing the district court’s decision, the Federal Circuit began by setting out the legal framework established by the Supreme Court for patent eligible subject matter in important earlier Supreme Court decisions: *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and *Funk Brother Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). In those cases, the Supreme Court stated that the distinction made “between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition’s identity compared with what exists in nature.” Relying on the Supreme Court’s earlier

rulings, the Federal Circuit therefore reasoned that Myriad's claims that "cover molecules that are markedly different, [that is] have a distinctive chemical identity and nature from molecules that exist in nature" are drawn to patent eligible subject matter under Section 101.

Specifically, with respect to the isolated DNA sequences, the Federal Circuit majority pointed out that these molecules no longer retain the chemical bond that the naturally occurring genes would have with other genetic materials, stating that the "covalent bonds in this case separate one chemical species from another." The Federal Circuit majority further emphasized that "the PTO has issued patents directed to DNA molecules for almost thirty years" and noted that any change in the law to exclude DNA inventions from the broad scope of Section 101 would have to come from Congress, not the courts.

While reversing the district court's decision on the patentability of isolated DNA sequences, however, the Federal Circuit affirmed the district court's decision on the patentability of some of Myriad's diagnostic method claims. Specifically, the Federal Circuit found that the claims directed to the methods of comparing or analyzing sequences only cover abstract mental processes and therefore fell outside Section 101 in view of the Supreme Court's famous *Bilski* decision.

Based on this decision by the Federal Circuit, isolated DNA sequences remain patent-eligible subject matter. The Federal Circuit, however, affirmed the district court's finding that the diagnostic method claims that are not tied to a machine or a transformative step are invalid. A

copy of the opinion can be found at <http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406.pdf>.

DISCLOSURE OF PRIOR ART: DUTY FREE IN THE CANADIAN PATENT OFFICE?

Falon Leach
Bereskin & Parr, LLP
Toronto, Ontario, Canada

*Federal Court of Appeal clarifies
scope of "good faith" section of the
Canadian Patent Act*

A characteristic of a strong patent is that it is clearly novel and inventive over prior art (public domain information). Patent Offices conduct a search for relevant prior art that is carefully examined against the patent application before granting the patent. The US Patent Office also imposes an ongoing good faith duty on patent applicants to submit a list of all known relevant prior art. The patent can be held invalid in court for inequitable conduct if the applicant does not make a full disclosure. Patents are often challenged on this basis.

There is no ongoing duty on Canadian patent applicants to disclose prior art. A list of prior art need only be submitted if and when the Canadian Patent Office requisitions prior art. The requisition is usually limited to requiring the applicant to provide prior art cited in corresponding patent applications filed in the US and Europe. If the applicant fails to make a good faith response by submitting all the requisitioned prior art within the time allowed, the Patent Office will i) deem the application abandoned and ii) send the applicant a notice that there is a one year period to satisfy the requisition and reinstate the

application.¹ Absent a requisition, the situation in Canada is similar to Europe and most other patent offices, where voluntary prior art disclosures are permitted, but left to the applicant's discretion. Some applicants make voluntary disclosures because they want the patent to appear stronger after having been granted over all the closest known prior art. Other applicants choose not to voluntarily disclose prior art to avoid incurring additional costs and arguing about prior art that is a 'red herring'.

Until *Weatherford*, a recent Appeal Court decision², the validity of issued Canadian patents had often been challenged on the basis of an alleged lack of good faith in responding to such prior art requisitions. The argument was that the patent application should have been deemed by law to have been abandoned during prosecution because a response to a Patent Office requisition was not made in good faith and the time for doing so had expired. The Court was asked to retroactively abandon such applications even though the Patent Office had treated the response as satisfactory years before. At first this type of challenge was widely considered to be a long shot, since there had been no previous success with such challenge. That changed when a pair of Federal Court trial level decisions³ upheld the argument. In those cases, the Court held that certain of the applicants' submissions to the

Patent Office made many years before in response to prior art requisitions were not made in good faith and, therefore, the applications were retroactively deemed to have been abandoned. As the one year period to reinstate had long since passed, the patents were invalid. Now this type of challenge appears to have been eliminated by *Weatherford* in which the Federal Court of Appeal held that these earlier trial level decisions ought not to be followed, and that the Court should not retroactively scrutinize submissions to the Patent Office made during the prosecution of the patent application.

The *Weatherford* decision is another instance of a Canadian Court showing reluctance to expand the scope of patent litigation into the prosecution history of the patent. An earlier example was the *Free World Trust* case⁴ in 2000, in which the Supreme Court of Canada rejected interpreting the scope of patent claims by reference to arguments and claim amendments that the applicant submitted to the Patent Office. The Court said that allowing this evidence would be "fuelling the already overheated engines of patent litigation."

An issued patent can still be invalidated in Court on the basis of willfully misleading statements (or omissions) to the Patent Office about the invention. These include i) failure to make adequate disclosure of how to implement the invention or ii) improper statements about the applicant and inventors that are material to the patent.⁵ Here, courts

¹ *Patent Act*, R.S.C. 1985, c. P-4, as amended, Section 73(1)(a)

² *Corlac Inc. et al. v. Weatherford Canada Ltd. et al.*, 2011 FCA 228 at Para.150 - an application for leave to appeal to the Supreme Court of Canada is pending. (Bereskin & Parr LLP acts for Weatherford in this litigation.)

³ *G.D. Searle & Co. v. Novopharm Ltd.* (2007), 56 C.P.R. (4th) 1 (FCTD) reversed (2007), 58 C.P.R. (4th) 1 (FCA) and *Lundbeck Canada Inc. v. Ratiopharm Inc.*, (2009), 79 C.P.R. (4th) 243 (FCTD)

⁴ *Free World Trust v. Électro Sante Inc.*, [2000] 2 S.C.R. 1024 at Para. 66

⁵ *Patent Act*, R.S.C. 1985, c. P-4, as amended, Section 53(1)

enforce the public interest in ensuring the patent was granted to the right person and that it will show others how to practice the invention. However, it appears that in the future courts will leave it to the Patent Office to police alleged defects in the prior art disclosed to the patent office or inaccurate arguments about prior art. This is much less risky for applicants because in the rare case where the Patent Office abandons an application for lack of good faith response to a requisition, the applicant will receive notice and a year to correctively reinstate the application.

Adam Bobker and Noel Courage are partners in the intellectual property law firm of Bereskin & Parr LLP. Adam was one of the counsel that represented Weatherford in the Federal Court of Appeal case discussed in this article.

INNOVATION PATENTS IN AUSTRALIA

Michael J. Houlihan
Houlihan²
Victoria, Australia

Introduction

In May 2001, Australia introduced a second-tier patent system called the Innovation Patent in order to protect developments that had a lower inventive threshold than that necessary to secure a granted Standard Patent.

The Innovation Patent system, which has many similarities to “Utility Models” or the like which are available in other foreign jurisdictions, was seen as a simple, quick and fairly cheap way to obtain Intellectual Property protection. The intention of the new system was designed to assist

Australian individuals and small to medium business enterprises (SMEs) in protecting inventions that contained or offered an incremental advance over the prior art, but where the advance lacked the required inventiveness to obtain a Standard Patent or where the advance might not be able to be covered by Design protection.

Comparison with Standard Patents

Like a number of Utility Models elsewhere, when compared to Standard Patents, the duration of the term of the Innovation Patent is shorter, the number of permitted Claims is fewer, the level of required patentability is lower, the class of protectable subject matter is narrower and substantive examination is not required in order to obtain the granted Innovation Patent.

The number of Innovation Patents that have been filed over the last 10 years averages at around less than 1,200 per year. In its first year, about 600 Applications were filed while in 2010/2011 the number was about 1,560. This 1,200 annual average represents a number less than 0.1% of the number of Standard Patent Applications filed in Australia.

The lack of apparent interest in the Innovation Patent system could be attributed to a number of factors such as Patent Applicants: (i) being unaware of the Innovation Patent system; (ii) preferring to seek the potentially available twenty (20) year Term for a Standard Patent compared to an eight (8) year Term for an Innovation Patent; (iii) believing that their invention will satisfy the higher inventiveness test for a Standard Patent; (iv) requiring greater scope of protection through a greater number of Claims in a Standard Patent compared to only being permitted five (5) Claims in the

Innovation Patent; (v) being precluded from pursuing an Innovation Patent because the relevant subject matter is directed to a plant, animal or biological processes for the generation of plants and animals; or possibly even a (vi) lack of faith in or concern about the Innovation Patent system by Patent Applicants and/or Australian IP professionals.

History

A few months after the introduction of the new system, an Australian Patent Attorney applied for and was issued an Innovation Patent for the WHEEL. The invention was titled “*Circular Transportation Facilitation Device*”. The Attorney set out to prove that the Innovation Patent system was flawed, because IP Australia did not examine the application and that in essence, it was an attempt to show that the system could issue a Patent for almost any subject matter. While the Innovation Patent was inevitably flawed and could be readily invalidated, the public ridicule and press reports surrounding the new Innovation Patent system spread around Australia and the patent world. The Attorney was awarded Harvard University’s IgNoble Prize for Technology. With such adverse press at that time, it was a brave IP professional who recommended the new system to its clients. Over the ensuing years, concerns were expressed as to whether Australian Courts would read down and limit the scope of Claim language to a simple literal interpretation of the terms, given that the Innovation Patent required a lower patentability test compared to a Standard Patent.

While the actual number of Innovation Patents being filed is still extremely small, recent decisions

emanating from the Australian Courts have now dispelled the earlier expressed concerns regarding the scope of Claims and the strength of Innovation Patents that have been examined and subsequently certified.

Process from filing to certification

Innovation Patents can be Convention or Non-convention applications, Divisional applications, but not Patent of Addition applications. Innovation Patents cannot be filed via the PCT route. However, it is possible to convert an Australian National Phase Entry of a Standard Patent application into an Innovation Patent application.

An Innovation Patent can usually be granted within a month of its filing date, since on filing it only undergoes a formalities check. In order to enforce an Innovation Patent against a third party, one must have the Patent examined and certified by IP Australia beforehand. This examination process can take a few months after the grant of the innovation Patent. Following certification, the Patentee has exactly same rights against third parties as would be available under a Standard Patent. In addition, a successful Innovation Patentee is able to seek the same extent of relief, i.e., an injunction, an account of profits or an award of damages against an infringing party.

Substantive examination of an Innovation patent can be requested by the Patentee or a third party or if directed by IP Australia at any time during its eight (8) year Term. An Innovation Patent must satisfy the same novelty criteria as that of the Standard Patent. However, the inventiveness threshold is lower in that only an innovative step is required

rather than an inventive step for a Standard Patent.

An innovative step according to s 7(4) of the *Patents Act 1990* (Cth), is defined as: “*an invention is taken to involve an innovative step when compared to the prior art base unless the invention would...only vary from... (the prior art information/reference) in ways that **make no substantial contribution to the working of the invention**”.* This determination is to be made by the relevant skilled person in the light of the common general knowledge as it existed in Australia at the claimed priority date.

With such a lower test compared to the inventiveness requirement of a Standard patent, it can be appreciated that where the novelty conferring feature of the invention can be seen to substantially contribute to the working of the invention, it would be difficult for a defendant to invalidate an Innovation Patent. Recent judgments issued from both the Federal Court and Full Federal Court of Australia have supported this position. Accordingly, certified Innovation Patents are now considered to be very strong, valid Patents.

If during the course of examination of a Standard Patent application, one encounters difficulty in that the claimed invention is not able to meet the higher inventive step threshold, one can convert the Standard Patent application to an Innovation Patent application. The conversion comes at the expense of only being able to obtain an eight (8) year rather than twenty (20) year Patent Term; however, it is most likely that the applicant will receive a certified Innovation Patent to cover the subject matter.

Current users of the system

Statistics available from IP Australia over the last few years show that foreigners and Australian companies and firms, rather than Australian individuals, are increasing their share of the number of certified Innovation Patents. This is thought to arise since foreigners and Australian companies and firms are incorporating Innovation Patents into their strategic Patent Portfolios, where they are using the system to protect higher level inventions rather than the original intention of the system which was to cover low level inventions. The system also offers them early issuing enforceable rights to shut out competitors or to provide a basis to threaten and/or start infringement proceedings.

Divisionals

One can file a Standard Patent application and during its pendency (i.e., up until three (3) months from when it is accepted for grant) file one or more Divisional Innovation Patent applications therefrom (remembering in addition to the three (3) month rule, that any Divisional has the filing date of its parent and the Divisional cannot be filed more than 8 years after the parent filing date). As a result of the Divisional process, one can file a Standard Patent and follow this with a Divisional Innovation Patent directed to the most commercially important aspect of the Standard Patent. While the Standard Patent is still pending and either while awaiting examination, or during examination, one can request that the Divisional Innovation Patent be examined and certified for use in an infringement proceeding. An infringement suit can be filed based on the certified Innovation Patent while the pending Standard Patent

application with greater claim scope runs its usual course. Therefore, one can file and obtain one or more divisional Innovation Patents and then wait until an infringer emerges on the scene, before requesting examination and certification thereof. Alternatively, when becoming aware of an infringer, and if the window of opportunity is still open, one should file a Divisional Innovation Patent, request examination and certification to be in a position to immediately threaten and/or institute proceedings.

Reasons to consider an Innovation Patent

Give consideration to an Innovation Patent in Australia when

1. A Patent Term of eight (8) years would be sufficient because of the short commercial life of the patented product, article, compound, composition or process.
2. The invention may not meet the higher inventive step requirement of a Standard Patent.
3. An infringement is on the scene or can be expected.
4. One requires an enforceable Patent that is very difficult to invalidate.
5. One wishes to obtain a Patent for the invention without the cost and expense of the application undergoing examination, and one is also prepared to wait until, and if necessary, to request examination to enforce it.

What future for Innovation Patents

At present, the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is before the Australian Senate, wherein Australia is working to align its laws and inventiveness standards with those of its major trading partners. The Innovation Patent with its current lower standard is inconsistent with the objectives of this Bill. The Government is also reviewing the Innovation Patent system and we wait to see what changes if any will arise there from.

THE CANADIAN PATENT PROMISE: A CONCERN FOR PHARMACEUTICAL INNOVATORS?

Arvie Anderson
Lawrence Welch
Eli Lilly and Company
United States

Canada's requirements for patentable utility apply almost exclusively to pharmaceutical patents. The current Canadian requirements for demonstration of a sound prediction of utility are in distinct contrast with utility requirements which existed prior to a seminal 2002 Canadian Supreme Court case involving the drug AZT.

This article will review recent applications of sound prediction within the Canadian courts and compare them with the utility requirements in the US and Europe. The article will also discuss the Canadian requirements as compared to how patentable utility is addressed in TRIPS, NAFTA and the PCT.

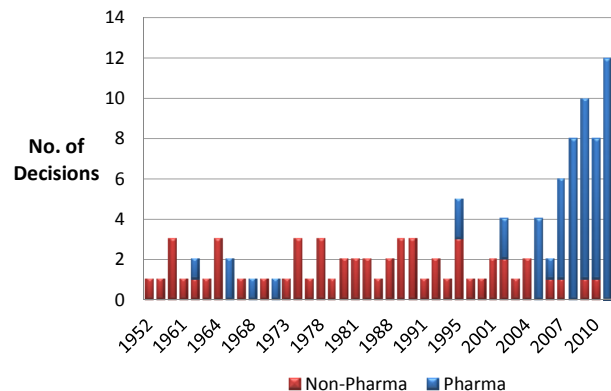
Increasing Prevalence Drug Patent Challenges on the Basis of Inutility in Canada

An analysis of Canadian Federal Court decisions rendered on the basis of utility illustrates an exponential increase in the number of pharmaceutical patents cases in Canada. In the fifty (50) years prior to the seminal Supreme Court case which introduced the contemporary concepts of utility and sound prediction into Canadian law, *Apotex Inc. v. Wellcome Found. Ltd.*, 2002 SCC 77, [2002] 4 SCR 153 [AZT], pharmaceutical cases decided on the basis of utility were quite infrequent.

As evident by Figure 1, in the fifty (50) years prior to the AZT decision, there were only eight (8) drug patent cases decided on the basis of inutility, that is, lack of utility in fact. Since AZT in 2002, however, there has been an exponential increase in the number of challenges to drug patents in Canada on the basis of utility. In 2011 alone, there were twelve (12) decisions rendered on the basis of utility. Further, in contrast to the pre-AZT period, increasingly all patents challenged on the basis of utility are pharmaceutical patents.¹

¹ Since 2008, out of 37 cases where inutility was alleged as a basis of invalidity by an alleged infringer in the Canadian Federal Courts, only 2 were non-biopharmaceutical patents. Thus over the last 3 years, inutility was alleged against drug patents almost exclusively, that is almost 95% of the time. In 2011, all patents challenged on the basis of inutility were drug patents.

Figure 1: Pharma v. Non-Pharma Decisions on Utility by Year



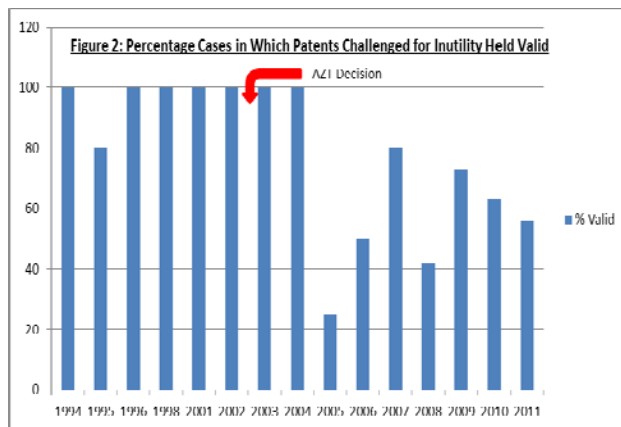
Trends in Utility Decisions since AZT (2002)

In the nearly ten years since the Supreme Court of Canada's decision in AZT, an increasing number of patents have been held invalid on the basis of inutility. While the Supreme Court upheld the validity of Wellcome's patent on the use of AZT, the doctrines of inutility and sound prediction have become an increasing basis for challenge of patents. In particular the disclosure requirement of the sound prediction analysis has expanded beyond that contemplated by the Courts pre-AZT. As a result, patents filed before 2002 that satisfied pre-AZT disclosure and utility requirements are now analyzed under a slightly different standard. Prior to AZT, consistent with the Canadian *Patent Act (the Act)*² and Canada's treaty obligations³, utility

² *Patent Act* (R.S.C., 1985, c. P-4, as amended).

³ Section 2 of the Canadian *Patent Act* corresponds to Article 27.1 of TRIPS and also Article 1709.1 of NAFTA which mandates that signatory nations such as Canada "shall "provide patent protection to inventions which are "new, involve an inventive step and are capable of industrial application." Further, Article 29.1 of TRIPS merely requires the applicant to "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". This language is identical to that found in the PCT Article 27 which has been specifically introduced into the Canadian statute.

had been generally treated by the courts as requiring utility in fact with the result that in the years prior to *AZT* inutility was rarely a successful means of patent challenge. (Prior to the *AZT* decision, where the ground of inutility was raised, the patents were mostly found valid.) As shown in Figure 2 below, post-*AZT*, patents are reliably valid less than 50% of the time for failing a standard that was developed after the patents were filed and issued. Further, many of the 50% of the “successful” cases where utility was found remain pending on appeal⁴.



In February of 2012, the Supreme Court of Canada will consider a case which includes the issue of when the disclosure of a patent specification is sufficient.⁵ The decision when rendered should further impact these trends and many patents both issued and pending.

⁴ Drugs for Which Patents are currently on Appeal in the Courts include Latanoprost (2011 FCA 236), Olanzapine (2011 FC 1288), Anastrozole (2011 FC 1023), Mycophenolate (2011 FC 875), Donepezil (2011 FC 547), Atomoxetine (2011 FCA 220), Lovastatin (2010 FC 1265), Sildenafil (2010 FCA 242) and Clopidogrel (2011 FC XXXX) (Reasons to be released imminently but patent held to lack demonstrated or a soundly predicted utility. Since the decision emanates from the Federal Court in an infringement action, it is presumed that the case will be appealed to the Canadian Federal Court of Appeal.)

⁵ *Novopharm v. Pfizer*, 2010 FCA 242.

Recent Applications of the Canadian Standards for Patentable Utility

An analysis of the results in recent cases shows that the Canadian utility standards have led to invalidation for inutility or finding allegations of inutility justified in proceedings brought under the *Patented Medicines (Notice of Compliance) Regulations* [(the *PM (NOC) Regulations*)] for at least eleven (11) patents⁶ where the pharmaceutical is plainly useful in fact. In these cases the Canadian court’s first determined so-called “promise” of the patent the outset of the utility analysis. Evidence of either a demonstration or sound prediction of utility is then compared to this promise. In some cases, after construction of an elevated “promise”, the Canadian courts have required long term clinical studies in patients⁷ in

⁶ Decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings include the following: *Strattera FCA*, 2011 FCA 220, 94 CPR (4th) 95, leave to appeal to SCC refused [2011] SCCA No 362 (QL); *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300, [*Ramipril FCA*]; *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711, 76 CPR (4th) 241 [*Amlodipine besylate*], affirmed 2010 FCA 204, 87 CPR (4th) 185 (FCA does not comment on utility), and *Olanzapine*, 2011 FC 1288. Decisions where allegations of inutility were found to be justified in *PM(NOC)* (s. 55.2) hearings include the following: *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, 95 CPR (4th) 193 [*Latanoprost FCA*]; *Evista*, 2009 FCA 97, 78 CPR (4th) 388, leave to appeal to SCC refused [2009] SCCA No 219 (QL); *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612 [*Revatio FC*]; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714, 88 CPR (4th) 28 [*Esomeprazole*]; *GlaxoSmithKline Inc. v. Pharmascience Inc.*, 2008 FC 593, 72 CPR (4th) 295 [*Valacyclovir*]; and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, 59 CPR (4th) 183 [*Viagra*], affirmed 2007 FCA 195, 60 CPR (4th) 177, leave to appeal to SCC refused [2007] SCCA No 371 (QL); *Sanofi-Aventis v. Apotex*, 2011 FC XXXX (reasons to be released imminently but patent held to lack demonstrated or a soundly predicted utility) [*Plavix*]. Collectively these products represent billions of dollars of sales lost due to judge-made heightened standards of utility.

⁷ See *Strattera FCA*, 2011 FCA 220, 94 CPR (4th) 95 (at para. 19, quoting trial decision: “In the case of the ‘735 Patent, the inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term.”). See also *Olanzapine*, 2011 FC 1288 (at para. 232: “The chronic nature of the condition treated by a patented compound must be taken into account when determining whether a patent’s promise has been

order to find utility. The concern for innovators of an elevated “promise” is a problem not only in litigation but also at the time of application filing. In either case it is uncertain how the Court will interpret the “promise” of the patent, particularly when it involved treatment of a chronic condition.⁸ The recent invalidations of the drug patents for *Strattera*, *Olanzapine* and *Latanoprost* on the basis of inutility highlight the constructions of the patent’s promise. In these cases, the Federal Court invalidated patents for the lack of proof of utility even though there was no evidence of actual inutility, and successful human clinical trial results were available at the time of filing. Further, all were successfully approved by the Ministry of Health in Canada for which generic companies were seeking to market their copies.

In *Strattera FCA*, Canadian Patent No. 2,209,735 (the “735 Patent”) claimed the use of atomoxetine for treating attention deficit hyperactivity disorder (“ADHD”) in adults, adolescents and children. The claimed utility was based on a 7-week, double-blind, placebo-controlled, cross-over trial to investigate atomoxetine’s use as an ADHD treatment. The Court construed the promise of the ‘735 patent as the use of atomoxetine to “effectively treat humans with ADHD” (at para. 19, quoting trial decision). However since ADHD may be characterized as a chronic disorder, the Court reasoned that proof of utility required sustained treatment and thus

demonstrated or can be soundly predicted”) and *Latanoprost FCA*, 2011 FCA 236, 95 CPR (4th) 193 (at para. 30: “In our case utility would be demonstrated if the patent disclosed studies showing latanoprost when administered on a chronic basis reduced intraocular pressure without causing substantial side effects.”).

⁸ See *Strattera FCA*, 2011 FCA 220, 94 CPR (4th) 95; *Olanzapine*, 2011 FC 1288; and *Latanoprost FCA*, 2011 FCA 236, 95 CPR (4th) 193.

held that the ‘735 implicitly promises “that atomoxetine will work in the longer term” (at para. 19, quoting trial decision). Consequently, the Court held that the utility requirement would be met only if there was sufficient evidence that, as of the Canadian filing date, atomoxetine was “clinically useful” in treating patients with ADHD in the longer term. The Court accepted generic arguments which speculated on inherent limitations of clinical trials (small sample size, too short of a trial, etc.) which paradoxically had been accepted by health regulatory authorities. On this basis, the Court held that due to the inherent limitations in the study, the results did not demonstrate the clinical usefulness of atomoxetine to treat ADHD. The patent was thus held invalid on the basis of inutility.

Similarly in *Latanoprost FCA* the Court of Appeal construed the promise of Canadian Patent No. 1,339,132 (the “132 Patent”) patent as treatment of glaucoma and ocular hypertension over the longer term. Overturning a lower Federal Court decision which found utility demonstrated in light of animal and healthy human study results, the Court of Appeal found it was an error to construe the promise without considering the nature of the disease it purports to treat effectively. In light of the fact that only single dose studies had been conducted, the Court of Appeal determined that the patent was based on a prediction rather than a demonstration, and found the patent to be invalid for not meeting the three-part sound prediction test. (No factual basis established by single dose studies as they are insufficient to support a chronic use; no line of reasoning which might be relied upon since references which form part of the art available at filing are insufficient (to support it); and consequently disclosure also found

insufficient.) Outcomes in cases like *Strattera FCA* and *Latanoprost FCA* call into question whether any drug patent directed toward treatment of a disease which may be characterized as a chronic disorder may be reliably sustained as its validity will depend on the subjective determination of the promise which may in turn require evidence of longer term proof of utility.⁹

Comparison of the Canadian Utility with International Standards

The Canadian requirements for proof of utility and that a patent disclose the basis of a sound prediction appears in conflict with the US and EU requirements that a patent simply contain an assertion of a specific and substantial utility and that the utility is in fact true. The focus of the utility inquiry, as was the case in *Canada pre-AZT*, is on utility in fact. Accordingly, an invention may not be patentable if it is alleged to operate in a manner clearly contrary to well-established physical laws (such as a perpetual motion machine¹⁰). While the European practice requires that the patents disclose the “industrial applicability” of the invention – i.e., the way in which the invention is capable of operation – it does not require the patent to contain proof of the operability of the invention¹¹.

The Canadian disclosure requirements for patentable utility thus appear at odds with international treaties such as the Agreement on

Trade Related Aspects of Intellectual Property Rights (TRIPS), the North American Free Trade Agreement (NAFTA), and the Patent Cooperation Treaty (PCT) which are consistent in their policies of providing a unified procedure for obtaining patent protection in member states. Both NAFTA and TRIPS expressly provide that “useful” and “industrial applicability” are synonymous. Article 27.1 of TRIPS and also Article 1709.1 of NAFTA both mandate that signatory nations such as Canada “shall” provide patent protection to inventions which are “new, involve an inventive step and are capable of industrial application.” Under generally accepted rules for interpretation of international treaties, Canada is not allowed to contravene a clear commitment to grant patents which it made as a signatory to the TRIPS Agreement or NAFTA.

Similarly, under the PCT applicants may seek patent protection in some or all of the 144 member countries by filing a single international application. The PCT requires that a claimed invention be industrially applicable, which as discussed above is satisfied if the invention can be made or used in any kind of industry¹². Like the European approach if the invention is alleged to have a “credible or plausible” utility, so long as the invention does not operate in a manner contrary to well-established physical laws, then the invention will be patentable as possessing industrial applicability¹³. Similarly, like the US approach, supporting submissions are required only in circumstances where the

⁹ See below for discussion of the novelty and obviousness “Catch 22” for patent applicants should they choose to delay filing while they await additional data supporting utility.

¹⁰ Guidelines for Examination in the European Patent Office, Part C – Chapter IV, Section 5.1.

¹¹ European Patent Convention, Articles 52 and 57.

¹² Patent Cooperation Treaty, Article 33(4).

¹³ Patent Cooperation Treaty International Search and Preliminary Examination Guidelines, Chapter 14; See also *Human Genome Sciences Inc v Eli Lilly & Co.*, [2011] UKSC 51 rev’g [2010] EWCA Civ 33 aff’g [2008] EWHC 1903 (Pat).

USPTO provides evidence that the stated specific and substantial utility is incredible¹⁴. Thus “useful” and “industrial applicability” are synonymous with the PCT and practically both the EU and US have approached the issue in the same manner. Further, while the PCT sufficiency requirements provide that the applicant disclose the invention in a manner sufficiently clear and complete for the utility of the invention to be carried out by a person of ordinary skill in the art, it does not require that proof of utility be contained within the application as filed¹⁵. Article 27 of the PCT specifies that no national law can require more than this.¹⁶ These provisions make it very clear that if the description is clear enough for one of ordinary skill to carry it out, no office can require more information in the specification as filed, though they certainly could require more information to establish inventive step, or utility, during prosecution.

innovators in a difficult “Catch 22” dilemma in view of the other substantive requirements for patentability. Should a patentee seek to comply with the enhanced obligations for proof of utility in Canada, they increase the risk of invalidity on the basis of novelty or obviousness. In other words, a patentee who might seek to establish utility for a drug which treats a chronic condition by conducting longer term clinical studies before filing their patent application would likely be exposed to an allegation of invalidity based on anticipation.¹⁷ It will be interesting to see how the Supreme Court of Canada may reconcile the utility requirements in light of international norms and treaty obligations.

Conclusions

The current trend of increasingly successful invalidations of drug patents under the Canadian utility requirements discussed above places

¹⁴ See *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 10-01500, 2011 BL 197400 (Fed. Cir. July 29, 2011).

¹⁵ Patent Cooperation Treaty, Article 5.

¹⁶ Article 27 of the PCT notes as follows: “(1) No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.”

2) The provisions of paragraph (1) neither affect the application of the provisions of Article 7(2) [relating to drawings] nor preclude any national law from requiring, once the processing of the international application has started in the designated Office, the furnishing:

---. 2. of documents not part of the international application but which constitute proof of allegations or statements made in that application.”

¹⁷ See *Strattera FC*, 2010 FC 915, 87 CPR (4th) 301 at paragraphs 46 through 48, where Novopharm argued that two oral conversations that fell outside the one-year grace period rendered the invention anticipated.