



IPO COMMITTEE NEWSLETTER

July 2010

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

Chair: Larry Welch, Eli Lilly & Co.

Vice Chair: Samson Helfgott, Katten Muchin Rosenman LLP

Board Liaison: Daniel J. Staudt, Siemens

CONTENTS

INPI Today Facts and Figures	2
<i>Claudio M. Szabas, ASPEBY – SZABAS, Rio De Janeiro, Brazil</i>	
Inequitable Conduct	4
<i>Janet I. Cord, Ladas & Parry, LLP, New York, New York</i>	
Why IP Owners Need To Worry About Privilege	5
<i>Leonora Hoicka, IBM Corporation, Armonk, NY</i>	
European Patent Office Changes Time Deadlines for Filing Divisional Applications	9
<i>Robert Smyth, Morgan, Lewis & Bockius LLP, Washington, D.C.</i>	
Argentine Tribunal of Second Instance Reversed a Ruling and Found Patent Infringed Awarding Monetary Damages	10
<i>Mariano Municoy, Moeller IP Advisors, Buenos Aires, Argentina</i>	
Obviousness Under Canadian Law	12
<i>Michael E. Charles, Bereskin & Parr, LLP, Canada</i>	

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, to provide background to IPO members. It should not be construed as providing legal advice or as representing the views of IPO.

INPI TODAY FACTS AND FIGURES

Claudio M. Szabas
ASPEBY – SZABAS
Rio De Janeiro, Brazil

On September 27, 2007, INPI, the Brazilian Patent and Trademark Office, was appointed by the General Assembly of the PCT Union as an International Searching Authority and Preliminary Examining Authority.

The fourth country in the world to enact a patent law in 1809, one of the founding members of the Paris Convention in 1882, member of the PCT since 1978 with its Patents and Trademark Office –INPI, acting as an RO, adopted from the very beginning English as the official language for filing international PCT applications. As a result of INPI's appointment, Portuguese became in 2007 the 9th filing and publication language of the PCT.

Some facts and figures

In 1998, the INPI (Brazilian PTO) patents database comprised about 25,000,000 references and an increase of 30,000 each month. However accurate these figures may be, the fact is that in the 90's it was not unusual to search for state of the art and prior art references in INPI on behalf of foreign patent associates practicing in countries of substantive patent examination.

Since 1998, a Master of Science degree has been a requirement to be admitted as a candidate for the Patent Examiners Training Program.

2006: the “year for change”

Since 2000, Brazilian patent examiners in Rio de Janeiro have been using the EPOQUE searching tool of the European Patent Office. Examinations, decisions, oral hearings, and file wrapper inspections take place in INPI – Rio de Janeiro.

In 2006, the INPI became the first Patent Office

outside the EPC to gain direct and permanent access to the EPOQUE Search Environment, which had been exclusive to EP member states' national offices.

Also in 2006, the number of patent examiners increased from 100 to 286, 30% of them holding a PhD degree. In 2009, INPI hired 50 additional examiners and presently, considering candidate dropouts, an average of about 300 patent examiners can be considered a conservative number.

Particularly, the number of examiners allocated to the examining divisions is about 45 Examiners to the Biotech division, 80% of them holding a PhD degree, 50 Examiners to the Physics/Electronics division (Difele), 50 Examiners to the Mechanical engineering division (Dipame), 40 Examiners to the civil engineering division (Dienci), 40 Examiners to the inorganic chemistry division (Diquin I), and 80 examiners to Diquin II, which examines pharmaceutical and polymer related inventions. Current expectations are that 180 additional candidates shall be admitted in 2011 while the goal is to achieve a staff of 600 patent examiners in 2014.

Fully versed with EPOQUE, and with BR patent applications already available on the espacenet, the INPI is providing the appropriate infrastructure as required in PCT/GL/ISPE/1 Chapter 21, Part VII addressing Quality, by also getting ready for the implementation of the EPIDOS, the European Patent Information and Documentation System, in addition to the existing managing tools envisioning examination in 2014 of patent applications filed in 2010 and as much as possible a paperless INPI.

Training “on-the-job”

As a rule of thumb, the performance and production of the new examiners should be equivalent to the corresponding ones of the senior examiner supervising the new examiners.

Action Examination	Product	Annual Forecast (A)	JAN	FEB	MAR	APR	Accrued (B)	Attained (B/A)%
Invoices and TT related Agreements	Decision on Invoices/ Agreements	1.540	115	110			225	14,61
Patent Applications	Decisions	14.380	283	1.484			1.767	12,29
Industrial Designs	Granted	5.000	249	208			457	9,14

This results in having three or four examiners being currently trained by each senior examiner. No random samples for assessing quality. Each and every office action undergoes a second pair of eyes review.

Well before INPI's appointment as ISA and IPEA, the well known training program agreements in different IPC areas with the respective EPO, German PTO, US, JPE, Chinese, and FrINPI patent offices continue to prepare Brazilian patent examiners to carry out substantive examination, improve their language skills, and disseminate this knowledge to patent examiners from Hispanic America, Africa and China who visit INPI. Continued education includes attendance at the Strasbourg University and the Max Planck Institute. In 2009, at least two patent examiners attended specific courses at Strasbourg University, 12 examiners were trained in the German PTO and some examiners spent 9 months in the USPTO.

The working group created in 2008 in order to establish procedures and requirements of administrative and technical implementation of a quality assurance program consists of a Coordinator, a Vice-Coordinator, 16 patent examiners representative of the aforesaid examining divisions, 3 administrative officers versed in PCT procedures, as well as a representative of CEDIN, the technological documentation center in charge for providing BR documentation to the espacenet. All members of the group are highly specialized in

quality management systems and / or industrial property (especially patents) and have counted with the participation of highly specialized consultants in quality management.

The above table is an excerpt of the Brazilian PTO results in 2010 (Demonstrativo da execução física- PPA2010, source www.inpi.gov.br).

On closing: **“Anything less than the maximal quality is bad for us”** is the concept of the Head Officer in charge for the implementation of the Quality Assurance Program and he goes further: **“The goal is the ISO9002 certification of INPI.”**

INEQUITABLE CONDUCT

Janet I. Cord
Ladas & Parry, LLP
New York, New York

The duty to disclose information that is material to patentability is found in 37 C.F.R. 1.56. This duty requires that each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the U.S. Patent and Trademark Office (PTO) which includes the duty to disclose to the PTO all information known to that individual to be material to patentability.

While this duty has been in place for many years, it has received more attention recently due to a series of cases including Therasense v. Dickinson, 953 F. 3d 1289 (Fed. Cir. 2010) that seems to be expanding the definition of what information must be brought to the attention of the examiner.

37 CFR 1.56 provides:

Information is material to patentability when is not cumulative of information already of record or being made of record in the application and (1) it establishes by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) it refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the office, or (ii) asserting an argument of patentability. A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden of proof standard, given each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 CFR 1.56 further states that "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."

Since the PTO does not investigate alleged inequitable conduct it is left to the courts to make this determination. A patent obtained through inequitable conduct is unenforceable. Inequitable conduct involves affirmative misrepresentation of a material fact, or failure to disclose material information with an intent to deceive the PTO. Materiality and intent to deceive are both required to establish inequitable conduct and according to the U.S. Court of Appeals for the Federal Circuit these are balanced to determine whether there is inequitable conduct. As intent to deceive may be difficult to prove, intent may be inferred from the circumstances.

In *Exergen v. Wal-Mart*, 575 F3d 1312 (Fed. Cir. 2009) the Federal Circuit stated that a pleading of inequitable conduct must include sufficient allegations from which a court may reasonably infer a specific individual knew of the withheld material information or of the falsity of the material representation; and withheld or misrepresented this information with specific intent to deceive the PTO.

In *Golden Hour Data Systems v. EMS Charts*, 91 USPQ2d 1556, (E.D. Tex. 2009) it was found that there was an inequitable conduct in failing to advise the examiner that a statement in the text of the application that certain objectives had not been achieved was incorrect when the applicant subsequently became aware of a brochure claiming that the objective had already been achieved by another party.

Failure to disclose official actions on related cases handled by other examiners who took a different view of the prior art was found to be inequitable conduct in *Larson Manufacturing Company v. Aluminart Products Ltd.*, 90 USPQ2d 1257 (Fed. Cir. 2009).

In *Therasense Inc. v. Becton Dickinson*, the Federal Circuit held that the failure to disclose

that the applicant had taken a different view as to the significance of a prior art reference in proceedings before the European Patent Office was found to be inequitable conduct.

On April 26, 2010 the Federal Circuit agreed to rehear *Therasense en banc*. The order from the Federal Circuit included six questions to be briefed:

- (1) Should the materiality - intent - balancing framework for inequitable conduct be modified or replaced?
- (2) If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?
- (3) What is the proper standard for materiality?
- (4) Under what circumstances it is proper to infer intent from materiality?
- (5) Should the balancing inquiry (balancing materiality and intent) be abandoned?
- (6) Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standard to be applied in the patent context?

Following its *en banc* rehearing order in *Therasense*, the Federal Circuit in *Optium Corporation v. Emcore Corporation*, 09-1265 (Fed. Cir. May 05, 2010) reiterated that inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to mislead or deceive the examiner, and those two elements materiality and intent must be proven by clear and convincing evidence. (Citation omitted.) When both materiality and intent have been established, the court must balance the equities and determine whether the applicant's conduct in prosecuting the patent application was egregious enough to warrant holding the entire patent enforceable.

In its decisions relating to inequitable conduct, the Federal Circuit has applied *Kingsdown Medical Consultants Ltd. v. Hollister Inc.*, 863 F. 2d 867, 876-77 (Fed. Cir. 1988) for the

proposition that the "intent" element of inequitable conduct is not simply intent to take the action or omission complained of but intent to deceive or mislead the patent examiner into granting the patent. In situations of non-disclosure of information rather than affirmative misrepresentation, clear and convincing evidence must show that the applicant made the deliberate decision to withhold known material reference. Thus "intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." (Citation omitted.)

Since the Federal Circuit has agreed to hear *Therasense en banc*, it would be expected that there may be changes to the way inequitable conduct is determined. However, in this author's opinion, while the Federal Circuit may offer further guidance in how inequitable conduct is determined it is unlikely to make sweeping changes in the requirements for finding inequitable conduct.

WHY IP OWNERS NEED TO WORRY ABOUT PRIVILEGE

Leonora Hoicka
IBM Corporation
Armonk, NY

Where (1) legal advice is sought (2) from a professional legal advisor in his or her capacity as such, (3) a communication relating to this purpose, (4) made in confidence (5) by the client (or attorney), (6) is, at the client's instance, permanently protected (7) from disclosure by the client or the legal advisor, (8) except if the privilege is waived.

This is a restatement of the classic formulation of the test for attorney-client privilege formulated by the American jurist, John Henry Wigmore, often referred to as the Wigmore test (see 8 Wigmore, Evidence, § 2285 at 527): *Bristol-Myers Squibb Co. v. Rhone Poulenc Rorer, Inc.*, 188 FRD 189, 189, 199 (SDNY

1999); *In re Rivastigimine Patent Litigation*, 2139 FRD 351 (SDNY 2006).

In *Sperry v. Florida*, 373 U.S. 379 (1963), the U.S. Supreme Court recognized that the work done by patent agents registered before the USPTO involves legal work “incident to the preparation and prosecution of patent applications before the Patent Office.” Following this decision, it was generally assumed that the confidential communications relating to patent preparation and prosecution were privileged, absent the client’s waiver of privilege, regardless whether such work was performed by a patent attorney (an individual called to a state bar or equivalent and registered before the PTO) or a non-lawyer patent agent acting independently (i.e., not on behalf of and under the direction of an attorney). In fact, this is not the case.

As uncovered in recent years in US and foreign litigation, there is a lack of harmonization on the privilege issue such that communications protected under the law of one jurisdiction may not be protected under the laws of another, and once produced without restriction in one state or country, are accessible through discovery elsewhere. This is particularly the case in respect of U.S. litigation. Disclosure of a confidential agent-client communication anywhere in the world will prevent the client from claiming privilege in U.S. discovery. Some countries have attempted to address this through legislation, with varying success.

While not an exhaustive survey, this article summarizes current pitfalls / attacks on privilege that should be considered in any strategy for handling a global patent portfolio.

Recognition of Privilege for Patent Agent Communications in the United States

Federal cases addressing the issue of privilege for non-attorney patent agent communications in light of *Sperry v. Florida* are divided. As stated in 1983 by the Supreme Court of California in *Welfare Rights Org. v. Crisan*, 33 Cal. 3d 766:

The majority view is that there is no privilege. (*Joh. A. Benckiser G.m.b.H., Chem. F. v. Hygrade Food Prod. Corp.* (D.N.J. 1975) 253 F.Supp. 999; see also *Duplan Corporation v. Deering Milliken, Inc.* (D.S.C. 1974) 397 F.Supp. 1146, 1169.) The minority position holds that the attorney-client privilege must be made available to communications of registered patent agents in order not to frustrate the congressional scheme. (*In re Ampicillin Antitrust Litigation* (D.D.C. 1978) 81 F.R.D. 377, 393-394 and cases cited at p. 392.) Said the court in the Ampicillin case: “That freedom of selection, protected by the Supreme Court in *Sperry*, would . . . be substantially impaired if as basic a protection as the attorney-client privilege were afforded to communications involving patent attorneys but not to those involving patent agents.” (Fn. omitted; *id.*, at p. 393.) The Ampicillin court, however, carefully limited the availability of the privilege to agents registered with the patent office and emphasized the fact that these agents are on equal footing with a patent attorney because they are subject to similar professional and ethical standards set by the patent office. (*Id.*, at pp. 393-394, fn. 32; see also 8 Wigmore, *supra*, § 2300a, at p. 582.)

This split in the case law continues to this day. Important commercial states such as Delaware and New York deny the applicability of privilege to client-agent communications absent an attorney directing the patent agent’s work: *Hercules, Inc. v. Exxon Corp.*, 434 F.Supp. 136, D.C.Del. (1977); *Willemijn Houdstermaatschaap BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1446, 13 U.S.P.Q.2d (BNA) 1001 (D. Del. 1989); *Detection Systems, Inc. v. Pittway Corp.*, 96 F.R.D. 152, (DCNY 1982); *Cargill, Inc. v. Sears Petroleum & Transport Corp.*, 2003 WL 22225580 (NDNY 2003); *In re Rivastigimine Patent Litigation*, 237 F.R.D. 69 (SDNY 2006) upheld on reconsideration in 239 F.R.D. 351.

In fact, in one of the most recent pronouncements on this issue, the Southern District of New York confined *Sperry v. Florida* to a narrow precedent:

To argue that because a patent agent competently engages in legal activities similar to those of an attorney, he should be accorded the status of an attorney is to turn the logic of *Sperry* on its head. *Sperry* held that although patent agents are not equivalent to attorneys, they may engage in the practice of law with respect to patent activities before the U.S. Patent Office, as authorized by Congress. Id. at 402, 83 S.Ct. 1322. But it does not follow that because the agent is permitted to engage in this defined subuniverse of legal practice, his activities are therefore equivalent to those of a practicing attorney.

Consequently, I decline to extend the attorney-client privilege to communications between clients and patent agents. (*In re Rivastigmine Patent Litigation*, supra.)

Meanwhile, the case law in other U.S. jurisdictions, including the District of Columbia, Florida, Illinois and Michigan, has evolved to provide that attorney-client privilege extends to registered patent agents, at least with respect to proceedings before the PTO: *In re Ampicillin Antitrust Litigation*, 81 F.R.D. 377 (DDC 1978); *In re Yarn Processing Patent Litigation*, 177 U.S.P.Q. 514 (S.D.Fla. 1973); *Mold-Masters Ltd. v. Husky Injection Molding Systems, Ltd.* 2001 WL 1268587 (N.D.Ill. 2001); *Dow Chemical Co. v. Atlantic Richfield Co.*, 227 U.S.P.Q. 129 (E.D.Mich. 1985).

Recognition of Privilege for Foreign Patent Agent Communications by US Courts

Notwithstanding the position of the courts of New York not to recognize attorney-client privilege for domestic patent agent communications, they are willing to consider the applicability of privilege to the communications of foreign patent agents. In 1992, the Eastern

District of New York found “that under British law, a British patent agent's communication with a domestic patent attorney is protected from disclosure. This court bases this conclusion on its interpretation of the Patent Act of 1988 together with domestic caselaw construing Great Britain's predecessor patent statute and British caselaw pertaining to a British patent agent's attorney client privilege.” (*Stryker Corp. v. Intermedics Orthopedics, Inc.*, 145 F.R.D. 298 (EDNY 1992)).

As explained by the Southern District of New York court in *In re Rivastigmine Patent Litigation*, supra, “[w]here, as here, a communication with a foreign patent agent or attorney involves a foreign patent application, as a matter of comity, courts look to the law of the country where the patent application is pending to examine whether that country's law provides a privilege comparable to U.S. attorney-client privilege.... That country's law will be followed unless doing so offends U.S. policy considerations.”

In the 1999 *Bristol-Myers* case cited above, the SDNY found that the communications from a French industrial property counsel were not entitled to evidentiary privilege comparable to attorney-client privilege as it was enjoyed by patent attorneys under United States law. France, a civil law jurisdiction, had no need for a common law type of privilege under its domestic litigation practice because of the lack of wide ranging discovery and the professional requirement to maintain confidentiality. Nevertheless, it subsequently enacted legislation similar to the British statute that had been found to confer evidentiary privilege on British patent agents in US litigation in the *Stryker* case.

New York and other states have also recognized privilege attaching to communications between a client and a Japanese patent attorney in view of the statutory privilege provided under Articles 197 and 220 of the Japanese Code of Civil Procedure: *Eisai Lt. v. Dr. Reddy's Laboratories Inc.*, 77 U.S.P.Q. 2d 1854 (SDNY 2005); *Murata Manufacturing Co., Ltd. v. Bel Fuse Inc.*, 2005 WL 281217 (E.D.Ill.).

In the 2006 *In re Rivastigmine Patent Litigation* case, referred to above, the SDNY reviewed several pieces of Swiss statutes obliging professionals, such as patent agents, to maintain the confidentiality of their clients' communications and found that these obligations could be overridden by court order. The NY court found that, by contrast, the evidentiary privilege, as defined under U.S. law, is absolute and can only be waived by the client. As a result, the Swiss confidentiality obligations could not be recognized as evidentiary privilege by US courts, and the communications in dispute could not be protected from discovery disclosure. In 2009, the Swiss government enacted legislation to regulate the patent profession and to create an attorney-client privilege relating to secrets entrusted to such patent professionals in the course of their work. This later statute has not yet, to the author's knowledge, been tested in U.S. litigation.

District Courts in some other states that refuse to recognize privilege for U.S. patent agent communications also refuse to recognize privilege attaching to the communications of foreign patent agents: see, for example, *Santrade, Ltd. v. General Elec. Co.*, 150 F.R.D. 539, 546 (EDNC 1993); *Duplan Corp. v. Deering Milliken, Inc.*, 397 F. Supp. 1146 (SDCA 1974); *Rayette-Faberge, Inc. v. John Oster Mfg. Co.*, 47 F.R.D. 524 (E.D.Wis. 1969).

Recognition of Privilege for Foreign Patent Agent Communications by Foreign Courts

As mentioned above, any disclosure of a confidential client-agent communication anywhere in the world destroys privilege in the U.S. Consequently, the other way in which confidential communications can be disclosed and become accessible to opposing parties in U.S. litigation is through discovery in foreign litigation. This has arisen, so far, in two other common law jurisdictions which have legal systems fairly similar to the U.S., Australia and Canada.

In Australia, privilege for patent attorney-client communications is found in section 200(2) of the Australian Patent Act 1990, which reads:

A communication between a registered patent attorney and the attorney's client in intellectual property matters, and any record or document made for the purposes of such communication, are privileged to the same extent as a communication between a solicitor and his or her client.

However, in 2004, the Federal Court of Australia construed the term "registered patent attorney" narrowly, limiting it to patent attorneys *registered in Australia*. This had the effect of denying privilege to the communications between the client and its U.K. patent attorney, notwithstanding the fact that the U.K. patent attorney's communications were privileged under U.K. law, pursuant to statutory privilege: *Eli Lilly & Co. v. Pfizer Ireland Pharmaceuticals* (2004), 137 F.C.R. 573 (Federal Court of Australia).

A number of Canadian decisions have held that communications between non-lawyer patent agents and their clients are not privileged. A leading Canadian decision is from the Canadian Federal Court of Appeal and states:

It is clear that, in this country, the professional legal privilege does not extend to patent agents. The sole reason for that, however, is that patent agents, as such are not members of the legal profession. That is why communications between them and their clients are not privileged even if those communications are made for the purpose of or giving legal advice or assistance. (*Lumonics Research Ltd. v. Gould, et al.* (1983), 70 C.P.R. (2d) 11 (FCA).)

It is also not settled law whether communications from Canadian patent agents who are also Canadian attorneys are privileged if the attorney/agent is acting in the capacity of a patent agent and not as a lawyer. A line of caselaw in the Federal Court suggests that it is necessary to consider what "hat" the lawyer/agent is wearing at the time the

advice/assistance was given, and that privilege may not apply if the lawyer was not acting in the capacity of a lawyer (e.g., was acting as an agent): *IBM Canada Ltd. v. Xerox of Canada Ltd. et al.* (1977), 32 C.P.R. (2d) 205 (FCA); *Montreal Fast Print(1975) ltd. v. Polylock Corporation* (1983), 75 C.P.R. (2d) 95 (FCTD); *Laboratories Servier v. Apotex Inc.* (2008), 2008 FC 321 (Fed. Ct.).

Finally, Canadian courts have applied the same standard to the communications of foreign patent agents, refusing to recognize privilege, even if the communications would be privileged where made: *Lilly Icos LLC v. Pfizer Ireland Pharmaceuticals* (2006), 55 C.P.R. (4th) 457 (Fed. Ct.) refusing to recognize the U.K. statutory privilege for patent attorneys recognized by New York courts.

Conclusion

The lack of harmonization on an effective privilege doctrine, uniformly protecting confidential legal advice and assistance from patent professionals to their clients bedevils the effective enforcement of a global patent portfolio. Because of the need to protect the disclosure of communications in any court in order to preserve privilege for U.S. litigation, patent holders may need to carefully consider the choice of venue for U.S. patent litigation and the timing of litigation outside the United States vis-à-vis the progress of a U.S. action. While this uneven global landscape for privilege continues, patent owners may even want to step back and review their patent procurement processes, to determine if special measures are required, in some states and countries, to add a layer of legal direction in order to preserve privilege.

EUROPEAN PATENT OFFICE CHANGES TIME DEADLINES FOR FILING DIVISIONAL APPLICATIONS

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

To further its goal of enhancing overall quality and legal certainty, the Administrative Council of the European Patent Office (EPO) voted on March 26, 2009 to amend EPC Rule 36 to establish time limits for filing divisional applications, thereby restricting the opportunity to file a “chain” of divisional applications.

Under the existing EPC Rule 36, a divisional application can be filed any time before grant, abandonment, or withdrawal of any pending parent application. Moreover, a “chain” or cascade of divisional applications may be filed indefinitely, allowing an applicant to maintain a series of pending divisional applications up to 20 years from the initial filing date.

The rule change to EPC Rule 36, however, will restrict the time window for filing divisional applications in two significant ways. First, divisional applications on the applicant’s own initiative (so-called voluntary divisional applications) will need to be filed within a two-year period from the date of the first communication by the EPO Examining Division with respect to the parent (i.e., previous) application or to an earlier application (in the case of a chain of applications). That would mean that, hypothetically, an applicant could voluntarily file a first divisional application from an original parent application, and a second divisional application from the first divisional application. However, both divisional applications would have to be filed within a period of two years from the date of the first communication (i.e., the Examination Report) by the EPO Examining Division on the original parent application.

Second, divisional applications filed as a response to an objection on lack of unity of invention (so-called “mandatory divisional applications”) will also have to be filed within a period of two years from the date of the communication by the EPO in which the relevant objection was raised for the first time. For example, if the EPO identified three different inventions (three-way non-unity of invention) on an original parent application, then the applicant would be required to file divisional applications for each of the two additional inventions within two years of that examination report. But if one of those divisional applications provoked a new objection on lack of unity of invention, then the date of the new objection would mark the beginning of a new two-year clock for filing divisional applications for the newly identified invention. It is interesting to note that this may also raise the possibility of creating chain divisional applications by deliberately including new claims in a divisional application to create a fresh lack of unity objection.

The EPO is expected to provide further clarifications regarding this rule change over the course of the next year, and it still remains unclear how the rule will be implemented in actual practice. This rule change to EPC Rule 36 will take force on April 1, 2010, and will provide a six-month grace period, lasting until October 1, 2010, for filing divisional applications under the existing rule outside of the new rule imposing the two-year time deadlines. This new rule represents a significant change in the ability to gain additional European patent coverage.

Applicants who would like to file divisional applications based upon existing patent applications should do so well in advance of the October 1, 2010 deadline given the likely rush by all parties to file divisional applications up to this deadline.

ARGENTINE TRIBUNAL OF SECOND INSTANCE REVERSED A RULING AND FOUND PATENT INFRINGED AWARDING MONETARY DAMAGES¹

**Mariano Municoy
Moeller IP Advisors
Buenos Aires, Argentina**

1. Importance of the Ruling

This is a very relevant local patent ruling in Argentina,² given the very small number of final decisions issued by the competent Court of Appeals³ over patent infringement, which has not reached even a case per year so far.

There are multiple reasons for this,⁴ but in this brief article we want to highlight the key points of the holding that illustrate some of the current trends when enforcing patents in Argentina.

Moreover, it is worth mentioning that the few final decision awarding monetary damages have applied generous standards for patentees, which, at least at some point, strengthen the value of local patents.

¹ Mariano Municoy, Argentine lawyer at Moeller IP Advisors, LL.M. in International Intellectual Property Law from Chicago-Kent College of Law (2004, USA) and LL.M. in Law and Economics from University Torcuato Di Tella (2009, Argentina).

² Decision of the Court of Appeals in Civil and Commercial Matters, Chamber III, date November 12, 2009 in re “Meril LTD v. Labyes SA y otro s/cese de uso de patentes, daños y perjuicios”, case no. 6631/03

³ Federal Judges on Civil and Commercial Matters have exclusive jurisdiction over patent cases regarding both their validity and infringement. Almost all patent cases are litigated in the City of Buenos Aires so the Court of Appeals on Civil and Commercial Matters sitting in this city have developed a “de facto” specialization.

⁴ Just to mention a few, it is worth mentioning that Argentina is not a member of the PCT, the existing backlog at the local PTO to examine and grant patents, the stricter requirements imposed by the reform of the Patent Law in 2004 (especially in relation to article 83) in order for judges to grant ex parte preliminary injunctions, among others.

2. Key Fact of the Case

According to the text of the decision, the key fact of the case to decide was whether patent No. 255,628 (Patent '628) protecting the active principle FIPRONIL, which has been broadly used as an insecticide since the middle of the 90's, was infringed or not.

Patent '628 was originally filed in Argentina under former Argentine Patent Law No. 111 by Rhone Poulenc Agroculture Limited (that later become Bayer Cropscience S.A.), which granted an exclusive license to Merial Ltd., the plaintiff in this case against Labyes S.A. (a local company dedicated to producing veterinary products) and other defendants.

The claim of Patent '628 on which Merial Ltd based its infringement action read as follows: "a derivative of N-Fenilpirazol excluding its use for the treatment of body animals carried out by a physician or veterinary as a therapy; a process to prepare it; a composition that encompass it; a method for the repression of plagues of arthropods, nematodes of plants, earthworm and protozoon as well as compounds useful as intermediaries."⁵

Therefore, the tribunal had to determine whether the infringing product was among the subject matter excluded from the claims or not.

According to the plaintiff, the infringing product was not a veterinary product so it should not be excluded from the reaching of the claims because it was used to clean the skin of animals from insects and acarus such as flea and ticks, which, in his view, was the right interpretation supported by the fact that veterinary and insecticides were included in different classes of the pertinent classification.

3. The Ruling

While in first instance the judge agreed with the defendant, in second instance, the tribunal

overturned that decision agreeing with the plaintiff.

Let us recall that under local law, determining the scope of patent claims is a legal issue to be exclusively decided by competent federal judges. In this case, the tribunal applied a standard consisting on analyzing the "intrinsic properties" of the active principle FIPRONIL, which was used in the infringing product.

Moreover, despite the fact that the tribunal recognized the technical complexities of the case related to chemistry and veterinary care, it stated that "common sense" played a very important role in the analysis of the case, which is a criterion incorporated in the Code of Civil and Commercial Procedures (article 163 paragraph 6).

Last but not least, the tribunal reviewed the contradictory opinions of the expert appointed by the court (a veterinary stating that the infringing product was not used to "cure" the organic alterations caused on animals by insects and acarus but this result was achieved by the same organism of the affected animal) and the one advising the defendant (a chemical engineer stating that the active principle was a drug). The tribunal pointed out the utility of the first opinion and disregarded the second one as biased.

4. Monetary Damages Awarded to the Plaintiff

Finally, the tribunal accepted the plaintiff's petition and awarded monetary damages applying the standards developed by local case law dealing with infringement of trademarks and patents, which are both subject matters over which federal judges on civil and commercial matters have exclusive jurisdiction and broad discretion.

Under these standards, the amount of damages was calculated as 30% of the commercial value of the infringing products (without using this term, the tribunals are applying the method of "reasonably royalty") or the 80% of the revenues

⁵ This is our own translation.

received by the infringer (this method would also be the equivalent to “lost of profits”).⁶

Therefore, the tribunal awarded damages for an amount of pesos 300,000 (\$1 (US) currently equals almost 4 pesos), which did not include interest because such a petition had not been made by the plaintiff at the beginning of the case.

OBVIOUSNESS UNDER CANADIAN LAW

Michael E. Charles
Bereskin & Parr LLP

Introduction

Canada has recently adopted “obvious to try” with the decision of the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc. (PLAVIX)*[1] in late 2008. The previous, long-standing Canadian obviousness test was more narrow and thus favoured patentees. It was derived from the approach of the U.K. courts before they adopted “obvious to try” decades ago and then expanded it to mere “worth a try,” leading the U.K. to be perceived as patent-hostile.

Now that Canada has adopted the U.K. and U.S. approach, the question is whether the climate for patentees will change. But the Supreme Court of Canada was careful to say that “obvious to try” would only invalidate where the invention was “more or less self evident” and cautioned that it is not “a panacea for infringers.” Subsequently, in deciding cases under the new obviousness standard, Canadian courts have been careful to apply the Supreme Court’s formulation, and not the U.K. “worth a try” test. Thus, overall, the Canadian obviousness test has been reformulated, but not substantially changed.

⁶ Similar standards were mentioned in a previous patent infringement case, re “IPESA SA versus Uniroyal Chemical Company INC s/acción meramente declarativa”, decided on March 14, 2006 by the Second Chamber of the same Court of Appeals.

The Supreme Court’s Decision in

The judge at first instance had upheld the patent at issue based on the prior, long-standing obviousness test:

“...The question to be asked is whether [the person of ordinary skill] would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.”[2]

The Supreme Court emphasized that obviousness is essentially a question of fact to be decided without verbal formulae[3], a “jury question.” It spoke of bringing Canadian law into harmony with U.S. and U.K. law, and particularly on the basis of the decision of the United States Supreme Court in *KSR*. [4] However, it ultimately adopted the four-step obviousness analysis of the English Court of Appeal in *Pozzoli SPA v. BDMO SA*[5]:

- (1) (a) Identify the notional “person skilled in the art”;
- (b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
- (3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed;
- (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?”[6]

It is in step (4) that “obvious to try” may arise. It depends on the field of technology. It applies where there is experimentation and empirical testing. The pharmaceutical field was specifically identified.[7]

In adopting “obvious to try,” the Supreme Court added a warning that it would not be a panacea for infringers.[8] Then, very significantly, it introduced the limitation formulated by the English Court of Appeal in the *Saint-Gobain* case[9]:

“[66] For a finding that an invention was “obvious to try,” there must be evidence to convince a judge on a balance of probabilities that it was more or less self-evident to try to obtain the invention. Mere possibility that something might turn up is not enough.”[10]

The “obvious to try” branch of the test was in turn broken down into non-exhaustive factors to be weighted according to the evidence in each case:

- (1) Is it more or less self-evident that what is being tried ought to work? Are there a finite number of identified predictable solutions known to persons skilled in the art?
- (2) What is the extent, nature and amount of effort required to achieve the invention? Are routine trials carried out or is the experimentation prolonged and arduous, such that the trials would not be considered routine?
- (3) Is there a motive provided in the prior art to find the solution the patent addresses?
- (4) The invention story, particularly fruitless alternatives pursued by the inventors.[11]

In the result the Supreme Court upheld the patent at issue applying the new obviousness test essentially based on the findings of fact of the judge at first instance.

How “Obvious to Try” Is Being Applied in Canada

The first, and most important decision on “obvious to try” after *PLAVIX* was that of the Federal Court of Appeal in *Apotex v. Pfizer (VIAGRA)*[12] in which the proper formulation of the “obvious to try” test and its application were determinative. At first instance, Pfizer’s second medical use patent for VIAGRA (sildenafil) for erectile dysfunction was held valid under the pre-*PLAVIX* obviousness test which excluded “obvious to try.”[13] In the U.K. however, several years earlier the Pfizer U.K. counterpart patent was found invalid as “worth a try” at trial and on appeal.[14] In its appeal in the Canadian proceeding, generic drug maker Apotex relied on the U.K. decisions as the blueprint for applying “obvious to try.”

The Court of Appeal had two main legal issues before it: firstly, does “worth a try” equate to “obvious to try,” and secondly whether an invention can be “obvious to try” even if expectations of success are that there is but a mere possibility that the invention will work.

On the first issue the Court concluded that “obvious to try” is to be applied precisely as formulated by the Supreme Court of Canada, and that it must be more or less self-evident that the invention will work, consistent with the Court’s emphasis on “very plain.” It was stressed that the mere possibility that something might turn up is not enough. Thus “worth a try” equates to something that is worthwhile trying, but not necessarily obvious.[15]

The second issue was essentially a corollary to the first. In both the Canadian and English cases it was found as a fact that expectations were that using sildenafil could work, and that it would be worthwhile trying. Sildenafil and compounds like it were one of many options. But in the U.K. this was combined with evidence of strong motive and the result was the invention was “obvious to try.” Essentially because the commercial upside of developing a successful oral erectile dysfunction medicine was so high, anything that could work would be tried and hence was “obvious to try”. But in Canada the

Court of Appeal rejected this aspect of the U.K. approach.[16]

The obvious to try test has been similarly applied in other cases involving pharmaceuticals at both the appellate[17] and trial levels.[18]

“Obvious to try” is having an effect in two particular areas in the pharmaceutical industry. These are salt selection inventions and drug formulations.

In the pharmaceutical field, the active medicinal ingredient is often commercialized in a salt form which gives it superior handling, processing, and storage properties. Some medicines are chemically unstable and salt selection can be the solution. However, there are about fifty pharmaceutically acceptable salts, and generally it is a matter of prioritizing the likely successful candidates and doing routine synthesis and formulation work until one or more are successful. This brings into play the “finite number of solutions” factor. Thus, Pfizer’s AMLODIPINE salt selection patent was held invalid under the new test.[19] Of course not all salt selection cases fit this fact pattern.

Drug formulations are used to facilitate administration of active medicinal ingredients, for example, to facilitate or improve oral dosing in tablet or capsule form. Formulation inventions which are a combination of known techniques, each of which has been selected and applied after experimentation, may not survive “obvious to try.”[20] The court has to be persuaded that the invention is more than the product of routine experimentation. Again, the result will be fact-driven and depend on the nature of the invention.

Conclusion

The obviousness test has been reformulated by the Supreme Court of Canada in *PLAVIX*, but not substantively changed. “Obvious to try” is only satisfied if it is “more or less self-evident” that the invention will work. In applying the new obviousness test, the Federal Court of Appeal

has distinguished it from mere “worth a try” and said that strong motivation will not render something obvious to try where expectations of success are merely that it *might* work.

Michael E. Charles, B.Eng.Sci. (Chem. Eng.), LL.B. is a partner with Bereskin & Parr LLP’s Litigation Practice group. Michael can be reached in Toronto at 416.957.1689 or mcharles@bereskinparr.com.

[1] *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.* (2008), 69 C.P.R. (4th) 251 (S.C.C.) (*PLAVIX*)

[2] *Beloit Canada Ltd. v. Valmet OY* (1986), 8 C.P.R. (3d) 289, at 297 (F.C.A.)

[3] *PLAVIX*, supra, note 1, para. 59

[4] *PLAVIX*, supra, note 1, para. 60

[5] *Pozzoli SPA v. BDMO SA*, [2007] F.S.R. 37, [2007] EWCA Civ 588

[6] *PLAVIX*, supra, note 1, para. 67

[7] *PLAVIX*, supra, note 1, para. 67

[8] *PLAVIX*, supra, note 1, para. 64

[9] *Saint-Gobain PAM SA v. Fusion Provida Ltd.*, [2005] EWCA Civ 177

[10] *PLAVIX*, supra, note 1, para. 66

[11] *PLAVIX*, supra, note 1, para. 69

[12] *Apotex Inc. v. Pfizer Canada Inc.*, (2009) 72 C.P.R. (4th) 141 (F.C.A.). The Federal Court of Appeal is the Canadian counterpart to the U.S. Court of Appeals for the Federal Circuit.

[13] *Pfizer Canada Inc. v. Apotex Inc.*, (2007) 61 C.P.R. (4th) 305 (F.C.)

[14] *Lilly Icos Ltd. v. Pfizer Ltd.*, [2001] F.S.R. 16, aff’d [2002] EWCA Civ 1 (C.A.)

[15] *Apotex*, supra, note 12, paras. 26-30

[16] *Apotex*, supra, note 12, paras. 43-45

[17] *Apotex v. Servier (Perindopril)*, 2009 FCA 222, affirming 2008 67 C.P.R. 4th 241

[18] *Sanofi-Synthelabo v. Apotex (Ramipril)*, 2009 FC 676, and e.g. *Eli Lilly v. Apotex*, 2009 FC 991, appeal pending as of March, 2010

[19] *Ratiopharm v. Pfizer*, 2009 FC 711, appeal pending as of March, 2010

[20] *Biovail v. Apotex* 2010 FC 46