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International Association for the Protection of Intellectual Property
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AIPPI Bureau

Greeting for the New Year

(John Bochnovic, President of AIPPI)
The year ahead will officially start the era of annual Congresses for AIPPI and, in the meantime, AIPPI's work continues at a more intense pace than ever with further work on our strategy review, amicus briefs and submissions, and greater cooperation and collaboration amongst non-governmental associations.

ASIPI Rocks in Punta Cana

(Felipe Claro, Vice President of AIPPI)
The recent ASIPI meeting in Punta Cana proved to be a useful place to interact with colleagues from the Americas and to promote the new AIPPI Central-America and Caribbean Regional Group.

The visibility of AIPPI at the European Commission and at OHIM

(Laurent Thibon, Deputy Secretary General of AIPPI)
An important step in the development of relations among AIPPI, the European Commission and OHIM has just been taken with the inscription of AIPPI in the Transparency Register of the European Union. At OHIM, AIPPI is now a member of the Observatory network.

Obituary for Martin J. Lutz (20 June 1939 to 29 December 2013)

(Thierry Calame, Reporter General of AIPPI)
Dr. Martin J. Lutz, former Secretary General and President of Honour of AIPPI, passed away on 29 December 2013, at the age of 74. AIPPI has lost one of its most esteemed and respected active members.

AIPPI 2014 Toronto Congress

AIPPI 2014 Toronto World Intellectual Property Congress, 14-17 September 2014

(Philip C. Mendes da Costa, Chair Organizing Committee)
The World Intellectual Property Congress is being designed to create a casual environment in which you can meet old friends and clients, and make new friends. Registration will open soon so keep a look out for the programme.

AIPPI 2014 Toronto World Intellectual Property Congress, 14-17 September 2014 (Sponsorship opportunity)

(Toronto 2014 Organizing Committee)
AIPPI 2014 Toronto World Intellectual Property Congress is approaching and the sponsorship brochure is now available. Sponsorship opportunities are going fast so we invite you to review the sponsorship brochure now.

Working Guidelines for the Toronto Working Questions

(AIPPI General Secretariat)
The Working Questions for Toronto 2014 are:
Q238 Second medical use and other second indication claims
Q239 The basic mark requirement under the Madrid System
Q240 Exhaustion issues in copyright law
Q241 IP licensing and insolvency

Please click the Question to access the respective Working Guidelines. We would like to encourage all members to actively support their National or Regional Group by participating in the study of the Questions. If you wish to participate, please report to the President and / or Secretary of your Group. We wish the Groups the best of success with their studies and are looking forward to receiving the Group Reports by **Monday 19 May 2014**.

AIPPI 2014 Toronto Congress, important dates and deadlines

(AIPPI General Secretariat)

- Opening of registration 31 March 2014
- Deadline for early bird registration fee 9 June 2014
- Deadline to regular registration fee 11 August 2014

For further details as well as all up to date information on the meeting we invite you to visit soon our meetings website www.aippi.net.

Forthcoming Events

March 2014: AIPPI IP Seminar 2014, 14 March 2014, KKR Hotel Tokyo

(Japanese Group of AIPPI)
For more information, please see the flyer and the registration form.

March 2014: Intellectual Property Seminar, ASIPI-ABAPI Sul, Porto Alegre, Brazil, 15 - 18 March 2014

(Brazilian Group of AIPPI)
For more information, please see: http://www.asipiportoalegre2014.com/en.

April 2014: AIPPI Turkey - 3rd IP Seminar, 7 - 8 April 2014, Harbiye Military Museum and Convention Center, Istanbul

(Turkish Group of AIPPI)
For more information, please see: http://www.aippiturkey.org/aippi_2014/en/

April 2014 French-Brazilian Seminar on the Functions of Intellectual Property Rights

With AIPPI support, a French-Brazilian Seminar will be held in Belo Horizonte on 8 and 9 April 2014 and in Rio de Janeiro on 11 April 2014. This Seminar will be an opportunity to share the experiences of academics and professionals of both countries.

Articles and notes

Australia: The High Court gives generics the rubber-stamp for “skinny labelling” (but no surprises on method of treatment patents)

(Matthew Swinn and David Fixler, Corrs Chambers Westgarth, Melbourne, Australia)
The High Court of Australia has confirmed that methods of medical treatment are patentable subject matter in Australia. However, it remains uncertain whether medical/surgical procedures are patentable. The High Court’s approach to infringement by supply is a welcome surprise for generic pharmaceutical companies.

Canada: IP Treaties in Canada’s Parliament

(Matthew Zischka, Smart & Biggar/Fetherstonhaugh, Toronto, Canada)
Canada’s government has taken the first step towards implementing the Madrid Protocol, the Singapore Treaty, the Nice Agreement, the Hague Agreement and the Patent Law Treaty into national law by tabling the treaties in its Parliament.

Chile: INAPI - Chile

(INAPI)
The National Institute of Industrial Property of Chile (INAPI) was appointed in 2012 as an Administration Office for the International Search and Preliminary Examination (ISA/IPEA) under the Patent Cooperation Treaty. It is the second ISA/IPEA office in South America, together with Brazil, and the second Spanish speaking office, together with Spain. Operation of this new office will start by the end of 2014. More information in www.inapi.cl/portal/prensa/607/w3-article-3467.html.

Also, the Chilean Agricultural Research Institute (INIA), through one of its branches, has been recognized as international authority for the deposit of microorganisms, according to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms. More information in www.wipo.int/treaties/en/registration/budapest/index.html.

Europe: European Commission calls for experts

(AIPPI General Secretariat)
Commission calls for experts to join its database of independent experts for research and innovation falling within the Horizon 2020 Programme.

Europe: OHIM Webinar on the new e-filing tool

(AIPPI General Secretariat)
OHIM has uploaded a recorded Webinar on the new e-filing tool, held on 27 November 2013.

France: Judgment of the Court of Justice of the EU Grand Chamber

18 July 2013, Case C-414/11
Daiichi Sankyo Co. v. DEMO Anonimos Viomikhaniki kai
Sanofi-Aventis Deutschland Emporiki Etairia Farmakon
(Catherine Mateu, Catherine Mateu, Paris, France)
The CJEU has ruled in a Greek patent / SPC case that article 27 of the TRIPS Agreement fell within the exclusive competence of the EU. This is a major decision in relation to international intellectual property law within the EU because all the TRIPS provisions may fall within the exclusive competence of the EU.

UK: Gilding the Lilly: Making Sense of the CJEU's recent SPC decisions

(Ed Oates and Frederick Nicolle, Carpmaels & Ransford LLP, London, UK)
AIPPI's seminar on the recent CJEU decisions concerning Supplementary Protection Certificates (SPCs), saw attendees from private practice, industry and the judiciary discussing whether the CJEU has now resolved the confusion left by Medeva, and where the law might go next.

US: Burden of Proving Infringement in Declaratory Judgment Action Brought by Licensee Rests with Licensor Patentee: United States Supreme Court in ***Medtronic***

(Kelly G. Hyndman, Sughrue Mion, PLLC, Washington, DC, United States)
The United States Supreme Court in *Medtronic v. Mirowski Family Ventures* overruled the Court of Appeals for the Federal Circuit which had held that, where a license prevents a patent licensor from making an infringement counterclaim, the licensee as a declaratory judgment plaintiff bears the burden of showing non-infringement. The U.S. Supreme Court disagreed with this holding, ruling that patentee always bears the burden of proving infringement.

AIPPI Bureau

Greeting for the New Year
(Article by John Bochnovic, President of AIPPI)

Dear AIPPI Members:

For almost all of you the New Year has arrived, and many of you are celebrating at this time the arrival of the Lunar New Year. I wish to extend to all of you on behalf of the AIPPI Bureau and General Secretariat, and on my own behalf, best wishes for good health, happiness and prosperity in the New Year.

This year stands to be memorable for myself and my colleagues in the Canadian Group as we prepare to host the AIPPI Congress in Toronto on September 14-18. It has been almost 20 years since the AIPPI Congress in Montreal and in the interim, the world has been transformed by technology, social media and the Internet, all creating novel issues and challenges for IP laws.

The Toronto Congress is expected to officially start the era of annual Congresses for AIPPI. However, those who attended the highly successful AIPPI Forum/ExCo in Helsinki in September recognised that with a record turnout of over 1000 it felt like a Congress on a somewhat smaller scale. The superb meeting in Helsinki confirmed at least to me that AIPPI is ready for a major annual meeting, while continuing to promote and support smaller meetings on a regional or national basis by those Groups interested.

A year ago, I wrote that the process of change and reform following the Strategy Project Report and Recommendations would continue beyond Toronto, and it will. In Toronto, there will be an opportunity for important discussion of further recommendations and changes. I would like to assure you that there has been ongoing work on this front, notwithstanding that you may not have received during this past year a high-volume of communication relating to changes to come forth from the Strategy Project. Many of you are aware of the Bureau Advisory Committee of highly experienced AIPPI members looking at the role and structure of the Bureau, Council of Presidents and Executive Committee of AIPPI. Ongoing review and revision of the AIPPI Statues and Regulations continues and with the leadership of John Osha, AIPPI is moving forward this year with a new website.

In the meantime, the essential work of AIPPI continues at a more intense pace than ever, having regard, for example, to the amicus briefs and other submissions of this kind which have been prepared and presented during the last six months. This activity not only raises the profile of AIPPI. More importantly, it truly has the possibility of influencing the development of IP law in key jurisdictions. AIPPI can play a uniquely neutral role in presenting its position (based on its resolutions), as well as the positions from around the world, in respect of specific legal issues. I urge all of you to bear this in mind when important cases or legislative debates arise in your respective countries, where a submission to a court or legislature on the part of AIPPI may be appropriate.

A theme which has surfaced during the past year is a desire for greater cooperation and collaboration amongst non-governmental associations. I foresee that AIPPI stands to benefit by more actively engaging in discussion and joint activity with major international non-governmental associations. The success of the joint effort with AIPLA and FICPI in the June 2013 Privilege Colloquium held in Paris provides an excellent example of the strength attained by joining with other associations in a common cause.

For me personally and for many members of the AIPPI family, 2014 started on a very sad note when we learned of the untimely and accidental death of Martin Lutz. I was fortunate in having had the opportunity to already be actively involved in AIPPI during the time when Martin led the Association in his role as Secretary General. Martin was a President of Honour and it was a testament to the strength and vision of his leadership which did so much to shape AIPPI.

I extend a heartfelt thank you to all those of you who contribute so much of your time and energy to the success of AIPPI. I include here of course my colleagues on the Bureau and in the General Secretariat, who have provided me with such splendid support during my Presidency. All of us look forward to seeing as many of you as possible during our travels this year as well as in Toronto in September!

ASIPI Rocks in Punta Cana
(Article by Felipe Claro, Vice President of AIPPI)

ASIPI Rocks in Punta Cana

On December 1-4, 2013 ASIPI had its annual meeting in Punta Cana, Dominican Republic.

Many professionals, local authorities and NGO representatives from different countries shared IP experiences in a friendly environment. The meeting had more than five hundred attendees at the huge Hard Rock Cafe Hotel. The initial fear that attendees would prefer the beach more than the working sessions vanished when attendees realized that it was necessary to take a tram to get from the convention area to the sea.

The Dominican ASIPI Vice-President, Pilar Troncoso, and its President, Juan Vanrell welcomed the overseas visitors and explained the program and planned activities.

International and local speakers debated interesting topics such as fluid trademarks, cloud computing, data protection, green marketing, social media IP tools, the fashion industry, IP valuation. Also, there was a panel on plain packaging and it considered the recent AIPPI resolution on this subject.

There were active discussions throughout the whole conference and interesting views on IP were presented to the audience that led to prolonged discussions outside the formal conference meetings.

The President of ASIPI surprised the ASIPI members with the launch of the ASIPI cloud system, consisting of an online working environment permitting access to ASIPI documentation and information from handheld devices. The new system included a special gift to ASIPI members, consisting of a Kindle with which it is possible to access all the ASIPI information uploaded by the association in the cloud.

The social program was very well organized and added a local Caribbean flavor to the event.

The attendees were happy with the outcome of the event and a very positive feedback was received by the Organizing Committee who felt that the meeting had been a tremendous success.

ASIPI invited the attending representatives of several NGO/National associations to share opinions and ideas about the current status of IP in the Americas and useful information was obtained from people taking part in the conversation.

On the second day, the recently created AIPPI Regional Group for Central America and the Caribbean organized a working breakfast to put together as many of its new members as possible. The breakfast was a tremendous success and was attended by more than 40 people who had some trouble fitting inside the breakfast room. The Group's new President, Edy Porta, l addressed the new members and then spoke personally to many attendees to answer questions and dispel doubts about the operations of the new Group. Some non-AIPPI members also attended the breakfast as a result of the great interest the new Group had generated in the region. AIPPI's Secretary General Team was represented by the Assistant Secretary General, Sergio Ellmann, from Argentina, and Cinzia Petruzzello, from AIPPI's Secretariat in Switzerland was also present. Also, Cinzia ran the AIPPI official booth during the meeting.

A fruitful conversation was held with the INTA new Chief Executive Officer. Etienne Sanz de Acedo, in which the possibility of organizing a joint event between both associations was discussed. In principle, a seminar on trademarks and designs might be organized in Singapore in 2015. More plans and details would need to be co-ordinated with Carla Schwartz from INTA. This was in line with the strategic planning of both associations, which were interested in working with key leaders and organizations of the IP community.

The visibility of AIPPI at the European Commission and at OHIM (Article by Laurent Thibon, Deputy Secretary General of AIPPI)

For several months, the Bureau has been working to develop stronger relations among AIPPI, the European Commission and OHIM. An important step forward took place on November 18, 2013 when the European Commission granted to AIPPI its inscription in the Transparency Register of the European Union. AIPPI is registered in Section III - Non-governmental organizations - platforms and networks and similar.

Such a step is essential to establish regular communication among AIPPI, the European Commission and its agencies. In particular, this inscription in the Transparency Register was a prerequisite for obtaining official status at OHIM.

On January 16, 2014, AIPPI was granted the status of observer at OHIM and became a member of the Observatory network (private sector stakeholders). As a consequence, AIPPI will now be invited as a member at the EU Observatory Meetings and will be able to participate in Working Groups at the Observatory.

The next step will be for AIPPI to obtain the status of observer at the Administrative Board and Budget Committee (ABBC) of OHIM. The application has been filed and is still pending.

Based on this new status of AIPPI at the European Commission, the Bureau will increase, either directly or through appropriate committees, the interaction of AIPPI with the European Commission and with OHIM.

For instance, this recent inscription of AIPPI in the Transparency Register will be used very soon by the Copyright Committee to file submission in response to a consultation on the review of the copyright system opened by the European Commission.

Obituary for Martin J. Lutz (20 June 1939 to 29 December 2013) (Article by Thierry Calame, Reporter General of AIPPI)

Dr. Martin J. Lutz, former Secretary General and President of Honour of AIPPI, passed away on 29 December 2013, at the age of 74. AIPPI has lost one of its most esteemed and respected active members.

Martin Lutz studied law at the Universities of Berlin, Munich, and Zurich. After his graduation in 1963, he became head of the legal department at SUISA, the Swiss collecting society for music authors and publishers. In 1964, he received his doctorate under Professor Pedrazzini with a dissertation on the limitations of copyright. In the same year he was also admitted to the bar.

Following his work at SUISA, Martin obtained a master's degree at the University of Michigan in Ann Arbor, USA, in 1967. That same year, he joined the law offices of Staehelin & Giezendanner, that later became Staehelin, Hafter, Jagmetti, Lutz & Partner and is today's firm Lenz & Staehelin. In 1972, Martin Lutz became partner and in 2005, counsel of Lenz & Staehelin.

In the almost 50 years of his professional career, Martin Lutz acted predominantly as an advisor and litigator in the area of patent, copyright and trademark law. Martin Lutz was also very active in the areas of media law, arbitration, corporate and trust law as well as tax law.

Martin always addressed legal issues with imagination and wit. Hardly ever was there a problem he could not solve. His legal analysis was crystal clear and his writings remarkably concise.

Martin Lutz was not only a passionate attorney but also an esteemed teacher. Over the decades, he introduced many young people to the world of intellectual property law. Many of today's Swiss IP specialists were trained by him and benefited from his knowledge and vast experience.

As longstanding Secretary General and President of Honour of AIPPI, Martin Lutz played an extraordinary role in shaping this Association. Martin Lutz was Assistant Secretary General and Deputy Secretary General from 1983 to 1989 and Secretary General from 1989 to 1998. Under his able management, AIPPI became more modern and effective: the Bureau was strengthened, a professional General Secretariat — still based in Zurich — was created, and effective working methods for dealing with current IP issues on a multijurisdictional level were developed and gradually enhanced.

In recognition of his extraordinary services for AIPPI and his outstanding contribution to the worldwide protection of intellectual property, Martin was elected President of Honour in 2000.

With his strong and charismatic personality, Martin certainly was an impressive and imposing figure. He will be missed greatly.

AIPPI 2014 Toronto Congress

AIPPI 2014 Toronto World Intellectual Property Congress Congress, 14-17 September 2014 (Article by Philip C. Mendes da Costa, Chair Organizing Committee)

The World Intellectual Property Congress of AIPPI is fast approaching. The program is in the final stages of preparation. The meeting is in Toronto — Canada' s world-class city - from 14 to 17 September 2014. The Congress is being designed to create a casual environment in which you can meet old friends and clients, and make new friends. Please keep a look out for the programme and register early.

The opening night reception will be held in our world-class symphony hall and will feature some of the best entertainment Canada has exported. For the cultural evening, we will recreate the different regions of Canada so that you can sample the music and cuisine of all parts of Canada, all without leaving Toronto. The Closing dinner will provide a spectacular performance, the details of which are being kept as a surprise.

The Organizing Committee expects that the memories of the AIPPI 2014 Toronto Congress will endure for a very long time.

AIPPI 2014 Toronto World Intellectual Property Congress, 14-17 September 2014 (Sponsorship opportunity) (Article by The Toronto 2014 Organizing Committee)

AIPPI 2014 Toronto World Intellectual Property Congress is taking place from 14 to 17 September in Toronto, Canada. We expect to welcome more than 2000 participants from all over the world. This is a unique opportunity to reach a wide audience of intellectual property professionals by becoming a sponsor, an exhibitor or even a media partner for this event. The following options are available:

Sponsorship
There is a wide range of items and social events available to choose from. Sponsorship not only creates visibility tailored to meet your specific marketing requirements but also gives you the opportunity to enhance your organization's recognition.

Exhibition
As an exhibitor at the AIPPI international Congress in Toronto you will gain full access to the wide-ranging exhibition area. Becoming an exhibitor not only gives you the opportunity to meet the participants, but also allows you to network with other exhibitors who are active in the intellectual property field. We would be pleased to reserve space for you.

Advertisements
We offer advertising space in a number of publications that will be available both prior to and during the Congress, including the Congress brochure and the list of participants. Both publications will be distributed to all attendees of the Congress.

Don't miss this exciting opportunity - 14 September is rapidly approaching and a number of items and events have already been spoken for. For further information please refer to our Sponsorship & Exhibition Brochure which is available at: https://www.aippi.org/download/toronto14/Sponsorship.pdf

Thank you for your interest and for supporting the AIPPI international IP Congress in Toronto!

Working Guidelines for the Toronto Working Questions
(AIPPI General Secretariat)

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(Turkish Group of AIPPI)

For more information, please see: http://www.aippiturkey.org/aippi_2014/en/

French-Brazilian Seminar on the Functions of Intellectual Property Rights

The French-Brazilian Seminar on the Functions of Intellectual Property Rights is a joint effort of academics and professionals of both countries and will be held in Belo Horizonte on 8 and 9 April, and in Rio de Janeiro on 11, April, 2014.

The functions of IP rights have been discussed in various jurisdictions for several decades and are essential to determining their importance to society. As part of a broader legal system, concurrent rights will always influence the protection of IP rights. Harmonizing IP rights and concurrent rights is not an easy task and will vary depending on the particularities of each jurisdiction. For example, the functions of IP rights might not be the same in developed and emerging countries.

Therefore, the purpose of these conferences is to gather IP rights holders, professors and professionals to discuss and compare developments in the functions of IP rights in France, the European Union and Brazil. During these conferences, speakers will discuss the functions of patents, trademarks, industrial designs and copyright.

Program:

Welcome speeches

General Introduction

- Social Function of Intellectual Property Rights
- Consumers and Intellectual Property Rights

Panel on Distinctive Signs Law

- Trademark functions in Brazilian Law — The Social Function
- The Ascent of Trademark Functions in European and French Law

Panel on Patent Law

- Limitations of Patent Rights in Europe and France
- Patent and Public Interests in Brazil

Panel on Design and Copyright

- Design and Copyright Functions in France and Europe
- Harmonizing Design and Copyright Rights with Public Interest in Brazil

Closing Ceremony

More details will be available soon.

Supporting institutions:

- Federal University of Minas Gerais
- Universidade Cândido Mendes
- Centre d'Études Internationales de la Propriété Intellectuelle — CEIPI
- CERDACC — Université de Haute Alsace
- AIPPI - Association Internationale pour la Protection de la Propriété Intellectuelle
- CNCPI
- Associaçao Brasileira da Propriedade Intelectual — ABPI

Supporting firms:

- Cabinet d'Avocats Fidal
- Cabinet d'Avocats AKHEOS
- Martignoni, Tinoco & Moraes Advogados Associados
- Leao Propriedade Intelectual
- De Lima Assafim Advogados Associados

Articles and notes

Australia: The High Court gives generics the rubber-stamp for "skinny labelling" (but no surprises on method of treatment patents)

(Matthew Swinn and David Fixler, Corrs Chambers Westgarth, Melbourne, Australia)

The *Sanofi v. Apotex* case [2014] HCA 50 (http://www.austlii.edu.au/au/cases/cth/HCA/2013/50.html) concerned Sanofi's patent to a method of using leflunomide to treat psoriasis. Apotex wished to introduce a generic version of leflunomide and its product information did not include psoriasis as an approved indication (its product was indicated for the treatment of psoriatic arthritis and rheumatoid arthritis).

The case before the High Court had two aspects:

1. Apotex's contention that methods of medical treatment are not patentable subject matter; and

2. Sanofi's argument that Apotex was liable under the infringement by supply provisions (s117) as it had "reason to believe" that its product would be put to an infringing use (i.e. used to treat psoriasis).

Method of treatment patents in Australia

While the High Court had not previously considered the issue, it was fairly well understood from decisions of lower courts that methods of treatment were patentable under Australian law.

In confirming that methods of treatment are patentable subject matter, the High Court was influenced by:

A. the absence of any express exclusion to the patentability of methods of medical treatment in the Patents Act;

B. the anomaly that would exist if pharmaceutical products were capable of being patentable but methods of treatment were not;

C. the recognition that methods of medical treatment satisfy the test for patentable subject matter set down by the High Court in the NRDC case (i.e. they are capable of producing an "artificially created state of affairs" and have economic utility); and

D. the lack of any basis to distinguish between methods of treatment that are medical and those that are "cosmetic" (the latter were found to be patentable in a previous case).

While Justices Crennan and Kiefel acknowledged that they did not need to address the issue in the context of this case, they observed that the activities or procedures of doctors may not be patentable subject matter in Australia.

The High Court's finding on infringement

In relation to the question of infringement, the Court identified that direct infringement could only be established if the product (leflunomide) is applied to treat the condition of psoriatic arthritis.

The High Court found that the method of treatment claim was "confined to" the "specific purpose" being the "unknown therapeutic use of leflunomide". This suggests that the purpose of the administration will be regarded as an essential feature of the claim and, it follows, that where there is an intention to use of the known product for another therapeutic purpose (not claimed), there will be no infringement.

Sanofi, therefore, relied on the infringement by supply provisions in the Act (s117). It needed to show that Apotex had "reason to believe" that its product would be put to an infringing use.

The High Court held that because Apotex's product information expressly stated that its product was not indicated for the condition described in the patent, Apotex did not infringe.

Reading the tea leaves

The High Court's finding that the practice of "disclaiming" a claimed medical use in product information and when obtaining regulatory approval is sufficient to prevent the supply of that product constituting an infringement, is inconsistent with the decision below and the position judges have taken in other cases. The counter-argument, which had enjoyed success (including in many interlocutory decisions), was based on an acceptance that the instructions or "carve out" in the product information would be ignored by prescribing doctors and pharmacists.

On balance, the decision seems to endorse the practice of disclaiming conditions that are covered by method of treatment claims (which has been referred to as "skinny labelling"). This will clearly be a source of frustration for patentees and of comfort for generic pharmaceutical companies keen to market new generic drugs for non-patented indications/uses whilst carving out any remaining patented indications/uses.

IP Treaties in Canada's Parliament
(Article by Matthew Zischka, Smart & Biggar/Fetherstonhaugh, Toronto, Canada)

On January 27, 2014, the Government of Canada simultaneously tabled five significant intellectual property law treaties in Canada's Parliament:

1. the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks;

2. the Singapore Treaty on the Law of Trademarks;

3. the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks;

4. the Hague Agreement Concerning the International Registration of Industrial Designs; and

5. the Patent Law Treaty.

The tabling of the treaties in Parliament is the first formal step in ratifying these treaties. The Government will now observe a waiting period of at least twenty-one sitting days. It is expected that some time after the waiting period, the Government will introduce implementing legislation in Parliament to conform Canada's intellectual property statutes and regulations to the treaties. Only once such implementation legislation is enacted, will Canada be formally bound by these treaties.

INAPI - Chile
(INAPI)

The National Institute of Industrial Property of Chile (INAPI) was appointed in 2012 as an Administration Office for the International Search and Preliminary Examination (ISA/IPEA) under the Patent Cooperation Treaty. It is the second ISA/IPEA office in South America, together with Brazil, and the second Spanish speaking office, together with Spain. Operation of this new office will start by the end of 2014. More information in www.inapi.cl/portal/prensa/607/w3-article-3467.html.

Also, the Chilean Agricultural Research Institute (INIA), through one of its branches, has been recognized as international authority for the deposit of microorganisms, according to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms. More information in www.wipo.int/treaties/en/registration/budapest/index.html.

European Commission calls for experts
(Text by AIPPI General Secretariat)

OHIM has uploaded a recorded Webinar on the new e-filing tool, held on 27 November 2013. The European Commission has launched a call for expression of interest for experts to evaluate proposals under Horizon 2020, the EU's new funding instrument for Research and Innovation (2014-2020).

For more information: http://ec.europa.eu/research/participants/portal/desktop/en/experts/index.html .

OHIM Webinar on the new e-filing tool
(Text by AIPPI General Secretariat)

OHIM has uploaded a recorded Webinar on the new e-filing tool, held on 27 November 2013. It introduces completely fresh navigation and filing features, a new classification guide, new options for users requiring advanced functionalities, and guidance on the e-filing process for first-time users. The webinar covers the new functionalities through the main e-filing steps: introduction of basic application data, creation of lists of goods and services, submission and payment. It includes also the questions and answers deriving from the event.

Judgment of the Court of Justice of the EU Grand Chamber 18, July, 2013, Case C-414/11 Daiichi Sankyo Co. v. DEMO Anonimos Viomikhaniki kai Sanofi-Aventis Deutschland Emporiki Etairia Farmakon
(Article by Catherine Mateu, Catherine Mateu, Paris, France)

The case was heard upon referral from the Court of First Instance in Athens, in a case in which the patent owner and its distributor ("the Plaintiff") were opposed to a party ("the Defendant") that had received an authorization to market generic medicines. The Plaintiff's patent application, filed in 1986 and extended by a supplementary protection certificate ("SPC") in 2006, contained claims for the protection of a chemical compound and for the process of its manufacture. However, Greek courts ruled that, based on reservations to the European Patent Convention ("EPC"), Greece's Industrial Property Office was prohibited from granting patents on pharmaceutical products.

The CJEU was asked whether, in light of the TRIPS Agreement and in particular Article 27, which provides for the patentability of pharmaceutical products, the SPC also covered the pharmaceutical product itself.

According to the referring court, Greek courts disagree on the TRIPS provisions regarding the patentability of pharmaceutical products. Also, the referring court was uncertain whether the CJEU should interpret these provisions.

In its judgment, the CJEU decided (1) that article 27 of the TRIPS Agreement is covered by the Common Commercial Policy and therefore falls within exclusive EU competence, (2) that pharmaceutical products are patentable, and (3) that articles 27 and 70 of TRIPS do not grant a right to extend the patent to the protection of the product itself if an application was granted for the manufacturing process only.

This referral has broad implications for Community competence on substantive patent law, and on conflict of law rules over time.

1. COMPETENCE

The first issue raised was whether article 27 of TRIPS falls within the primary competence of EU member states, and if so, whether national courts may grant direct effect to this provision.

Contrary to the Advocate General's observations, the CJEU held that article 27 falls within the exclusive competence of the EU, including the Common Commercial Policy and particularly "commercial aspects of intellectual property." The Court also noted that its opinions prior to treaty modifications were no longer applicable.

Based on these findings, the CJEU stated that there was no need to consider whether national courts may accord direct effect to Article 27.

This is a major decision in respect of international intellectual property law within the EU because all the TRIPS provisions may fall within the exclusive competence of the EU.

First, with regard to the eventual "direct effect" of TRIPS, it is no longer a question of national laws of member states (as held in case C-431/05). From now on, presumably, member states will not be able to give direct effect to TRIPS provisions, but can interpret Community law "as far as may be possible in the light of the wording and purpose" of TRIPS (Dior case C-300/98 and 392/98, and Merck case C-431/05), as the CJEU had held that TRIPS had no direct effect (Dior case C-300/98 and 392/98).

Second, all TRIPS provisions may fall within the exclusive competence of the EU. Certainly, many provisions of intellectual property law have been harmonized, restricting the competence of member states to a very narrow field. However, this finding may lead, as the Advocate General wrote, to "the general and immediate ' expulsion' of the Member State from the negotiations of such agreements", and to affect indirect harmonisation. As a result, almost no intellectual property law provisions are left to EU member states.

2. THE PATENTABILITY OF PHARMACEUTICAL PRODUCTS

The second question, which raised fewer issues, was whether the invention of a pharmaceutical product, is patentable subject matter in the sense of Article 27 of TRIPS.

The CJEU held that Article 27 must be interpreted as meaning that the invention of a pharmaceutical product can be patentable subject matter.

3. TEMPORAL EFFECTS

The third question was whether, based on TRIPS, a patent granted only for the process of manufacture of a pharmaceutical product protected the pharmaceutical product itself.

The CJEU held that a patent obtained for a manufacturing process, following an application claiming the invention of both a product and its manufacturing process, did not automatically grant patent protection on the product.

Because of the Greek reservation to the EPC, the Plaintiff, which had filed a patent application for both a pharmaceutical product and its manufacturing process, could obtain a patent on the process only. Patent protection was extended by an SPC.

In 1995, the year when TRIPS entered into force, the patentability of pharmaceutical products was possible in Greece, as its reservation had expired in 1992.

The fundamental issue was whether the SPC granted to the Plaintiff in 2006 also covered the pharmaceutical product itself.

The CJEU noted that the SPC was subject to the same limitations as those affecting the basic patent, and that it was for the referring court to verify whether the reservations to EPC applied to national patents.

The CJEU held that TRIPS provisions could not grant to a patent effects it never had. This non-retroactive application of intellectual property laws appears quite common to practitioners.

Considering that reservations to EPC on patentability of pharmaceutical products were made only by Austria, Spain and Greece (the last ones expired in 1992), and that patent protection is granted for 20 years from the date of its application, the consequences of this particular issue appear limited.

Gilding the Lilly: Making Sense of the CJEU's recent SPC decisions

(Article by Ed Oates and Frederick Nicolle, Carpmaels & Ransford LLP, London, UK)

Looking at the background to *Lilly* (C-493/12), Actavis (C-443/12) and *Georgetown II* (C-484/12), it was noted that the CJEU decisions over the last few years had inadequately clarified the meaning of Article 3(a) of the SPC Regulation. The statement in *Medeva* (C-322/10) that the product must be "specified" in the wording of the claims of the basic patent had added to the confusion. Ambiguous remarks in the recent CJEU decisions had similarly led to uncertainty over whether a one-SPC-per-patent rule should be applied universally.

The speakers noted that a recurring and unhelpful theme in the cases under discussion was the CJEU's preference to deviate from the precise questions referred to it. In *Lilly*, for example, the CJEU was asked specifically to explain the criteria applicable under Article 3(a) of the SPC Regulation. However, the CJEU redefined the question, asking whether "in order for an active ingredient to be regarded as 'protected by a basic patent in force'..., the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula..."

The CJEU held that the answer is a matter of national law, but did add that the rules governing infringement are irrelevant. So, it was suggested that the test might not be so much an "infringement test" (i.e requiring an infringing act, a complication which the CJEU appears keen to avoid) but rather a "falling in the

scope of the claims" test. The Court also stated that functionally defined claims must relate "implicitly, but necessarily and specifically, to the active ingredient in question", words which will inevitably cause further argument.

In *Actavis*, the referred questions concerned firstly whether the term "diuretic" specified or identified hydrochlorothiazide, and secondly whether a second SPC to a combination of irbesartan and hydrochlorothiazide is invalid because the patent had already supported an SPC to irbesartan alone. The CJEU declined to answer the first point and redefined the second, asking if the patentee could obtain "on the basis of that same patent but an MA for a different medicinal product containing that active ingredient in combination with another active ingredient which is not protected as such by the patent, a second SPC relating to that combination of active ingredients." It was suggested that the statement that "hydrochlorothiazide... is not protected as such" was a reference to the absence of a claim to the individual compound, rather than a suggestion that the term "diuretic" is too broad to "protect" hydrochlorothiazide.

In *Georgetown II*, the CJEU again redefined the referred questions, asking whether "on the basis of a basic patent and an MA in respect of a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained an SPC for that combination of active ingredients, which is protected by the basic patent Article 3(c) must be interpreted as precluding that patent holder from also obtaining an SPC in respect of one of those active ingredients which is also protected as such, individually, by that patent." Although the CJEU allowed Georgetown's SPC, it is clear from Actavis that more than one SPC per patent is not allowed in all situations. Unsatisfactorily, it is not clear why exactly Georgetown was permitted more than one SPC on its patent whereas Actavis was not. One possible reason identified by the speakers was that Actavis's second SPC was not directed to the "core inventive advance" of the basic patent — but, if this was a material factor, this new requirement poses more questions than it answers.

One speaker commented that, in general terms, it was "very tricky to draw conclusions from CJEU decisions". Thus, while the precise meaning of the decisions was debated at length, it was unanimously felt that they give rise to more questions than answers.

Burden of Proving Infringement in Declaratory Judgment Action Brought by Licensee Rests with Licensor Patentee: United States Supreme Court in Medtronic.

(Article by Kelly G. Hyndman, Sughrue Mion, PLLC, Washington, DC, United States)

On September 18, 2012, the United States Court of Appeals for the Federal Circuit (CAFC) ruled that, under certain circumstances, a patent licensee had a burden to prove non-infringement, instead of the patentee having to prove infringement (*Medtronic Inc. v. Boston Scientific Corp*., 695 F.3d 1266 (Fed. Cir. 2012). On January 22, 2014, a unanimous opinion authored by Justice Stephen Breyer in *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 571 U.S. _____ (2014) overruled the CAFC, removing this possible exception to the rule that a patentee always bears the burden of proving infringement.

In the United States, it has long been clear that a patent owner has the burden of proving infringement, even when the claim of infringement is made as a counter-claim in a declaratory judgment action.

In this particular situation, however, the license agreement underlying the dispute theoretically foreclosed the patentee from asserting such a counter-claim.

Here, Medtronic had a license, since 1991, for certain Mirowski patents. The dispute arose around whether certain new products of Medtronic came within the scope of the license. If any claims of the licensed Mirowski patents were readable upon the new Medtronic devices, then Medtronic would owe royalties to Mirowski. Otherwise, no royalties would be owed. Per the terms of the license agreement, whenever

Medtronic and Mirowski disagreed in this regard, Medtronic would have to pay the disputed royalties into an escrow account and Medtronic would file a declaratory judgment action to have the question settled. The prevailing party in the action would then receive the escrowed royalty payments.

One of the special circumstances that complicated the analysis included the fact that Medtronic was a licensee of the patents; Medtronic had every right to use the patented technology under the existing license. Since Medtronic had a license to the patents, Medtronic could not as a strictly legal matter infringe them.

Therefore, at the time of the declaratory judgment action, Medtronic could properly file the action to ask for a determination that the claims did not cover the new devices, but Mirowski could not file a counter-claim for patent infringement by Medtronic.

Mirowski took the position that, since Mirowski could not bring a patent infringement counter-claim, the declaratory judgment plaintiff Medtronic therefore had the basic plaintiff's burden to prove that it deserved the relief it sought. This "normal default rule" was thought by Mirowski to require Medtronic to prove its devices were not covered by any Mirowski patent claim.

During oral arguments, Justice Antonin Scalia pointed out to counsel for Mirowski that "it is often the case, in declaratory judgment actions, that the defendant in the action cannot counterclaim." Furthermore, Justice Scalia noted that the "whole purpose of the declaratory judgment statute is to enable you to sue before the other side has a cause of action against you".

The Supreme Court concluded that, even though an infringement counter-claim could not be brought in this declaratory judgment action, the fundamental analysis to be undertaken was an infringement analysis, and that infringement must always be proven by the patent owner. Moreover, the Supreme Court found a number of factors that would disturb the patent system if certain cases required proof of non-infringement instead of requiring a patent owner to prove infringement in all situations.

A copy of the opinion is available at http://www.supremecourt.gov/opinions/13pdf/12-1128_h315.pdf.

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