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**ISSN 2226-6771**

[2014] Vol. 3 No. 2 NTUT J. of Intell. Prop. L. & Mgmt.

## TABLE OF CONTENTS

**Regular Articles**

**Chia-Jui Su**, *"Branded or Generic," the Legal Analysis and Strategic Management of Pharmaceutical Patent Disputes—The Taiwan Model*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 102 (2014).

**Mindaugas Kiskis**, *Transparency for Efficiency of the International Patent System*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 118 (2014).

**Arif Jamil** & **Tania Sultana Bonny**, *Fostering Innovation and Affordability: An Empirical Study Delving into Intellectual Property Protection of Human Stem Cell Based Invention/Innovation*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 133 (2014).

**Ping-Hsun Chen** & **Ting-Wei Huang**, *Judicial Standard for the Well-Knownness of Trademarks in the Hotel Industry under the Case Law of the Taiwan Intellectual Property Court*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 164 (2014).

**Quick Views**

**Mark Bartholomew**, *Federal Circuit Blocks Trademark for Being Disparaging to Muslims*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 178 (2014).

**Benjamin McEniery**, *Australia: Myriad Gene Patents Look Good*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 181 (2014).

**Lynda J. Oswald**, *Akamai: Is the Answer in the Common Law?*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 184 (2014).

**ISSN 2226-6771**

[2014] Vol. 3 No. 2 NTUT J. of Intell. Prop. L. & Mgmt.

**Jorge Contreras**, *Tesla Motors and the Rise of Non-ICT Patent Pledges*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 188 (2014).

**Derek Dahlgren**, *The Proper Role for the Presumption of Validity*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 191 (2014).

**Eric Goldman**, *How the DMCA's Online Copyright Safe Harbor Failed*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 195 (2014).

**Gaia Bernstein**, *The Rise of the End User in Patent Litigationand Attorney Fee Shifting*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 199 (2014).

**Ya-Chi Chiang**, *Review of the CJEU Judgment on the Application of Site Blocking Order*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 202 (2014).

**Student Note**

**Yasuto Shirae**, *Copyright Protection on Pornography in Japan*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 213 (2014).

**Editorial Note**

**Ping-Hsun Chen**, *Editorial Note on the Volume 3 Number 2 Issue of 2014*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 219 (2014).

[2014] Vol. 3 No. 2 NTUT J. of Intell. Prop. L. & Mgmt.

# "Branded or Generic," the Legal Analysis and Strategic Management of Pharmaceutical Patent Disputes—The Taiwan Model

Chia-Jui Su*

**Abstract**

Because of intensive research and innovation in pharmaceutical industries, legal disputes and strategic management of intellectual property (IP) has become increasingly critical between competing pharmaceutical manufacturers. From specialized IP jurisdiction, industrial capacity and pharmaceutical market prospective, Taiwan is an appropriate research model for industries to elucidate patent disputes between branded and generic pharmaceutical companies. After analyzing recent pharmaceutical patent decisions held in the IP Court of Taiwan, and comparing them with China Patent Act and the U.S. patent laws and precedents, a three-stage model was developed to categorize pharmaceutical patent disputes between global branded and local generic companies. First, in the preparation stage, either branded or generic companies apply different legal strategies to extend or exempt of patent exclusivity respectively. Second, in the injunction stage, this article demonstrates why specialized IP jurisdiction, financial burden for countersecurity and abuse of IP rights affect generics to stay in the market. Third, in the litigation stage, This article illustrates how indirect infringement protection, validity of patents, and physicians' defense play the crucial roles of patent litigations in Greater China area. Finally, to integrate the strategic considerations and commercial effects of these legal battles, this patent dispute model in pharmaceutics provides a useful guideline and some suggestions for both generic and branded companies that intend to develop or sustain their pharmaceutical business in Asia or globally.

Keywords: Patent, infringement, pharmaceutics, branded, generic

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* M.D., Esq., Ph.D. Candidate, Institute of Technology Law, National Chiao Tung University; Adjunctive lecturer at National Yang-Ming University; LL.M. in IP & Tech Law, Washington University in St Louis School of Law; M.D., National Yang-Ming University; New York Bar and Taiwan Bar admitted. Contact email: jarret.su@gmail.com.

## I. Introduction

In recent years, the legal strategies and intellectual property (IP) managements has become increasingly critical in many industries. For example, in September 2013, Microsoft and Nokia announced that they had agreed on a transaction worth EUR 5.44 billion. Microsoft not only purchased Nokia's Devices and Services business for EUR 3.79 billion, but, more importantly, also paid EUR 1.65 billion to license Nokia's patents.[1] Additionally, Google purchased Motorola Mobility for US $12.5 billion in 2011, and announced that "Motorola Mobility's patent portfolio will help protect the Android ecosystem."[2] Although Google subsequently sold Motorola Mobility to Lenovo for US $2.91 billion in January 2014, Google still retains the vast majority of Motorola's patents.[3]

As for pharmaceutics, in 2013, the Supreme Court of the United States in *FTC v. Actavis Inc*. considered whether it is presumed to be lawful for branded manufacturers to use reverse-payment settlements to keep generic competitors out of the pharmaceutical market for some period of time prior expiration of drug patents.[4] The consideration of legal strategies and IP managements in pharmaceutics should be also crucial and should include anti-competitive issues because of the healthcare rights and public policy.[5]

Taiwan is an appropriate research area for pharmaceutical industries to elucidate IP disputes between branded and generic pharmaceutical companies. From a legal perspective, similarly to the U.S. Court of Appeals for the Federal Circuit, Taiwan established the Intellectual Property Court (hereinafter, "IP Court") with specific jurisdictions for IP-related disputes. From an industrial perspective, Taiwan and the United States have well-recognized manufacturing capacities and are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as the PIC/S), which only four

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[1] *See* Microsoft News Center, *Microsoft to Acquire Nokia's Devices & Services Business, License Nokia's Patents and Mapping Services*, Sept. 03, 2013, http://www.microsoft.com/en-us/news/press/2013/sep13/09-02announcementpr.aspx (last visited Aug. 1, 2014).

[2] Google, *Facts about Google's Acquisition of Motorola*, http://www.google.com/press/motorola/ (last visited Aug. 1, 2014).

[3] *See* Larry Page, *Lenovo to Acquire Motorola Mobility*, OFFICIAL BLOG, Jan. 29, 2014, http://googleblog.blogspot.tw/2014/01/lenovo-to-acquire-motorola-mobility.html (last visited Aug. 1, 2014).

[4] *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

[5] *See, e.g.*, Daniel A. Crane, *Actavis, the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions*, 15 MINN. J. L. SCI. & TECH. 51 (2014); William W. Fisher III & Felix Oberholzer-Gee, *Strategic Management of Intellectual Property: An Integrated Approach*, 55(4) CALIFORNIA MANAGEMENT REVIEW 157 (2013).

Asian countries have qualified for.[6] From a market perspective, Taiwan shares its culture with China, forms part of an integrated supply chain, and has become the appropriate touchstone for global pharmaceutical companies to explore the booming pharmaceutical markets in the Greater China.[7]

Thus, by systemically analyzing pharmaceutical patent decisions held in the Taiwanese IP Court, and comparing them with U.S. patent laws and precedents, this article develops a three-staged model to categorize pharmaceutical patent disputes between branded and generic companies. In the first preparation stage, we demonstrate how pharmaceutical companies apply legal strategies to exempt or extend patent protection. Second, in the injunction stage, this article analyzes how specialized IP jurisdiction, financial burden for countersecurity, and abuse of IP rights affect generics to stay in the market. Third, in the litigation stage, this article illustrates why indirect infringement protection, validity of patents, and physicians' defense play the crucial roles in Greater China area. Finally, this paper provides pragmatic suggestions for generic or branded companies to apply this three-staged model to develop or sustain their pharmaceutical business in Asia or globally.

## II. Preparation Stage:

In pharmaceutics, the exclusivity effect of patent terms can be strategically modified. Prior expiration of drug patents, generic manufacturers can use the research exemption from patent infringement and to obtain drug approvals as soon as possible. Conversely, branded manufacturers submit numerous types of "evergreening" patent application for soon-to-expire patents to extend the core patent protection as long as possible.[8]

### A. Research Exemptions for Generic Companies

To ensure drug safety and efficacy, under U.S. FDA regulations, all drugs must undergo clinical trials to obtain New Drug Approval (hereinafter, "NDA") or Abbreviated NDA (hereinafter, "ANDA"). This administrative filing process can require several months to years. Therefore, generic company must conduct clinical trials for filing ANDA applications to enable generics market entry immediately following the branded patent expiration.

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[6] *See, e.g.*, Pharmaceutical Inspection Co-operation Scheme homepage, PIC/S, http://www.picscheme.org/pics.php (last visited Aug. 1, 2014), Members & Partners, http://www.picscheme.org/members.php (last visited Aug. 1, 2014).

[7] *See* Mei-Hsin Wang, *Recent Patent Litigation on Pharmaceuticals in Great China*, 2 NTUT J. OF INTELL. PROP. L. & MGMT. 58, 68 (2013).

[8] *See* Su-Hua Lee, *A Study on Pharmaceutical Patents: Some Observations from Evergreening Patent of Pharmaceutical Sector in Taiwan*, 41 NTU L.J. 647, 667 (2012).

However, conducting drug research or trials prior to patent expiration can result in patent infringement.

In the United States, the Federal Circuit in *Roche Prods. v. Bolar Pharm.* previously ruled that the experiments performed by the generic company, Bolar, had a commercial purpose and, therefore, violated Roche's patent rights.[9] However, in consideration of the positive effect of such drugs on human health, the U.S. Congress subsequently passed the Hatch-Waxman Act in 1984. This act exempted parties involved in pharmaceutical R&D experiments that are pursuant to FDA regulations from infringement (also known as the FDA safe-harbor exemption).[10] The Federal Circuit consequently upheld this research exemption in many famous cases.[11] In the case of *Merck KGaA v. Integra Lifesciences I, Ltd.*, the Supreme Court construed the FDA safe-harbor provision and held unanimously that the Hatch-Waxman Act can exempt all uses of compounds that are reasonably related to submission of information to the government under any law regulating the manufacture, use, or distribution of drugs from infringement.[12] The similar research exceptions are also ensured by EC Directives in EU and by Article 30 of the TRIPs Agreement in WTO.[13]

In Taiwan, the research exemption provision can be also applied to experiments or clinical trials.[14] In *Eli Lilly v. TTY Biopharm*, Eli Lilly (Lilly),

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[9] *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861, 863 (Fed. Cir. 1984).

[10] *See* 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.").

[11] *See also* Intermediacs, Inc. v. Ventriex Co., Inc. 991 F.2d 808 (Fed. Cir. 1993); Eli Lilly Sc Co. v.Medtronic, Inc., 872 F.2d 402 (Fed. Cir. 1989); Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F. 3d 1226 (Fed. Cir. 2003).

[12] *See* Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005).

[13] In the European Union, equivalent exemptions are allowed under EC Directives 2004/28/EC and 2004/27/EC. Additionally, Article 30 of the TRIPS Agreement provides, "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

[14] The previous Patent Act of Taiwan exempted noncommercial behaviors or acts to exploit the invention for research, teaching, or experimental purposes. However, as in the *Bolar* case, whether clinical trials performed by generics prior to branded patent expiration constitute "noncommercial behavior," as outlined in the Patent Act, remains unclear. In 2005, the Pharmaceutical Affairs Act of Taiwan was amended as stating, "The patent right of the new drug shall not be applicable to research, teaching, or testing prior to the application for registration by the pharmaceutical firms." This act clearly exempted pharmaceutical firms from infringements related to researching, teaching, or testing drugs prior to the application for ANDA registration. Subsequently, pharmaceutical legal disputes shifted from the

the patent holder for the anticancer drug Gemcitabine, claimed that the clinical trials of generic Gemcitabine injection conducted by TTY Biopharm (TTY) violated Lilly's Taiwan patent No 66262, 110476, and 109978. TTY claimed that its attempt to improve the Gemcitabine formulation was in compliance with the "research, teaching, or testing" condition, as described in the Pharmaceutical Affairs Act of Taiwan. TTY further argued that improving the formulation from Lilly's "freeze-drying lyophilization powder" to TTY's "soluble injection" required highly advanced techniques, thus meeting the requirements of the research exemption provision. However, the courts decided that improving the Gemcitabine formulation did not meet the "research, teaching, or testing" requirement, and thus ruled that TTY had infringed on Lilly's patent rights and must pay NT$ 2 million in compensation.[15]

This Gemcitabine dispute also involved related actions in China because TTY's active pharmaceutical ingredient (API) of Gemcitabine was primarily manufactured by a Chinese pharmaceutical company, Hansoh Pharmaceutical. Lilly filed litigations against Hansoh in 2001 at the People High Court in JianSu Province, but finally failed in 2010.[16] The People Supreme Court favored Hansoh Pharmaceutical and ruled that Lilly should pay a total 162,810 RMB.[17]

This Gemcitabine dispute provides several salient facts. First, because the pharmaceutical supply chain is integrated throughout the Greater China area, patent holders must consider possible differences in pharmaceutical statutes and judicial systems between China and Taiwan. In 2013, the Patent Act of Taiwan newly amended and integrated the research exemption provision of the Pharmaceutical Affairs Act, and the scope and standards of pharmaceutical research exemption are now more clearly defined.[18] However, the Patent Law of the People's Republic of China simply states that any person can be exempt from patent infringement under the condition

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concern of whether clinical trials constituted "commercial behavior" to that of whether these clinical trials constituted "research, teaching, or testing."

[15] *See* Eli Lilly v. TTY, Taiwan High Court, 94 Zei-Sun Zi no. 26 (2006), *rev'd* by Taiwan Supreme Court, 96 Tai-Sun Zi no. 1710 (2007).

[16] *See* JianSu People High Court, 2001 Su-Min-San-Chu Zi no.1 (2002).

[17] *See* People Supreme Court, 2009 Min-San-Zun Zi no. 6; *see also* Wang, *supra* note 7, at 60-61.

[18] In Taiwan, Article 59 of the Patent Act states, "The effects of an invention patent right shall not extend to the following circumstances: … 2.) necessary acts to exploit the invention for research or experimental purpose(s)." Article 60 states, "The effects of the patent right shall not extend to research and trials, including their practical requirements, necessary for obtaining registration and market approval of drugs under the Pharmaceutical Affairs Act or obtaining market approval of pharmaceuticals from a foreign country."

of using the relevant patent for the purpose of scientific research and experimentation.[19] Therefore, the scope of the research exemption in China may allow some leeway for judicial construction.

Second, although the Taiwanese generic company TTY lost the intermediate judicial decision, this case eventually ended in a settlement.[20] TTY was allowed to manufacture and sell its generic Gemcitabine in Taiwan, and its API was provided by Lilly's approved suppliers. This reconciliation demonstrated that patent litigations hinge on business interests rather than legal justice.

### B. Evergreening Patents for Branded Companies

On the other hand, branded companies attempt to "evergreen" their patent life by filing multiple subsidiary patents prior to the core patent expiration.[21] Strategies to extend the life of a pharmaceutical patent include modifying formulations, designing new administration routes, switching chirality or enantiomers, finding novel uses or indications, combining existing drugs, and metabolizing materials.[22]

In Taiwan, for example, Merck Sharp & Dohme (MSD) had extended the core patent life of Alendroid acid, a drug for osteoporosis, by modifying the dosage from once per day to once per week.[23] AstraZeneca extended the core patent life of Esomeprazole, a blockbuster drug to treat peptic ulcers, by converting the omeprazole's optical isomers.[24] The patent extension of pioglitazone, another blockbuster drug produced by Takeda to treat diabetes, was achieved by drug combination and active metabolite patents.[25]

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[19] Patent Law of the People's Republic of China art. 69 ("The following shall not be deemed to be patent right infringement: … (4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation.").

[20] *See* the settlement announcement of Lily and TTY, http://www.tty.com.tw/news/show_news.php?subaction=showfull&id=1287113572&archive=&template=Custom (last visited Aug. 1, 2014).

[21] *See* Lee, *supra* note 8

[22] *See* Himanshu Gupta, Suresh Kumar, Saroj Kumar Roy, & R. S. Gaud, *Patent Protection Strategies*, 2(1) J. PHARM. BIOALLIED SCI. 2 (2010); *see also* Richard Li-dar Wang & Pei-Chen Huang, *Patent Protection of Pharmacologically Active Metabolites: Theoretical and Technological Analysis on the Jurisprudence of Four Regions*, 29 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 493 (2013).

[23] *See* Taiwan Patent no. 226833 (Pharmaceutical Composition for Inhibiting Bone Resorption).

[24] *See* Taiwan Patent no. 11446 (Omeprazole and its Alkaline Salts with High Optically Purity, their Pharmaceutical Compositions, Process for Preparation Including their Intermediates and Application in Pharmaceuticals).

[25] *See*, *e.g.*, Taiwan Patent no. 135500 (Pharmceutical Compoisition for Prophylaxis and Treatment of Diabetes); Taiwan Patent no. 63119 (Thiazolidinedione Derivative, Production

**1. Aventis Pharma S.A. v. TTY Biopharm**

The case of *Aventis Pharma S.A. v. TTY Biopharm*, heard in the Taiwanese IP Court, can demonstrate how evergreening patents extended the protection period by using a modified formulation.[26] The API of Taxotere®, a cancer treatment drug produced by Aventis, was docetaxel trihydrate; however, Tyxan®, a generic injection produced by TTY, also used docetaxel as its API after 2008. Because the patent protection period for the docetaxel compound expired in 2007, Aventis used several methods to extend the drug patent for Taxotere®. For example, in 1992, Aventis filed for a Taiwanese patent No. 197394 for an improved formulation.[27] This '394 patent successfully extended protection of the original docetaxel patent from 2007 to 2012 In addition, in 1993, Aventis applied for another Taiwanese patent No 76742 for a modified formula containing a surfactant and water solution.[28] This '742 patent also extended patent protection to November 2013, and provided the basis for litigation against TTY in 2008.[29] On the other hand, TTY successfully invented around and preemptively obtained another patent for a three-part injectable formulation.[30] TTY finally won this litigation.[31]

**2. Takeda Pharma v. China Chemical & Pharmaceutical Co.**

The case of *Takeda Pharma v. China Chemical & Pharmaceutical Co. (CCPC)* is another example to show how evergreening patent extended patent protection by drug combination and active metabolites.[32] Takeda's blockbuster diabetes drug, Actos®, which used pioglitazone hydrochloride as the API, and the basic patent for pioglitazone (Taiwanese patent No 26611) expired in 1994. Therefore, Takeda filed for Taiwanese patent No 135500 by

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and Use Thereof).

[26] *See* Aventis Pharma S.A. v. TTY Biopharm, Taiwan IP Court, 98 Min-Kan-Su Xi no. 95 (2010).

[27] *See* Taiwan Patent no. 197394 (Compositions Suitable for the Production of Injectable Perfusion). The details of the patent primarily indicated that because of the low solubility of taxane, surfactants and ethanol were added for injection use.

[28] *See* Taiwan Patent no. 76742 (Two-Part Injectable Composition Comprising a Taxane Derivative in a Surface Acitve Agent and an Additive to Prevent Gelling on Dilution).

[29] *See* Aventis Pharma S.A. v. TTY Biopharm, *supra* note 26.

[30] *See* Taiwan Patent no. 321471 (Three-Part Injectable Composition Comprising Docetaxel in a Surface Active Agent and an Additive to Prevent Gelling on Dilution And Diluents). The patent was granted because this formulation can reduce aggregation phenomenon andfacilitate nursing clinicalpreparation.

[31] *See* Aventis Pharma S.A. v. TTY Biopharm, Taiwan IP Court, 98 Min-Kan-Su Xi no. 95 (2009).

[32] *See* Takeda Pharma v. CCPC, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009).

introducing a combination therapy that added an insulin-secreting stimulator to pioglitazone, extending patent protection to June 11, 2016.[33] Moreover, because the human body biochemically metabolizes pioglitazone hydrochloride into a thiazolidinedione derivative, Takeda further applied for Taiwanese patent No 63119 for the natural metabolites, extending patent protection to April 10, 2012.[34]

These two pioglitazone evergreening patents, the combination and metabolite patents, provided grounds for the litigation filed against another two generic manufactures in Taiwan, CCCP and Genovate. Details of the subsequent patent litigations are described in the section III B 2.

According to an investigation reported by the U.S. Federal Trade Commission, 75% of generic manufacturers have been sued by original patent holders, and evergreening of patents was a major reason for litigation.[35] Similar situations have been observed in Taiwan. The aforementioned cases held in the Taiwanese IP Court demonstrate a practical model for branded manufacturers to continuously attack generics by evergreening patents, and for the generics to defend themselves by invent-around patents.

## III. Injunction Stage

Remedies in patent infringement primarily include monetary compensation and equitable relief. Preliminary injunctions, in equity, are critical in legal and business strategy.[36] If a branded company argues that a generic's behavior has resulted in material harm or imminent danger, after providing a security, they can be granted a preliminary injunction to prevent the generic from manufacturing and selling the infringing products, or force them to destroy the products. The unfair use of preliminary injunction will also induce some anti-competitive issues. In Greater China area, the Code of

[33] *See* Taiwan Patent no. 135500 (Pharmceutical Compoisition for Prophylaxis and Treatment of Diabetes).

[34] *See* Taiwan Patent no. 63119 (Thiazolidinedione Derivative, Production and Use Thereof).

[35] *See* Federal Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study (last visited Aug. 1, 2014).

[36] In the U.S., the plaintiff seeking the preliminary injunction must fulfill all four requirements (1) that there is a substantial likelihood of success on the merits of the case, (2)that the plaintiff faces a substantial threat of irreparable damage or injury if the injunction is not granted,(3)that the balance of harms weighs in favor of the plaintiff seeking the preliminary injunction, and (4) that the grant of an injunction would serve the public interest.

Civil Procedure of Taiwan and the Patent Law of the People's Republic of China also includes similar injunction provisions.[37]

To clearly indicate the legal and commercial effect of preliminary injunctions on legal strategy and IP management, this paper presents two preliminary injunctions related to the same Takeda "blockbuster" diabetes drug, Actos®, which resulted in two dramatically distinct effects.

**A. Takeda v. Genovate Biotechnology**

In the first case, Genovate had applied ANDA of Vippar® for pioglitazone, the same API of Takeda's Actos®, and received a qualification notice from Taiwan's pharmaceutical authority. However, Takeda promptly claimed that Genovate had violated Takeda's patent for pioglitazone combination therapy, and requested a preliminary injunction.[38] Takeda was granted the preliminary injunction after providing a security of approximately New Taiwan Dollars (NTD) 43 million (approximately US$ 1.4 million).[39] The district court then issued an injunction order to suspend the final ANDA approval. However, Takeda lost the final decision four years later.[40]

Genovate subsequently filed a law suit against Takeda under unfair competition and abuse of rights for a market delay.[41] Takeda argued that, as a patent holder, no abuse of IP rights occurred because the motion of the preliminary injunction constituted an exercise of legal rights according to civil procedures. However, the IP Court ruled that inappropriate behavior such as the abuse of rights or the breach of good faith, resulting in a negative effect on trading order, must be subject to compensation for unfair competition. Because the motion of preliminary injunction filed by Takeda

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[37] In Taiwan, the preliminary injunction was codified as the "injunction maintaining a temporary status quo." *See* Article 538 of Taiwan Code of Civil Procedure art. 538 ("Where necessary for purposes of preventing material harm or imminent danger or other similar circumstances, an application may be made for an injunction maintaining a temporary status quo with regard to the legal relation in dispute."). In China, Article 66 of The Patent Law of the People's Republic of China provided, "If the patentee or interested party has evidence to prove that another person is committing or is about to commit a patent infringement, which, unless being checked in time, may cause irreparable harm to his lawful rights and interests, he may, before taking legal action, file an application to request that the people's court order to have such act ceased. When filing such an application, the applicant shall provide guarantee."

[38] *See* Taiwan Patent no. 135500 (Pharmceutical Compoisition for Prophylaxis and Treatment of Diabetes).

[39] *See* Takeda v. Genovate, Taichung District Court, 93 Tsai-Chuan no. 3340 (2004).

[40] *See* Takeda v. Genovate, Taiwan Supreme Court, 98 Tai-Sun Zi no. 367 (2009).

[41] *See* Genovate v. Takeda, Taiwan IP Court, 99 Min-Kung-Sun no. 3 (2010), *aff.* by Taiwan Supreme Court, 101 Tai-Sun Zi no. 235 (2012).

was based on a flawed expert report, Takeda had either grossly negligent or knowingly attempted to take advantage of the injunction proceedings, and had, therefore, engaged in unfair competition. The IP Court finally ruled that Takeda was liable for NT$50 million (approximately US$1.6 million) in compensation for this anticompetitive behavior.[42]

**B. Takeda v. CCPC**

In the second case, CCPC had obtained ANDA for pioglitazone and Takeda also filed for a preliminary injunction. Conversely, after CCPC provided a countersecurity of approximately NT $140 million (approximately US $4.5 million), the preliminary injunction was revoked.[43] CCPC promptly entered the market and began to sell their generic drug. Although the final court ruling of this case was identical to that of *Takeda v. Genovate* (i.e., that no violation of Takeda's patent rights had occurred), the business implications of the two cases differed dramatically.

These two different injunctions, concerning the same drug of pioglitazone, provide at least two lessons as follows. First, from a strategic perspective, if a small generic company cannot afford to pay a full countersecurity in a timely manner, it can be prohibited from manufacturing and selling the product, or required to destroy the products. However, because countersecurity may range around millions of U.S. dollars, they are unaffordable for small-scale generics. Even if small generic companies finally win such lawsuits, as in *Takeda v. Genovate*, they suffer a delay in bringing the product to market. Therefore, motions for preliminary injunctions filed by patent holders can either apply capital pressure on small generics or keep them out of the market.

Second, from a legal perspective, because the time allowed for courts to review motions of injunction relief is extremely short and because determining pharmaceutical patent infringement requires specialized knowledge, courts are limited in their ability to reach sound judgments. Therefore, patent holders can take advantage of filing a motion of injunction against generics, or use the prolonged litigation process to maintain a market monopoly. The specialized IP court systems, which established in some countries, plays a critical role in making timely decisions to prevent the possible unfair use of preliminary injunctions.[44]

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[42] *See* Genovate v. Takeda, Taiwan IP Court, 99 Min-Kung-Sun no. 3 (2010); *see also* Announcement by Genovate on Aug 16, 2012, http://mops.twse.com.tw/mops/web/t05st01 (last visited Aug. 1, 2014).

[43] *See* Takeda v. CCPC, Taiwan High Court, Kang-Geng-1 no. 3 (2008).

[44] Currently, at least nine countries or areas worldwide have established a specialized IP court, including Germany, the United Kingdom, the United States, Japan, South Korea, Singapore, Thailand, Taiwan, and the European Union.

## III. Litigation Stage

Following a preliminary injunction, a court considers whether a patent is valid, whether the product in question infringes on the patent, whether any defense of infringement exists, and how to calculate damages for compensation. In the following section, cases held in the Taiwanese IP Court are used to discuss the differences of patent systems between Taiwan and the United States regarding the validity of evergreening patents, enforcement of indirect infringement, and physicians' defense against infringement.

### A. Patent Validity

In pharmaceutics, the opinions concerning patent validity showed extremely diverse in different jurisdictions. For the example of pharmaceutical metabolite patents, the active metabolites are produced by natural biological reaction of the human body after drugs intake. In the U.S., in *Schering Corp v Geneva Pharms., Inc,* the Federal Circuit applied the "inherent anticipation doctrine" to invalid the metabolite patent concerning an antihistamine substance because the physiologically produced metabolite could be anticipated by pre-metabolite compound, and its novelty had been lost.[45] In India, under the "product of nature" doctrine, the 2005 Patents (Amendment) Act recognizes the active metabolite as a "new type of known substance," and thus considers metabolite invention as merely discovery without patentability.[46] However, in Taiwan, the IP Court did not invalidate the active metabolite patent, but ruled that no infringement had occurred because human body physically metabolizes generic drugs *in vivo* should be not constitute "exploiting" the metabolite patent for infringement liability.[47]

Besides, to challenge the validity of a patent, two legal strategies, either arguing in IP court for invalidation or in IP Office for revocation, are commonly used.[48] In Taiwan, Alendroid acid, a drug for osteoporosis or

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[45] *See* Schering Corp v. Geneva Pharms., Inc. 339 F.3d 1373 (Fed. Cir. 2003); *see also* Wang & Huang, *supra* note 22, at 497-501.

[46] *See* Section 3 of the India Patents (Amendment) Act of 2005 (Act No. 15 of 2005) ("(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or .... Explanation.-For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."), http://www.wipo.int/wipolex/en/details.jsp?id=2407 (last visited Aug. 1, 2014).

[47] *See* Takeda v. CCPC, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009); *see also* Wang & Huang, *Supra* note 22.

[48] For patent litigation, the invalidation rate in the Taiwanese IP Court is as high as 60%.

Paget's disease, clearly demonstrates the effects of these two patent-validity strategies on pharmaceutical patent disputes. In the case of *MSD v. Novartis Taiwan*, MSD argued that the generic drug Alendronate (Sandoz 70-mg) sold by Novartis Taiwan violated its Taiwanese No 226833 patent and filed a motion for injunction and a plea for compensation.[49] This '833 patent was evergreened to extend MSD's core patent life of Alendroid acid by modifying the oral dosage from 10mg daily to 70mg weekly, which can enhance patient compliance and reduce gastric complications. The Taiwanese IP Court ruled that MSD's patent was invalid based on the grounds of "obviousness" for dosage modification.[50] In addition, another local generic manufacturer filed a request with the Taiwanese IP Office for the invalidation of this patent based on Article 71 of the Patent Act, and this patent was subsequently revoked in 2011.[51]

**B. Indirect Infringement**

From the perspective of patent protection, the different IP enforcement systems will produce various industrial impacts. In the United States, the patent enforcement systems include not only direct infringement provisions (35 U.S.C. § 271 (a)), but also indirect infringement provisions (35 U.S.C. § 271 (b), (c)). By contrast, the Patent Act of Taiwan and the Patent Law of the People's Republic of China provide only direct infringement provisions; the provisions for indirect infringement are not expressly codified.[52] Therefore, in the Greater China area, patent enforcement must be supplemented by the tort concept of joint and several liability according to the Civil Code in Taiwan and Tort Law in China.[53] This difference greatly affects IP

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*See* American Chamber of Commerce in Taipei, ISSUES-Chinese, http://www.amcham.com.tw/topics-archive/topics-archive-2012/vol-42-no-07/3625-issues-chinese-449 (last visited Aug. 1, 2014).

[49] *See* Taiwan Patent no. I226833 (Pharmaceutical Composition for Inhibiting Bone Resorption).

[50] *See, e.g.*, MSD v. Norvatis, Taiwan IP Court, 99 Min-Kan-Su Zi no. 149 (2011); 100 Min-Kan-Sun no. 21 (2012).

[51] *See* Taiwan IP Office Decision, Zh-Kan 3(4) 02021 no. 10020498200 Regarding Patent no. 226833, revoked on June, 13, 2011; *see also* http://alveice.blogspot.tw/2011/07/merck-alendronate-fosamax.html (in Chineses) (last visited Aug. 1, 2014),

[52] *See* Chapter VII of Protection of Patent Rights, Patent Law of the People's Republic of China, http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html (last visited Aug. 1, 2014).

[53] *See* Taiwan Civil Code art. 185, para. 1 ("If several persons have wrongfully damaged the rights of another jointly, they are jointly liable for the injury arising therefrom."), para. 2 ("Instigators and accomplices are deemed to be joint tortfeasors."); Tort Law of the People's Republic of China art. 8 ("Where two or more persons jointly commit a tort, causing harm to

management and the litigation strategies adopted.

In Taiwan, *Takeda v. CCPC* is an apt example for indirect infringement.[54] Takeda manufactured and sold the diabetes drug Actos®, with the API of pioglitazone, which basic patents expired in 1994. Takeda filed an action against CCPC's pioglitazone-based generic Glitos®, claiming infringement of two evergreening patents for pioglitazone. These two patents were an active metabolites patent (the '119 Patent) and a drug combination patent (the '500 Patent), which also described in this article of section II B (2).[55]

First, for the infringement of active metabolites patent, Takeda argued that when any patient took and metabolized the generic Glitos® into active metabolites, the patient directly infringed Takeda's active metabolite patent; the manufacturer CCPC was thus considered as an accomplice or contributory infringer.

Second, for the infringement of drug combination patent, Takeda argued that when any physician prescribed drugs that combined generic Glitos® and other drugs to treat diabetes, the physician violated Takeda's combination patent as the direct infringer and CCPC violated the patent as a accomplice or contributory infringer. In addition, CCPC was also a instigator to induce physicians to infringe on Takeda's combination patent by labeling Glitos® in such a way of drug combination therapy.[56]

The Taiwanese IP Court ruled that the generic of CCPC neither directly violated Takeda's metabolite and combination patents, nor constituted joint liability or indirect infringement.[57]

Concerning the active metabolite patent, the IP Court did not invalidate patent validity, but ruled that the claimed metabolite of pioglitazone which unconsciously converted by human body was not construed as the consequence of human control behavior or commercial sales. Therefore, the patient did not "exploiting" the metabolite patent and no infringement had occurred.[58] CCPC was thus not considered as an accomplice or contributory infringer.

Concerning the combination patent, the IP Court further explained that physicians prescribe drug combination therapy to treat diabetes based on their own professional knowledge and under individual patient's condition.

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another person, they shall be liable jointly and severally."), art. 9 ("One who abets or assists another person in committing a tort shall be liable jointly and severally with the tortfeasor.").

[54] *See* Takeda v. CCPC, Taiwan IP Court, 97 Min-Kan-Sun no 20. (2009).

[55] *See, e.g.*, Taiwan Patent no. 135500 (Pharmceutical Compoisition for Prophylaxis And Treatment of Diabetes); Taiwan Patent no. 63119 (Thiazolidinedione Derivative, Production and Use Thereof).

[56] *See* Takeda v. CCPC, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009).

[57] *See id.*

[58] *See also* Wang & Huang, *supra* note 22, at 505-07.

Therefore, CCPC labeled the generic for combination therapy should not construed as either an instigators or accomplice under the tort laws. In addition, the second instance of Taiwanese IP Court clearly construed that no provisions for indirect infringements, such as contributory infringement and induced infringement, are codified in the Patent Act of Taiwan.[59]

### C. Physicians' Defense against Infringement

In the U.S., under 35 USC § 287(c)(1), patent systems protect medical practitioners and healthcare entities from possible infringement when performing medical activities.[60] In Taiwan, the exemption scope of physician's defense is much narrower than that of defense in the U.S. physicians can be only exempted from infringement when they prescribe combination prescriptions by Article 61 of the Taiwanese Patent Act.[61] In *Takeda v. CCPC*, because the Taiwanese IP Court directly ruled that physicians who prescribed combination therapies did not infringe Takeda's combination patents, the court did not further apply this provision of physician's defense against infringement.

From a strategic perspective, in addition to this physician defense, even when medical institutions or physicians actually engage in direct infringement of patent rights through the procurement or prescription of generic drugs, brand-name manufacturers are disinclined to press legal charges against these healthcare providers to avoid threatening their business relationship.

## VI. Conclusion

From the perspective of IP management, the outcome of litigation is not the only or primary objective. Empirical results have revealed that more than 80% of patent litigations end in settlements.[62] When patent holders file litigation, not only are they required to pay huge litigation costs, but they risk

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[59] *See* Takeda v. CCPC, Taiwan IP Court, 97 Min-Kan-Sun no. 20 (2009).

[60] *See* 35 U.S.C. § 287(c)(1) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271 (a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.").

[61] *See* Patent Act of Taiwan art. 61 ("The effects of the patent right for the invention of medicines to be manufactured by mixing two or more medicines or for the invention of a process thereof shall not extend to the preparing of medicines in accordance with a prescription from a physician, or the medicines so prepared.").

[62] *See* Jay P. Kesan & Gwendolyn G. Ball, *How Are Patent Cases Resolved? An Empirical Examination of the Adjudication and Settlement of Patent Disputes*, 84 WASH. U. L. REV. 237, 262-264 (2006).

their patents being declared invalid, especially in Taiwanese IP Court.[63] Even when non-practicing entities file repeated litigation, the real goal is to receive settlements, rather than determining whether particular products constitute patent right infringement.[64] The legal strategies and IP managements designed for competing pharmaceutical manufacturers should also hinge on substantial business interests rather than merely legal justice.

By comparing the patent laws and precedents concerning pharmaceutical disputes heard in Taiwan and in the U.S., this article develops a three-staged model for pharmaceutical patent disputes. This dispute model can demonstrate useful guidelines and provide pragmatic suggestions for both local generic and global branded companies. First, for the extension of patent exclusivity, generic companies should pay more attention to search out and invent around the evergreening patents hidden by branded companies, because no compulsory patent disclosure, like the Orange-Book listing in the U.S., are required in Greater China area. Second, for the out-of-market effects of preliminary injunctions, start-up generic companies should consider the possible financial burden of countersecurity, and arrange in advance. Fortunately, the specialized IP courts, established in Taiwan and upcoming in China, will enhance court's ability to make a sound and timely judgment of preliminary injunction to avoid unfair abuses of IP rights. Besides, to consider the high invalidation rate of patent litigations and the lack of indirect infringement enforcement implemented in Taiwan and China, branded companies must create their legal localization strategies and strengthen their IP portfolio managements comprehensively to develop or sustain their blooming business in Greater China or in Asia.

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[63] *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (demonstrating that 46% of patents litigated to judgment are held invalid; similar invalidity rate was also found in Taiwan's intellectual property court); s*ee also* The American Chamber of Commerce in Taipei, ISSUES-Chinese, http://www.amcham.com.tw/topics-archive/topics-archive-2012/vol-42-no-07/3625-issues-chinese-449 (last visited Aug. 1, 2014).

[64] *See* John R. Allison, Mark A. Lemley, & Joshua Walke, *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 GEORGETOWN L.J. 677, 678 (2011).

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# Transparency for Efficiency of the International Patent System

Mindaugas Kiskis*

**Abstract**

Confidentiality of patent applications and delayed release of other patent documents have been the underlying principles of the patent system, but the realities of the modern networked innovation systems undermine their justification. Moreover, traditional secrecy of the patent system may be at least partially responsible for the problems currently challenging the system – that is – deterioration in the patent quality, patent thickets, and evergreening. Lack of transparency may also be standing in a way of efficiency and new innovation. Limiting the secrecy may promote faster technology development and lower the cost (by reducing the volume of low quality applications, where patentability defects would be more easily discoverable). The paper overviews the historical transparency of the patent systems and argues that it is increasingly unjustified. More specifically the transparency through the PCT procedure at the European Patent Office, publication of the search and review outcomes, as well as some features of the main international public patent databases are investigated. The findings have implications to most patent systems worldwide. The paper advocates the need to increase transparency of the patent system in several ways: by advancing the publication of the patent application and the search and review outcomes, as well as by improving patent data availability in the databases. In addition to the systemic benefits, this would also ensure that important patent data is available earlier and is more discoverable, thus contributing to greater efficiency of the patent system.

Keywords: Patent, secrecy, search and review, patentability, patent database

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* Professor, Institute of Digital Technologies, Mykolas Romeris University (Lithuania); Ph.D 02' in Law, Mykolas Romeris University; MBA 05', Vytautas Magnus University; Markle Fellow 02', Wolfson College, Oxford University; Fulbright Scholar 07'-08' Sandra Day O'Connor College of Law, Arizona State University. The author takes sole responsibility for the content of the paper. Contact email: mindaugas@kiskis.eu.

## I. Introduction

Patents on inventions have been central to the innovation systems around the globe for at least fifty years.[1] Economic and technological development, as well as globalization, have contributed to the explosion of patent applications and patent grants worldwide. Over the last few decades the regulatory and economic policies pertaining to the patent systems have facilitated increasing filings for patent protection, but largely forgot to address transparency and efficiency in the patent systems. Coincidentally, the patent adversities (poor quality patents, patent trolling, patent thickets) have increased as much (if not more) as the volume of patent applications.[2]

The topic of patent information publication has been somewhat forgotten in the legal research. Most available scholarly work on this topic published around the 1995-2000 reform of the patent application publication in the United States.[3] This is unfortunate, since the issues raised in this literature remain largely unaddressed, patent systems are ever more stressed and beset by abuses, while the innovation systems have evolved.

This paper argues that transparency of the international patent system must be urgently addressed in follow up to the application increasing reforms. Transparency is by far insufficient in view of the increasing application volumes and faster technological development. Lack of transparency is caused by the historical secrecy rules, which are much less relevant in the current global social and technological context. Shorter publication terms (e.g., fixed to international priority term (12 months)) shall be considered and key patent documentation (documentation on search and review outcomes) must be made available immediately and must be available in modern searchable formats. More transparency is urgently needed in order to ensure that important patent data is more available earlier and is more discoverable, thus contributing to the overall efficiency of the patent system.

The paper specifically investigates and advocates the need to increase transparency of the patent system in three ways: (1) by further shortening the secrecy terms for patent applications; (2) by making the search and review outcomes available in searchable and data mining friendly formats (e.g., XML); also (3) by improving international patent databases. Accordingly, the Part I of the paper provides the context on the explosive growth of the patent systems, which makes transparency/efficiency reform an urgent matter. Part

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[1] *See* Zvi Griliches, *Patent Statistics as Economic Indicators: A Survey*, 28 JOURNAL OF ECONOMIC LITERATURE 1661, 1661-707 (1990).

[2] *See* Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 101, 101-28 (2008), *available at* http://www.law.emory.edu/fileadmin/journals/elj/58/58.1/Lemley_Sampat.pdf.

[3] *See* literatures referred in footnotes 11, 16, 19, and 23.

II of the paper discusses traditional patent application secrecy principle and justifications thereof, goes to show that they have been mostly eliminated or offset by the legal development and social interests in faster transparency. Part III of the paper deals with the transparency of patentability information and other limitations of the international patent databases.

## II. Growing Patent Application Volumes Urge for More Efficiency

Worldwide patent applications filed through the Patent Cooperation Treaty (PCT) procedure have doubled in less than decade, as shown in the Fig. 1 below.

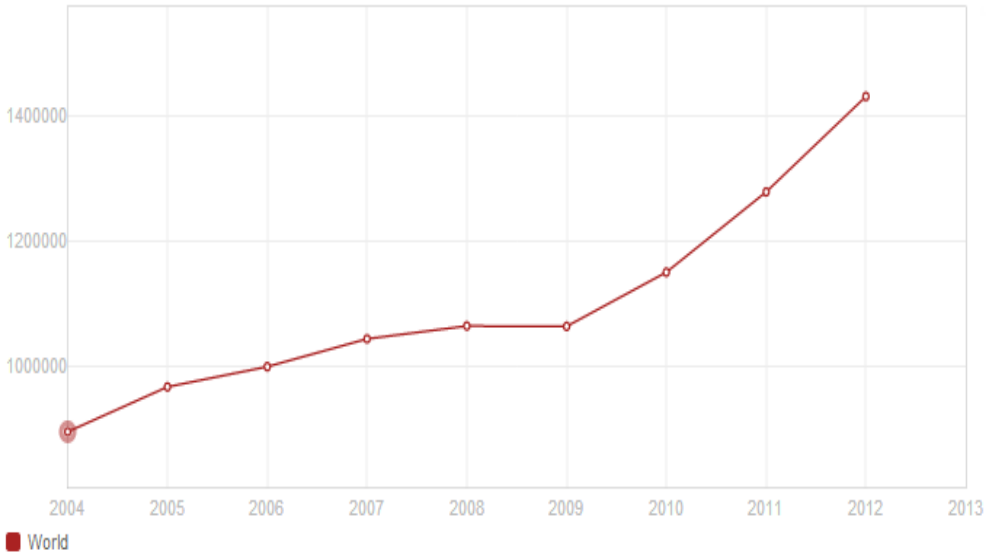


Figure 1: Worldwide patent applications filed through the Patent Cooperation Treaty (Source: World Bank[4]).

Most recently the patent application numbers have accelerated even further. China has emerged as the new leader in the world patent application filings. In 2012, China's State Intellectual Property Office ("SIPO") granted more patents than any other patent office in the world. In 2012 more than 1.26 million patent applications were filed with SIPO and represent a 31% annual increase. Based on official public policy China's government has set a goal of granting 2 million patents per year by 2015. It is noteworthy that almost 80% of China's patents were awarded to domestic applicants in 2012. Compare this to fewer than 50% of all patents going to domestic applicants

[4] *See* World Bank, Patent Applications, Residents, http://data.worldbank.org/indicator/IP.PAT.RESD/countries?display=graph (last visited Nov. 9, 2014).

in the EU or the U.S.[5]

Internationally patent applications are exploding as well. China is rapidly ascending to the top of the users of the PCT system with the annual growth in PCT patent applications of +15.6%. Overall annual PCT patent applications in 2013 exceeded the 200,000 mark for the first time. The total number of the PCT filings in 2013 amounted to 205,300, representing 5.1% growth compared with 2012.[6]

The increasing globalization and patent application volumes already stress the patent system. Patent offices at both national and international level y struggle to cope with said increases in the number of patent applications. Many patent offices have built up extensive and growing backlogs of patent applications which are awaiting processing, causing increases in pending time. Increase of patent application volumes and growing patent prosecution backlogs have negative effects on patent quality,[7] are undesirable and incur socio-legal costs for several different reasons:

(1) applicants may be encouraged to pursue patents for lower patentability inventions because they know there is a possibility of grant;
(2) lower quality patents create an environment where infringement and litigation is more likely since the validity of patents is more questionable; this may also incentivize the filing of more low quality patent applications;
(3) incorrectly granted patents incur costs arising from patent protection (monopoly protection) without providing the benefit of incentivizing true innovation;
(4) any patents (regardless of quality) carry secondary benefits for the applicant and inventors, especially in terms of intimidation (patent trolling), individual career and bragging rights.

Patent application growth also challenges would be inventors and applicants due to the need to trawl huge amounts of information, reduced

[5] *See* WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO], WHO FILED THE MOST PCT PATENT APPLICATIONS IN 2013?, *available at* http://www.wipo.int/export/sites/www/ipstats/en/docs/infographics_patents_2013.pdf (last visited Nov. 9, 2014).

[6] *See* WIPO, *US and China Drive International Patent Filing Growth in Record-Setting Year*, PR/2014/755 (Mar. 13, 2014), http://www.wipo.int/pressroom/en/articles/2014/article_0002.html.

[7] *See* David Encaoua, Dominique Guellec, & Catalina Martínez, *Patent Systems for Encouraging Innovation: Lessons from Economic Analysis*, 35 RESEARCH POLICY 1423, 1423-40 (2006); *see also* DOMINIQUE GUELLEC & BRUNO VAN POTTELSBERGHE DE LA POTTERIE, THE ECONOMICS OF THE EUROPEAN PATENT SYSTEM (Oxford University Press 2007).

certainties on patentability and increased global technological competition. When filing a new patent application, inventors and applicants can not be sure of the patentability because they can only refer to information on relatively old patent applications (at least 18 months) and even older patentability information (search and review data). Applicants also face increasing burden and cost of digging through massive volumes of patent information sometimes just to find that the researched applications lack patentability or are abandoned. At the same time non-descriptive, vague or plainly useless patent applications hide undiscovered behind the veil of secrecy or unintelligible data formats. This situation clearly increases the potential for patent abuse, trolling and patent thickets. In its own right, the delays in disclosure of technological and patentability information stifle innovation by preventing the reuse of this information for subsequent research and innovation and may cause social inefficiencies (e.g., public funding may be inadvertently granted to the research, which is already described in the filed patent applications).

Nevertheless, over the last twenty years policy makers, legislators and patent offices worldwide have taken direct steps to facilitate patent filings, such as financial support for patenting costs, reduced fees, allowing for provisional applications, introduction of the electronic filing and electronic communication between the applicant and the patent office, etc. Bold regional action, such as the new European Unitary patent legal framework is also aimed at making patent system even more accessible. All of this increases the acuteness of the efficiency problem experienced by the patent systems worldwide. Facilitating new applications may just further clog the patent systems, if the efficiency of the overall patent system is not markedly improved.

The attempts to facilitate patenting may exacerbate these problems, thus further compromising the efficiency of the patent system. It is noteworthy that the basic social goal is to stimulate innovative activities, and not just to increase the volume of the patent applications.[8]

All of the above is happening against the backdrop of increasingly faster technological development, global knowledge exchange and shorter lifecycles – e.g. in the fields of computer and digital communications technologies the product lifecycle rarely exceeds 18 months.[9] Note that same 18 months is the standard time for the patent application to be

[8] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 265-90 (1977).

[9] *See* KAMRAN L. BILIR, PATENT LAWS, PRODUCT LIFECYCLE LENGTHS, AND MULTINATIONAL ACTIVITY, *available at* http://www.ssc.wisc.edu/~kbilir/Bilir_IP_and_MNCs.pdf (last visited Nov. 9, 2014).

published. Information on the examination of the patent application (such as the search and review documentation) is published even later.

Transparency of the international patent system is one of the ways to increase efficiency, and is unfortunately mainly overlooked in existing legal and policy reforms over the last two decades. In view of the increasing application volumes, global knowledge flows and faster technological development transparency is by far insufficient. Patent transparency manifests in public availability of patent information. The concept of transparency as used in this paper embraces both the disclosure of the invention, which is normally provided in the patent application, as well as the public availability of information on the expert assessment of this patent application and current status thereof. Unfortunately, secrecy rather than transparency seems to be the guiding historical principle of patent system design, but it is positively overdue for re-evaluation.

## III. Application Secrecy at the Foundations of the Patent Systems

The current secrecy of patent applications for 18 months from the earliest priority date is relatively recent approach and is not directly set in the international patent law. Up until the end of the XX century, many countries followed the principle of complete secrecy of patent applications and only published patent applications after grant of the patent. For special cases, such as innovations with national security importance, full secrecy is still imposed and patent grants withheld.

Pre-grant secrecy extends on the basic pre-filing secrecy requirement, which is essential in order to establish novelty of the invention. More fundamentally it was accepted by the architects of the national patent systems that the inventor may wish to maintain the secrecy of the invention regardless of the patent application, and secrecy is central especially in order to allow the inventor a secret withdrawal or amendments of the patent application.[10]

On the other hand, the secrecy of the patent applications runs contrary to the basic social interests of disclosure and access to knowledge. Disclosure is another founding principle of the patent system.[11] It is generally accepted that patent monopoly is given for a period of time specifically in exchange for the inventor (applicant) disclosing to the public how to make or practice

[10] *See* JOHN F. DUFFY ET AL., EARLY PATENT PUBLICATION: A BOON OR BANE? A DISCUSSION ON THE LEGAL AND ECONOMIC EFFECTS OF PUBLISHING PATENT APPLICATIONS AFTER EIGHTEEN MONTHS OF FILING, *available at* http://www.cardozoaelj.com/wp-content/uploads/2013/02/Early-Patent-Publication.pdf.

[11] *See* JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES REL. 8 VOL. 2 (Thomson/West 2012).

the invention.[12] Note that disclosure is directly connected to the grant of the patent in this traditional concept of a patent, and hence it was accepted verbatim for more than two centuries in a form of pre-grant secrecy. Pre-grant secrecy was also justified by practical considerations.

The leader of the full pre-grant secrecy approach has always been the United States. On top of the said basic secrecy principles, there were four main utilitarian reasons to maintain secrecy of the patent applications in the U.S.:

(1) historically in the U.S., the term of patent was calculated from the grant, rather from the filing of the application, and provisional protection for ungranted applications was not available;
(2) historically in the U.S., the patent grants relied on so called first to invent principle (as opposed to first to file);
(3) the pre-grant secrecy historically was maintained as one of the ways to protect international patent rights for the national inventors;
(4) pre-grant secrecy also served to allow the applicants certain headway in terms of developing manufacturing leadership and improvements of the original invention.

Lately the pre-grant secrecy justifications have started to disintegrate, while other social considerations have become more prominent. The first two aforesaid reasons have faded with the U.S. integration into the international patent system. The term of a patent was uniformized to twenty years counted from the filing date in most developed countries before 1995 (2000 in the U.S.) according to the Article 33 of the WTO TRIPS. In the U.S. it actually meant an extension of 3 years (from 17 to 20 years). The first to invent was abandoned by the U.S. patent law in favor of first to file at the end of 2011, along with other reforms introduced by the Leahy-Smith America Invents Act.

The third reason was addressed directly through the development of the international patent law. Indeed in the early days of the patent systems, prior to the advent of the international patent law, the key argument against national pre-grant publishing of the patent applications was the need of a reasonable period of time for the applicant to file patent application in foreign jurisdictions. Publication in one jurisdiction prior to filing in another would compromise the novelty of the application for the purpose of the secondary fillings in foreign jurisdictions. Now this is dealt with under the application of the international priority rights under the Article 4 of the Paris

[12] *See* for instance Article 100(b) and Article 138(1)(b) of the European Patent Convention; Decision T 1452/06 of 10 May 2007 (Boards of Appeal of the European Patent Office), Point 23 of the Reasons ("A basic principle of the patent system is that exclusive rights can only be granted in exchange for a full disclosure of the invention.").

Convention for the Protection of Industrial Property and the Article 8 of the Patent Cooperation Treaty.

The fourth reason is arguably the most important remaining justification for maintaining patent application secrecy. It is guided by the industrial economics of translating the invention and bringing it into market,[13] but is also challenged by accelerating modern technology development cycles, economic separation of development (research) and manufacturing (often outsourced), as well as networked innovation systems reliant on rapid diffusion of new technological knowledge.

Pre-grant secrecy has always been treated differently in different countries. In some countries (Australia) the patent system swung between full transparency (publishing patent applications immediately or in just couple of months after filing) and full secrecy (publishing after grant).[14]

Following up on the Article 93 of the European Patent Convention of 1973 most European countries counties have maintained uniform patent application publication standard of the 18 months after filing. Subsequently, the 18 months after first priority publishing deadline became the de facto international standard, although it is mainly regulated in the national patent laws and in some cased in the regional patent treaties (such as the EPC).

Opposite the said pro-secrecy arguments, there have always been important pro-transparency considerations. In countries which calculate patent terms from the date of application (what is now established as an international standard in the WTO TRIPS) the publication was considered helpful for the filing of the application, examination and opposition process.[15] It is obvious that the patentability defects, analogues of the invention, or objections to the patentability are more likely to be ascertained earlier, if the patent applications are published sooner. Moreover, the lengthy secrecy period was considered detrimental to the competition. Competing manufacturers would be able to ascertain at an early date whether they are infringing or likely to infringe an invention which is the subject of an application for a patent, thus avoid wasteful allocation of their resources.[16] Finally, a basic social interest in the efficient allocation of limited public resources generally favors greater transparency of the patent information.

The other remaining disadvantage of early publication is restriction on

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[13] *See* Klaus Kultti, Tuomas Takalo, & Juuso Toikka, *Simultaneous Model of Innovation, Secrecy, and Patent Policy*, 96(2) THE AMERICAN ECONOMIC REVIEW 82, 82-86 (2006).

[14] *See* MICHAEL CAINE, THE HISTORY OF PRE-ACCEPTANCE PATENT PUBLICATION IN AUSTRALIA (Melbourne, Davies Collison Cave 2012), *available at* http://www.davies.com.au/publication_pdfs/3The%20History%20of%20preAcceptance.pdf.

[15] *See* Qin Shi, *Reexamination, Opposition, or Litigation-Legislative Efforts to Create a Post-Grant Patent Quality Control System*, 31 AIPLA Q. J. 433 (2003).

[16] *See* DUFFY ET AL., *supra* note 10.

applicant's right to amend his patent application after publication.[17] In theory early publication enables competitors of applicants to learn about the technology and development focus on which the applicant is interested. In times when countries followed different rules for the publication of the patent applications, the latter was especially important consideration, and may have allowed foreign competitors to gather information at a much earlier date than the domestic applicants may have obtained from the patent applications in foreign countries. Currently this disadvantage remains speculative.

Overall the analyzed scholarly discussion of the pre-grant secrecy is ideologically polarized and the positions taken depend on the preferences for either the social interests in greater transparency and access to knowledge, or the private interests in secrecy and disposal of the patent applications. Empirical evidence is, unfortunately, rather scarce. Nonetheless, it is obvious that gradual abandonment of the secrecy in the second half of the XX century is a reflection of realities of the modern innovation systems and processes, as well as a soft surrender to the global flows of technical information. It was also encouraged by the private abuses of the patent application secrecy for selfish and contra-innovatory purposes.[18] The secrecy of the patent applications has directly caused the so called submarine patents that were central in the early patent trolls' arsenal.

More recently patent application secrecy contributed to the patentability uncertainties, depreciating quality of patents, growth in patent thickets and patent trolling. It is now universally accepted that legal uncertainties on patentability and patent thickets increase patent disputes and subsequently discourage innovation, investment and commerce.[19] Thus, patent application secrecy may turn to harm the applicant itself and depreciate the value of the patent, since the applicant may not be aware of competing applications at the time of filing. Conflicting and overlapping patents are of limited, if any, value for the applicants and the society, since they are not subsequently exploited in downstream product developments or licensing agreements, they also prohibit enforcement[20] and instead form the dead weight in the patent systems. Such patents take away resources that could have been spent on

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[17] *See id.*

[18] *See* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63 (2004), *available* at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=462404.

[19] *See* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK (Princeton University Press 2008).

[20] *See* Federico Munari & Maurizio Sobrero, *Economic and Management Perspectives on the Value of Patents*, *in* THE ECONOMIC VALUATION OF PATENTS: METHODS AND APPLICATIONS 56 (Federico Munari & Raffaele Oriani ed., Edward Elgar Publishing 2010).

fruitful R&D and other socially valuable activities. Due to the exponential growth and unprecedented globalization of the patent systems, the risks for patent trolling, patent thickets and other contra-innovatory effects of the non-transparent systems are also much advanced.

Pre 1995 secrecy of the patent applications in the U.S. is the key culprit for the so called evergreening practices – practices of manipulating the patent prosecution process and lengthening of the patent office procedures, aimed to maximize the available patent protection terms. Since the U.S. has abandoned the full pre-grant secrecy of the patent applications only as of the end of 2000, some of the patent applications filed prior to 1995 are still surfacing.[21]

On a more general level the lack of transparency further compromises the innovation process and efficient allocation of resources, especially in view of the accelerating technology development and knowledge diffusion based innovation systems. Delay in publication may be especially detrimental for high-innovation and high-competition areas, where the likelihood of conflicting or overlapping patent applications is innately higher.

The relatively recent change of the secrecy rules in the U.S. (the change was initiated in 1995, enacted in 1999 and came into effect as of 2000), although was limited to the national applications which are converted into the international PCT applications, also provides some evidence that no detrimental effects on patenting activities resulted from the significant shortening of the patent application secrecy period. At the very least, faster publication of the patent applications produced greater legal certainty and positive effects on the diffusion of innovative activities in the U.S.[22] Combining this with the above discussed social considerations provides a good starting argument to renew a discussion on further shortening of the patent application publication terms.

## III. Transparency of patentability information and other limitations of the international patent databases

Another layer of patent secrecy in the patent applications can be attained by willing applicants through obscurity of patent claims and descriptions of the inventions. Although lack of descriptiveness is generally considered a patenting defect, the patent system is awash with poorly

[21] *See, e.g.*, patent on blockbuster pharmaceutical etanercept (U.S. Pat. No. 8,063,182) granted by the USPTO in 2012, while claiming priority on the original application filed in 1990.

[22] *See* Daniel K.N. Johnson & David Popp, Forced Out of the Closet: The Impact of the American Inventors Protection Act on the Timing of Patent Disclosure (National Bureau of Economic Research Working Paper No. 8374, 2001), *available at* http://www.nber.org/papers/w8374.

disclosed patents. The current reality of the patent systems worldwide is that patents are granted for inventions, which are not sufficiently novel, lack inventive step and are described often in rather generic terms.[23] Sometimes even deliberate efforts are undertaken (and are tolerated by the patent offices) in order to complicate descriptions and search of patent information. Disappointingly, even the EPO training material, designed for would be applicants, suggests tolerance for obscure descriptions,[24] although EPO is generally known for its rigorous prosecution of patent applications.

Invention disclosure has always been contentions, but it is increasingly important above all due to the growth of the volume of information in the patent systems. For assessing the patentability of the new patent application one needs to trawl through all available information on the technology and past applications. Disclosure may be addressed through certain standardization of patent applications, but progress in this field is extremely complicated and slow, so far it has been partially achieved only in few very specialized areas (e.g., standard rules for nucleotide or amino acid sequence disclosure[25]). Although the latter is an example of good practice, which certainly increases transparency, the disclosure is not investigated further in this paper.

Instead, as it was noted, it is worthwhile to review the public availability of information on the expert assessment of the patent applications and current status thereof.

During the typical patent prosecution process the patentability of the claimed invention is authoritatively evaluated by the pertinent patent office through the search and review process. Normally, defects (lack) in any of the patentability characteristics shall be an obstacle to grant of the patent, and generally shall be addressed by the applicant either by abandoning the patent application (not pursuing the grant) or by making amendments to the patent application.

If the patent application is not subject to search and examination, then patentability is not established at all. Unfortunately, this has become the standard case for national patents in many countries. Whether to undergo the search and examination remains the unilateral decision of the applicant. It is increasingly possible to obtain a national patent without search and review, and in many jurisdictions this is now the default option.[26] In this case the

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[23] *See* Bessen & Meurer, *supra* note 19.

[24] *See* http://www.epo.org/learning-events/materials/kit/modules.html, especially Case study A – Toy ball

[25] *See* Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in International Patent Applications under the PCT, http://www.wipo.int/pct/en/texts/ai/annex_c.html.

[26] *See* ALEXANDER STACK, INTERNATIONAL PATENT LAW: COOPERATION,

further information on the patent application (in addition to the application itself) is only limited to legal status information.

If search and review is performed, then the individual patentability parameters – novelty, inventive step and industrial applicability are expertly assessed. Search and review process from the legal point of view results in non-binding evaluation – an opinion, which can or can not be taken into account when issuing a patent. Although there is a general trend in many patent offices to grant patents, even if there are hesitations about patentability,[27] the search and review outcomes remain very valuable source of information if the validity of the patent is later contested in the courts of law. The search and review outcomes also provide useful information for the original applicant, other applicants, and parties working in the same technological fields in delineating the state of art and interpretations of inventive step in the field. Objections to faster publishing thereof are generally the same as objections against the publication of the patent applications and hence are mostly obsolete.

In the PCT procedure there are two main search and review outcome documents evaluating the patentability of the invention – the International Search Report (ISR) (form PCT/ISA/210) and the Written Opinion of the International Search Authority (WOISA) (form PCT/ISA/237). These forms are generally available within the full published document file of the patent application in the publicly available international patent databases. For the purpose of this paper the EPO PCT process was reviewed, although the process is very similar in all major patent bureaus.

In the first document – the ISR – the EPO uses the so called A, D, E, I, L, O, P, T, X, Y system. The WOISA adopts a binary (Yes/No) evaluation of the individual patentability parameters – novelty, inventive step and industrial applicability criteria. The ISR and the WOISA are both published only in the WIPO Patentscope database.[28] Only the EPO ISR (form PCT/ISA/210) is published in the EPO Espacenet database[29] and is usually not separately identified in the patent information file. Unfortunately publication in the in the WIPO Patentscope database is subject to further delays compared to the publication date of the patent application for which it is issued.[30] Most recently the EPO attempts to publish the ISR together with

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HARMONIZATION, AND AN INSTITUTIONAL ANALYSIS OF WIPO AND THE WTO 96-115 (Edward Elgar Publishing 2011).

[27] *See* Bernard Caillaud & Anne Duchene, *Patent Office in Innovation Policy: Nobody's Perfect*, 29 INTERNATIONAL JOURNAL OF INDUSTRIAL ORGANIZATION 242, 242-252 (2011).

[28] *See* http:// patentscope.wipo.int/search/en/search.jsf.

[29] *See* http://worldwide.espacenet.com/advancedSearch?locale=en_EP.

[30] For example, the application WO2009134110 was filed as PCT application on June 18, 2008 with the priority of April 30, 2008, which was originally published by the EPO on

the application, but the publication of the WOISA is still arbitrarily delayed. This delay produces little value for the applicant, since WOISA is not a final mandatory document and there are many examples where patents were granted following on the negative WOISA (i.e., where patentability was originally found to be defective), but the delay in publication compromises availability of important patent information for the other parties.

In addition to the publication delay and due to ambiguous (likely legacy format) reasons the search and review forms are provided only in scanned picture format. Certainly this is not justified by the lack of resources. Note that the forms only contain textual information – references to sources and expert conclusions (no pictures, formulas or graphs), thus providing it in modern text based formats (e.g., XML) would require less resources than scanned pictures (even significant resource economy may be possible). No searchable or otherwise easily processed forms are provided, thus severely handicapping research, and especially automatic patent data mining and processing. All in all, such situation is unjustifiable in 2014.

Closer investigation of the EPO and WIPO public patent information databases reveals further curious shortcomings. As it was noted, the EPO Espacenet database generally does not publish WOISA form, although provides an ISR form. Both are available only through WIPO Patentscope. Furthermore, only the EPO Espacenet provides information on the current legal status of the application (limited to the EPO member countries) and/or national patents issued for these applications. Although due to specific national phase requirements neither EPO, nor WIPO are the final authorities issuing a patent, it is disappointing that status information is not systematically processed. Finally, neither database allows useful custom search queries for the provided patent information, e.g., only bibliographic data, abstract, description and claims of the patent are searchable. For example, it is not possible to search for the patent applications originating from the specific country of the applicant or inventor.

In defense of the EPO, it must be acknowledged that other patent offices' databases, especially SIPO databases (as much as they are available in English) are even worse in terms of patent information transparency, availability and format friendliness to modern data search and processing.

Although the above discussed aspects rather technical than legal, they cause legal effects and provide very significant constraints on the transparency of the patent information, and in 2014 they are not justifiable by technological or social confines. While advancing the publication of the patent application requires major legal reforms in multiple jurisdictions, the

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November 5, 2009; the PCT/ISA/237 for this application was published on October 31, 2010, despite is was originally made available to the applicant on August 25, 2008.

changes in ISR/WOISA publication and especially the discussed improvements in the published document formats, as well as patent database contents may be implemented without significant legal reforms through basic changes of the patent office rules. The latter two steps alone would improve transparency through the increase in discoverability of the important patent information, would tremendously simplify research, and would contribute to the overall efficiency of the patent system.

## IV. Conclusion

Although secrecy lies at the beginnings of the national patent systems, the modern international patent system has been able to address most of the original concerns. The remaining secrecy in the patent systems is only precariously supported by the need for the applicant to amend the original patent application or to file for improvements. This reason alone shall not justify the need to keep the application secret for 18 months after filing.

18 months of secrecy (and legacy of past full secrecy which is still lingering in some counties) are contributing to the most notable problems in the modern patent systems, such as patentability uncertainties, lesser patent quality, patent thickets, patent trolling, and evergreening. Due to the accelerating technological development and growing role of fast knowledge diffusion in the innovation systems, the lack of timely disclosure of patent information also stands in the way of new innovation. These arguments and the lack of negative effects from the U.S. experience in significantly advancing the publication of patent applications (in 2000) provide compelling argument in favor of further shortening of the patent application publication terms. It must be noted that certain warming to the possibility of the review of the publication rules very recently appeared in the patent office circles.[31]

A useful time threshold to be considered for patent application publication may be the date of conversion into the PCT application or the expiration of the priority term of 12 months. By this data most applicants have rather clear plan for the patent application and are ready to commit to the significant fees of filing an international patent application. Earlier terms are less feasible due to significantly diverging national rules, filing in national languages, etc.

Transparency of the patent systems must also be upgraded by improving the poor disclosure standards, and especially in addressing the publishing of

[31] *See* UK INTELLECTUAL PROPERTY OFFICE, DISCUSSION DOCUMENT: PUBLICATION OF PATENT APPLICATIONS (August 2014), *available at* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/341899/discussion-patent-applications.pdf.

the search and review outcomes. As it was noted, objections to faster publishing thereof are generally obsolete and not empirically supported. Based on the analysis of the EPO and PCT processes and pertinent public patent databases it may also be concluded that the international patent information databases are clearly out of synch with the modern information and data processing technologies. The databases also contain a plethora of other omissions – there is no centralized data on the current status of applications and/or national patents issued for these applications, there are no possibilities to search for the country of the applicant or inventors. The essential patent search and review documentation for the PCT applications is publicized with a delay, and in archaic and unfriendly formats, which severely handicap discoverability and necessitate manual review in the age of automated data mining and search technologies.

The transparency of search and review information would simplify the patent search, would be useful for research and evaluating of patentability of new technologies, and it would also increase the confidence level of the patent systems, while discouraging lesser patentability (at least by giving it more publicity), and while decreasing inefficiencies in public patent support policies and research spending. More speculative benefits may be a decrease in patent trolling (a bundle questionable patentability patents still has intimidation value) and patent thickets. Finally, lower costs and faster patent prosecution for the patent offices may be appreciated.

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# Fostering Innovation and Affordability: An Empirical Study Delving into Intellectual Property Protection of Human Stem Cell Based Invention/Innovation

Arif Jamil[*] & Tania Sultana Bonny[†]

**Abstract**

The research article is based on the quantitative analysis of six (6) questions from the thirteen (13) questions comprising the questionnaire used in the doctoral study of the first author. The survey was conducted over a span of five months and 31 respondents from 16 different countries participated in the study. The survey questionnaire being a "mixed-type' was analyzed both quantitatively and qualitatively. This article is the publication of the quantitative analysis of those six (6) questions that deal with the intellectual property protection of human Stem Cell based Inventions/ Innovations (hSCI). The study investigated the appropriateness of the patent system for hSCI. The respondents having diverse background on Intellectual Property Right (IPR), bioethics and life science made substantial contribution in understanding the future IPR protection for hSCI. However, due to constraint in sample size, very few results from the logistic regression relationship analysis of different variables were statistically significant. While the existing patent system was favored by the legal professionals for the protection of hSCI, the respondents from the countries of high income economy are interested to see a new legal framework for inventions that uses the biological material of human origin and targeted to heath care. The elderly age group (51-65 years) did not support the proprietary nature of the IPR for hSCI. As the patent system works more territorially, than internationally, developing a new international legal framework for the intellectual property protection of hSCI or inventions that use the biological

[*] Ph.D Research Fellow (2012-2015), Erasmus Mundus Joint International Doctoral Degree in Law, Science and Technology (LAST-JD). As part of the mobility of the Doctoral Programme, the researcher has attended CIRSFID, University of Bologna, University of Turin, Mykolas Romeris University, Centre for Ethics and Law in the Life Sciences (CELLS), and Leibniz University Hannover. The study is coordinated by the CIRSFID, University of Bologna, and the supervisors are Prof. Dr. Mindaugas Kiškis, Mykolas Romeris University, Vilnius; Prof. Dra. María Casado and Prof. Dr. Itziar Lecuona, University of Barcelona. The Director of the Programme (LAST-JD) is Prof. Dr. Monica Palmirani, University of Bologna.

[†] Ph.D. Research Fellow (2013–Onward), Dept. of Environmental & Global Health, University of Florida, U.S.A.; Lecturer, Dept. of Microbiology, University of Dhaka, Bangladesh. Affiliation: Department of Environmental and Global Health, University of Florida, USA; Department of Microbiology, University of Dhaka, Bangladesh.

material of human origin is also a challenging task, considering the prevailing differences of opinion on ethical issues among the countries. There can be some changes in the patent system to pave the way for wider access to the therapy, but the idea of developing a new legal framework for those inventions targeted to health care found support to serve that purpose as well.

Keywords: Stem cell, invention, innovation, patent

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## I. Introduction

The patent system is multilayered comprising of the international, regional and national legal framework. It also differs amongst countries in substantive interpretation of the patentability and exclusion from the patentability.[1] Samantha A. Jameson comments, "[i]n the U.S., patent law is not considered an appropriate place to exercise moral judgments about science."[2] But in Europe, an invention can be excluded from patenting on the grounds of *ordre public* or morality.[3]

*Diamond v. Chakrabarty*[4] commenced the era of patenting the living things. It is the first case where the United States Supreme Court declared

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[1] Patenting inventions derived from human embryonic stem cell lines is possible in the U.S.A. Some of those U.S. patents on hESC related inventions include United States Patent No. 8,785,185, issued on July 22, 2014, assigned to Janssen Biotech, Inc. (Horsham, PA) and The Cleveland Clinic Foundation (Cleveland, OH) by the inventors Jean Xu and Jan Jensen; United States Patent No. 8,742,200, issued on June 3, 2014, assigned to Advanced Cell Technology, Inc. (Marlborough, MA) by the inventors Young Gie Chung, Robert Lanza and Irina V. Klimanskaya; United States Patent No. 8,710,190, issued on April 29, 2014, assigned to Agency for Science, Technology and Research (Singapore, SG) by the inventors Andre Choo and Steve Oh. *See* United States Patent and Trademark Office, *USPTO Patent Full-Text and Image Database*, *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=3&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&co1=AND&d=PTXT&s1=%22human+embryonic%22&s2=%22stem+cell%22&Page=Next&OS=%22human+embryonic%22+AND+%22stem+cell%22&RS=%22human+embryonic%22+AND+%22stem+cell%22 (last visited July 28, 2014).

On the contrary, a wide ban exists on patenting the inventions that destroys the human embryo in Europe. The judgment of CJEU in the case of *Oliver Brüstle* (2011) interpreted the relevant provisions of the Biotech Directive (1998) in a very strict way and the decision will curtail the hESC research freedom to a great extent, as it limits the patentability of inventions encompassing the destruction of human embryo. *Oliver Brüstle v. Greenpeace e.V*, C-34/10, Judgment of the Court (Grand Chamber) 18 Oct. 2011, *available at* http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10 (last visited July 25, 2014). According to Article 6 of the Biotech Directive, "uses of human embryos for industrial or commercial purposes" shall entail an invention "unpatentable", on the grounds of "ordre public or morality." Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, O.J.L.213, P. 0013-0021, (30/07/1998).

[2] Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in The United States and the European Union*, 35 AIPLA Q.J. 193, 202 (2007).

[3] According to the Article 53 (a) of the European Patent Convention, "inventions the commercial exploitation of which would be contrary to 'ordre public' or 'morality' are excluded from patenting." European Patent Convention, Oct. 5, 1973, a*vailable at* http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ar53.html.

[4] 447 U.S. 303 (1980).

that the microorganisms and its process are patentable inventions under the section 101[5] of the U.S. Code.[6] In the United States, the inclusion of microorganism as patentable invention happened in 1980 (by the decision of *Diamond v. Chakrabarty*), several decades after the plant patent for the asexually reproduced plants were made available in 1930 (through the Plant Patent Act, 1930).[7] Although the newer kinds of inventions/innovations were included under the umbrella of patent successively in the technologically advanced word, the question appears that how appropriate it is to offer patent for such inventions that require the reconstruction of the perceptional and definitional boundary of the "invention" itself and its patentability. Human Stem Cell based Inventions/Innovations (hereinafter referred to as hSCI) having its distinct and evolving approach of reinventing itself as a science, makes it a perfect topic to conduct an investigative empirical study on its patenting. For the purpose of this research, the hSCI shall mean those creations that originate from all kinds of the human stem cell researches. The human stem cell researches, at present, showing promising progress in hESC (human Embryonic Stem Cell), SCNT (Somatic Cell Nuclear Transfer) and iPSC (induced Pluripotent Stem Cell) technologies. The hESC based inventions/innovations face a substantial barrier in patenting in some jurisdictions for the exclusion on "ethical" grounds, due to embryo destruction for the derivation of the stem cells. Since patent is apparently the most lucrative and feasible tool for the recovery of investment in research and development available to the inventors and sponsors, its appropriateness and contribution in offering the "*incentive for innovation*" and making the therapies *accessible* in affordable means is tested through this empirical research.

The empirical study and the subsequent data analyses conducted, both qualitative[8] and quantitative, are limited by the small number of participating respondents. As it is extremely difficult to have responses from a sufficiently large number of randomly chosen experts from such diverse backgrounds related to Intellectual Property Right ("IPR"), bioethics and life sciences, adopting a convenience sampling approach was the most rational and feasible choice. Accordingly, 31 respondents representing 16 different countries across the globe[9] took part in the study. The sample size despite

[5] 35 U.S.C. § 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C § 101 (2011).

[6] *See* Diamond v. Chakrabarty 447 U.S. 303 (1980).

[7] At present, 35 U.S.C. § 161 provides the provision for plant patent in the U.S.A.

[8] The qualitative analysis conducted for the study is not included in this paper.

[9] The countries are from the continents of Africa, Americas, Asia, and Europe.

being relatively small is acceptable from the statistical point of view. Although the numerical summary provided a good overview of the response pattern, through tabular and graphical representations, it does not necessarily indicate association between two variables involved in the study questions to be statistically significant. As most of the variables were categorical in nature, properly coding them into dummy variables with binary values and employing logistic regression analyses to check for possible association seemed most appropriate. Due to the sample size constraints, relatively few numbers of associations turned out to be statistically "significant" at an alpha level of 0.05 while many results did show "promising trends." Nevertheless, the significant results and the positive trends observed using this small number of respondents are definitely intriguing and deserve due consideration. From a qualitative standpoint, the respondents were quite diverse in their opinion and many chose to express in their own words rather than selecting the suggested options that were provided in the questionnaire. This publication represents the quantitative analysis of the 6 questions from the 13 questions in the questionnaire of the study.

The article is comprised of five chapters. Chapter I give a brief introduction. Chapter II elaborates the empirical study design which includes the key questions explored through the study, the participating respondents and their demographic features, an overall sketch of the sequential steps in the data analysis and the primary objectives for performing this analysis. Chapter III presents an instrumental structure of the data analysis methodology involved. It incorporates the survey numerical summary and the predictor-response variable relationships being tested in tabular forms. The software code translations of STATA SE 13 related to binary and continuous variables are provided in the footnotes of this chapter. The key findings from the numerical summary and logistic regression analysis are incorporated in Chapter IV. An overall interpretation of the "significant" findings from the regression analysis conducted through the software is also eloquently presented in this chapter. Due to the limitation of characters, the complete "Logistic Regression Analysis Table" and the "STATA Software Output" are not published in this writing. Finally, Chapter V presents a brief conclusion by the way of recommendation.

## II. Empirical Study Design

The study took place between September 2013 and January 2014. The study was conducted to see the appropriateness of the patent system for the hSCI and to explore the best possible way to protect those innovations that would create the environment for wider accessibility of the therapy in one hand and allow adequate incentive for the invention/ innovation on the other hand. How the experts/professionals suggest and view the current

circumstances and what they see as areas deserving attention in future was investigated through a partly structured, partly open-ended questionnaire. It was a difficult task to find and reach to the appropriate respondents, as the respondents for the study were needed to be experts or professionals in one or more fields connected to the bioethics, intellectual property law and life science.[10] The study was conducted by sending the questionnaire template by email to the expert respondents and the answers were also received by email correspondence. The respondents were free to choose from the suggested options and also write their own answers or comments as they deem fit. Age group, gender, country (with respective Gross National Income) and profession are the demographic independent/predictor variables for the purpose of the data analysis. Names of the respondents were optional and for the purpose of the statistical analysis, it has not been taken into account.

The empirical study and the subsequent data analyses conducted and presented in this writing comprise of the following sequential steps shown in Figure 1.

[10] The interdisciplinary nature of the study made it a challenging endeavor to find the appropriate respondents.

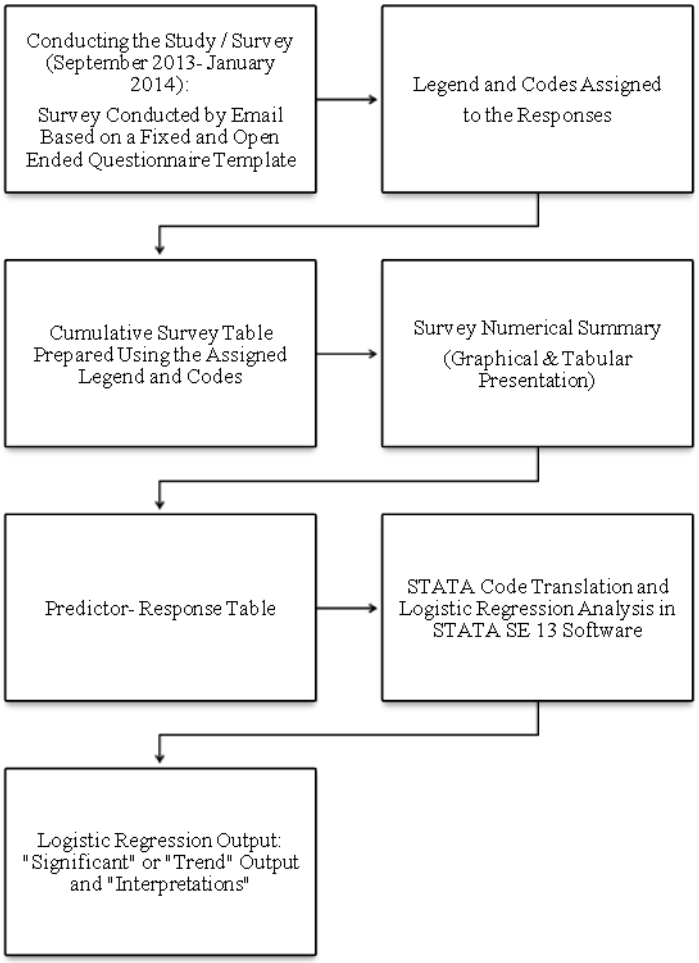


Figure 1: Research and Quantitative Data Analysis: Sequence of Actions

**A. Survey Questions and the Expert Respondents**

Considering the diverse approach the respondents might have due to their different fields of expertise, country backgrounds and personal experience, the questions in the questionnaire are designed from a more general approach, rather than making it too specific to certain context. Only 6 questions from the total of 13 questions of the questionnaire are chosen for this article. The questions chosen for this writing are the following:

**Question 6[11]:** Do you think patent protection as it exists today is the best way to provide incentive to human stem cell inventions/ innovations?[12]

[11] As it was numbered in the questionnaire.

[12] The responses with the codes for the data analysis are the following:

• Yes = coded as 0

• No = coded as 1

**Question 7:** Do you think that a new protection mechanism/ framework can be/ should be developed within the purview of intellectual property law (IPR), separate from patent, for the inventions/ innovations that use biological materials of human origin and targeted to health care?[13]

**Question 8:** How many years of protection (term of protection for commercial exploitation) is appropriate for human stem cell inventions/ innovations?[14]

**Question 10:** Who, according to your opinion, should be entitled to the intellectual property rights (IPR) of human stem cell inventions/ innovations?[15]

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• No, because patent has embarked into too much complications and uncertainty of enforcement = coded as 2

• No, because it is inappropriate for rewarding inventions/innovations in life science = coded as 3

• No, because patented inventions are property of the patentee/assignee and it invokes exclusive commercialization = coded as 4

• No, because patented human stem cell invention/innovation is a form of commercialization of 'life' = coded as 5

• Other responses/ opinions = coded as 6

• 3+5 = coded as 7

• 3+ 6 = coded as 8

• 4+5 = coded as 9

• 2+3+4 = coded as 10

[13] The responses with the codes for the data analysis are the following:

• Yes (can be) = coded as 1

• Yes (should be) = coded as 2

• No = coded as 0

• Other opinion = coded as 3

• 0 + 3 = coded as 4

[14] The responses with the codes for the data analysis are the following:

• More than 20 years = coded as 1

• 20 years = coded as 2

• 15 years = coded as 3

• 10 years = coded as 4

• 5 years = coded as 5

• No protection = coded as 0

• 1+ 2= coded as 6

[15] The responses with the codes for the data analysis are the following:

• Scientist/ Inventor = coded as 1

• Employer organization/ University/ Assignee = coded as 2

• Both Scientist/ Inventor and Employer organization/ University/ Assignee = coded as 3

• State through its Department responsible for heath care = coded as 4

• None of the above /other opinion = coded as 5 (Note: In other opinion some experts have mentioned some of the entity mentioned above jointly with their prescribed entity)

• No one should own IPR of human stem cell inventions/ innovations = coded as 0

**Question 12:** Do you think legal obligation for issuing "licenses on easy terms" or "compulsory licenses" and "technology transfer" can bring benefit to the patients by ensuring availability of medication/treatment at a reduced cost and may also serve as incentive for the IPR right owner of human stem cell inventions/innovations at the same time?[16]

**Question 13:** Do you think public opinion should be sought and be given importance after the invention/ innovation is put to the market for commercial exploitation, in order to measure the impacts of the IPR protected invention/ innovation on the health care receiver?[17]

The following tables from the survey numerical summary show from which countries the respondents are taking apart. From the perspective of Gross National Income ("GNI") per capita, the participation appears as follows:

Table 1

| Country | Frequency | Percent | Cumulative % |
|---|---|---|---|
| **Bangladesh** | 1 | 3.23 | 3.23 |
| **Botswana** | 1 | 3.23 | 6.45 |
| **Chile** | 1 | 3.23 | 9.68 |
| **India** | 1 | 3.23 | 12.9 |
| **Denmark** | 1 | 3.23 | 16.13 |
| **Egypt** | 2 | 6.45 | 22.58 |

• 1+ 5 = coded as 6
• 3+ 4 = coded as 7

[16] The responses with the codes for the data analysis are the following:
• Yes = coded as 1
• Yes, but for the cost reduction the public health care sector has to be involved = coded as 2
• Yes, cost reduction is possible if the licenses are issued in favor of local pharmaceutical companies/ hospitals and therapies and medications are manufactured and produced locally = coded as 3
• I think yes but I am not so sure = coded as 4
• No = coded as 0
• Other opinion = coded as 5
• 0+5 = coded as 6
• 2+3 = coded as 7

[17] The responses with the codes for the data analysis are the following:
• Yes= coded as 1
• Yes, and public opinion can be received online= coded as 2
• No= coded as 0
• Specific opinion/ suggestion about seeking public opinion = coded as 3
• 0+3 = coded as 4
• 1+2 = coded as 5

| | | | |
|---|---|---|---|
| **Kyrgyzstan** | 1 | 3.23 | 25.81 |
| **Malaysia** | 1 | 3.23 | 29.03 |
| **Italy** | 5 | 16.13 | 45.16 |
| **Japan** | 1 | 3.23 | 48.39 |
| **Lithuania** | 8 | 25.81 | 74.19 |
| **Spain** | 1 | 3.23 | 77.42 |
| **Suriname** | 1 | 3.23 | 80.65 |
| **UAE** | 1 | 3.23 | 83.87 |
| **USA** | 4 | 12.9 | 96.77 |
| **Mexico** | 1 | 3.23 | 100 |
| **Total** | **31** | **100** | |

Table 2

| **Country** | **Gross National Income (GNI) per capita in US$**[18] | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|---|
| **Bangladesh** | 840 | 1 | 3.23 | 3.23 |
| **Kyrgyzstan** | 990 | 1 | 3.23 | 6.45 |
| **India** | 1580 | 1 | 3.23 | 9.68 |
| **Egypt** | 2980 | 2 | 6.45 | 16.13 |
| **Botswana** | 7650 | 1 | 3.23 | 19.35 |
| **Suriname** | 8680 | 1 | 3.23 | 22.58 |
| **Mexico** | 9640 | 1 | 3.23 | 25.81 |
| **Malaysia** | 9820 | 1 | 3.23 | 29.03 |
| **Lithuania** | 13830 | 8 | 25.81 | 54.84 |
| **Chile** | 14310 | 1 | 3.23 | 58.06 |
| **Spain** | 29620 | 1 | 3.23 | 61.29 |
| **Italy** | 33860 | 5 | 16.13 | 77.42 |
| **UAE** | 35770 | 1 | 3.23 | 80.65 |
| **Japan** | 47880 | 1 | 3.23 | 83.87 |
| **U.S.A.** | 52340 | 4 | 12.9 | 96.77 |
| **Denmark** | 59850 | 1 | 3.23 | 100 |

[18] *See* World Bank, *GNI Per Capita, Atlas Method (Current US$)*, http://data.worldbank.org/indicator/NY.GNP.PCAP.CD/countries (last visited Mar. 4, 2014) (update frequency of GNI per capita data is quarterly and the referred one represents 4th quarterly update in December, 2013).

| | | | | |
|---|---|---|---|---|
| **Total** | | **31** | **100** | |

Following the World Bank Classification of Countries[19] based on GNI per capita, the respondents can be grouped as follows:

Table 3

| Country Economy Group | Frequency | Percent | Cumulative % |
|---|---|---|---|
| **High** | 22 | 70.97 | 70.97 |
| **Low** | 2 | 6.45 | 77.42 |
| **Lower middle** | 3 | 9.68 | 87.1 |
| **Upper middle** | 4 | 12.9 | 100 |
| **Total** | **31** | **100** | |

The respondents have the expertise in the respective "profession" mentioned in the table below[20]:

Table 4

| Profession | Frequency | Percent | Cumulative % |
|---|---|---|---|
| **Academic** | 2 | 6.45 | 6.45 |
| **Ethicist/Bioethicist** | 2 | 6.45 | 12.9 |
| **Lawyer** | 5 | 16.13 | 29.03 |
| **Patent Examiner** | 2 | 6.45 | 35.48 |
| **Patient Advocate** | 2 | 6.45 | 41.94 |
| **Physician** | 1 | 3.23 | 45.16 |
| **Researcher** | 2 | 6.45 | 51.61 |
| **Academic & Lawyer** | 3 | 9.68 | 61.29 |
| **Academic & Researcher** | 3 | 9.68 | 70.97 |
| **Academic, Bioethicist & Physician** | 1 | 3.23 | 74.19 |

[19] *See* World Bank, *New Country Classifications*, http://data.worldbank.org/news/new-country-classifications (last visited Mar. 4, 2014).

[20] The most of the professionals appear to have background related to IPR, bioethics and life science. The patient advocate, physician and ethicist also took part. Since multiple respondents had several professional identity/ affiliation, there were grouping for the purpose of analysis according to the reference of the professions the respondents made.

| | | | |
|---|---|---|---|
| **Academic, Bioethicist & Lawyer** | 1 | 3.23 | 77.42 |
| **Academic, Lawyer & Patient** | 1 | 3.23 | 80.65 |
| **Bioethicist & Lawyer** | 1 | 3.23 | 83.87 |
| **Bioethicist & Researcher** | 1 | 3.23 | 87.1 |
| **Lawyer & Scientist** | 1 | 3.23 | 90.32 |
| **Patent Examiner & Researcher** | 1 | 3.23 | 93.55 |
| **Scientist & Researcher (any field)** | 2 | 6.45 | 100 |
| **Total** | **31** | **100** | |

From the perspective of gender, the respondents are of following number:

Table 5

| Gender | Frequency | Percent | Cumulative % |
|---|---|---|---|
| **Male** | 18 | 58.06 | 58.06 |
| **Female** | 13 | 41.94 | 100 |
| **Total** | **31** | **100** | |

They identify themselves into following age groups:

Table 6

| Age Groups (Years) | Frequency | Percent | Cumulative % |
|---|---|---|---|
| **Less than & 25** | 1 | 3.23 | 3.23 |
| **26-30** | 8 | 25.81 | 29.03 |
| **31-35** | 9 | 29.03 | 58.06 |
| **36-40** | 4 | 12.9 | 70.97 |
| **41-45** | 2 | 6.45 | 77.42 |
| **46-50** | 3 | 9.68 | 87.1 |
| **51-55** | 1 | 3.23 | 90.32 |
| **56-60** | 1 | 3.23 | 93.55 |
| **More than 65** | 2 | 6.45 | 100 |
| **Total** | **31** | **100** | |

### B. Objectives from the Perspectives of Intellectual Property Protection Of hSCI

The above mentioned course of data analysis was employed to pursue the following objectives:

- To examine if the patent offers the best protection to hSCI;
- To explore if there is any need of new IPR protection framework;
- To find if there will be any benefit of imposing legal obligation on the IPR owner of hSCI; and
- To know if seeking public opinion is necessary to observe the post marketing impact of IPR protection on the health care receiver.

## III. Survey Data Analysis

### A. Methodology

Responses to the survey questionnaire collected over email were mostly categorical in nature. Respondents were free to choose from the suggested options and/or include their own opinion as well. In order to perform a quantitative analysis, it was, therefore, necessary to code and compile the responses. Microsoft excel was used to compile all the responses into an excel file and this dataset was used to prepare the numerical summary and for further data analysis. Survey numerical summary comprised of frequency distribution table and graphical representation for each variable. This summary served as a good way to consolidate and look at the response pattern at a glance.

As most of the questions were designed in context, we wanted to analyze how the response to one question was related to another and how much it varied among different respondents. Our goal was to look for possible associations of related variables comprising the questionnaire. Some of the variables were hypothesized to be independent and predictor of another dependent or response variable. We, therefore, came up with a predictor-response variable table to check for possible association. This required performing logistic regression analysis in STATA SE 13 software, and in order to do that all the variables with multiple options were converted in the most logical manner into binary responses (STATA code translation).[21]

[21] *Age group split up into 3 binary subgroups:
*Binary code: Ageb (if age of the respondents is 35 years or below)
- Ageb = 1 (35 years or below)
- Ageb = 0 (36 years and above)

*Binary code: Ageb1 (if age of the respondents is 30 years or below)
- Ageb1 = 1 (30 years or below)
- Ageb1 = 0 (31 years and above)

*Binary code: Ageb2 (if age of the respondents is 40 years or below)

- Ageb2 = 1 (40 years or below)
- Ageb2 = 0 (41 years and above)

*Age group as a continuous predictor (non-binary): coded as Ageb3

- Ageb3 = 0 (30 years or below)
- Ageb3 = 1 (31 to 50 years)
- Ageb3 = 2 (51 to 65 years)

*Gender to binary code: genderb

- genderb = 0 (Male)
- genderb = 1 (Female)

*Country economy based on Gross National Income (GNI) to binary code: gnib1(High Economy Group or not)

- gnib1 = 0 (if income is <12616$)
- gnib1 = 1 (if income is > = 12616$)

*Profession split up into 6 binary subgroups:

*Binary code: professionb1(Belong to legal professions or not)

- professionb1 = 0 (if does not belong to the legal profession)
- professionb1 = 1 (if belongs to the legal profession)

*Binary code: professionb2 (Belong to academia or not)

- professionb2 = 0 (if does not belong to academia)
- professionb2 = 1 (if belongs to academia)

*Binary code: professionb3 (Bioethicists or not)

- professionb3 = 0 (if not bioethicist)
- professionb3 = 1 (if bioethicist)

*Binary code: professionb4 (Patient /patient advocate, or not)

- professionb4 = 0 (if not Patient/ patient advocate)
- professionb4 = 1 (if Patient/ patient advocate)

*Binary code: professionb5 (Patent examiner, or not)

- professionb5 = 0 (if not Patent examiner)
- professionb5 = 1 (if Patent examiner)

*Binary code: professionb6 (Researcher, or not)

- professionb6 = 0 (if not Researcher)
- professionb6 = 1 (if Researcher)

*Q6 to binary code: q6b

Do you think patent protection as it exists today is the best way to provide incentive to human stem cell inventions/ innovations?

- q6b = 1 if Yes
- q6b = 0 if No

*Q7 to binary code: q7b

Do you think that a new protection mechanism/ framework can be/ should be developed within the purview of intellectual property law (IPR), separate from patent, for the inventions/ innovations that use biological materials of human origin and targeted to health care?

- q7b = 1 if Yes
- q7b = 0 if No

*Q8 to split up into 4 binary subgroups:

Results of logistic regression analysis were expressed in odds ratio (OR) and two-tailed confidence interval (CI) for each OR assumed an alpha of 0.05.

---

How many years of protection (term of protection for commercial exploitation) is appropriate for human stem cell inventions/ innovations?

*Binary code for those opting for 20 years of protection: q8b1

- q8b1 = 1 if Yes
- q8b1 = 0 if No

*Binary code for those opting for more than 20 years of protection: q8b2

- q8b2 = 1 if Yes
- q8b2 = 0 if No

*Binary code for those who opt for less than 20 years of protection: q8b3

- q8b3 = 1 if Yes
- q8b3 = 0 if No

*Binary code for those opting for no protection: q8b4

- q8b4 = 1 if Yes (who opted for "No" protection)
- q8b4 = 0 if No

* Q10 split up into 4 binary subgroups:

Who, according to your opinion, should be entitled to the intellectual property rights (IPR) of human stem cell inventions/ innovations?

*Binary code for both scientists and organization: q10b1

- q10b1 = 1 if Yes
- q10b1 = 0 if No

*Binary code for only scientists: q10b2

- q10b2 = 1 if Yes
- q10b2 = 0 if No

*Binary code where respondents think none should own IPR: q10b3

- q10b3 = 1 if Yes
- q10b3 = 0 if No

*Binary code where respondents think only scientists or both scientists & organization should own IPR: q10b4

- q10b4=1 if Yes
- q10b4=0 if No

*Q12 to binary code: q12b

Do you think legal obligation for issuing 'licenses on easy terms' or 'compulsory licenses' and 'technology transfer' can bring benefit to the patients by ensuring availability of medication/ treatment at a reduced cost and may also serve as incentive for the IPR right owner of human stem cell inventions/ innovations at the same time?

- q12b = 1 if yes
- q12b = 0 if No

*Q13 to binary code: q13b

Do you think *public opinion* should be sought and be given importance after the invention/ innovation is put to the market for commercial exploitation, in order to measure the impacts of the IPR protected invention/ innovation on the health care receiver?

- q13b = 1 if yes
- q13b = 0 if No

The following table summarizes the possible associations between the predictor and response variables [22] that were tested using the logistic regression analysis.

Table 7

| **Predictor Variable** | **Binary Predictor Variable** | **Response Variable** | **Binary Response Variable** |
|---|---|---|---|
| Profession | professionb1- b6 | Does existing patent protection provide the best incentive? (Q6) | q6b |
| Profession | professionb1 - b6 | Can/Should a new protection framework be developed ?(Q7) | q7b |
| Profession | professionb1 – b6 | What is the appropriate term of protection for commercial exploitation? (Q8) | q8b1- b4 |
| Profession | professionb1 – b6 | Who should be entitled to the intellectual property rights? (Q10) | q10b1- b4 |
| Profession | professionb1 – b6 | Do you think issuing legal obligation can be beneficial? (Q12) | q12b |
| GNI group | gnib1 | Can/Should a new protection framework be developed ?(Q7) | q7b |
| GNI group | gnib1 | What is the appropriate term of protection for commercial exploitation? (Q8) | q8b1- b4 |
| GNI group | gnib1 | Who should be entitled to the intellectual property rights? (Q10) | q10b1- b4 |
| GNI group | gnib1 | Do you think issuing legal obligation can be beneficial? (Q12) | q12b |
| GNI group | gnib1 | Do you think *public opinion* should be sought | q13b |

[22] The STATA code translations for the predictor and response variables are detailed in footnote 21.

| | | | |
|---|---|---|---|
| | | and be given importance? (Q13) | |
| Age group | Ageb, Ageb1-3 | Does existing patent protection provide the best incentive? (Q6) | q6b |
| Age group | Ageb, Ageb1-3 | Can/Should a new protection framework be developed? (Q7) | q7b |
| Age group | Ageb, Ageb1-3 | What is the appropriate term of protection for commercial exploitation? (Q8) | q8b1- b4 |
| Age group | Ageb, Ageb1-3 | Who should be entitled to the intellectual property rights? (Q10) | q10b1- b4 |
| Age group | Ageb, Ageb1-3 | Do you think issuing legal obligation can be beneficial? (Q12) | q12b |
| Age group | Ageb, Ageb1-3 | Do you think *public opinion* should be sought and be given importance? (Q13) | q13b |
| Q6 | q6b | Can/Should a new protection framework be developed ?(Q7) | q7b |
| Q6 | q6b | Who should be entitled to the intellectual property rights? (Q10) | q10b1- b4 |
| Q6 | q6b | Do you think issuing legal obligation can be beneficial? (Q12) | q12b |
| Q7 | q7b | What is the appropriate term of protection for commercial exploitation? (Q8) | q8b1- b4 |
| Q7 | q7b | Who should be entitled to the intellectual property rights? (Q10) | q10b1- b4 |
| Q7 | q7b | Do you think issuing legal obligation can be beneficial? (Q12) | q12b |

| | | | |
|---|---|---|---|
| Q7 | q7b | Do you think *public opinion* should be sought and be given importance? (Q13) | q13b |
| Q8 | q8b | Does existing patent protection provide the best incentive? (Q6) | q6b |
| Q10 | q10b1- b4 | Can/Should a new protection framework be developed? (Q7) | q7b |
| Q10 | q10b1- b4 | What is the appropriate term of protection for commercial exploitation? (Q8) | q8b1- b4 |
| Q13 | q13b | Does existing patent protection provide the best incentive? (Q6) | q6b |

**B. Question-Wise Summary**
**Question 6[23]:**

Table 8

| **Does Existing Patent Protection provide the Best Incentive to human Stem Cell (hSC) based Innovations/Inventions?** | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|
| **Yes** | 13 | 41.94 | 41.94 |
| **No** | 2 | 6.45 | 48.39 |
| **No: Complications & uncertainty of enforcement** | 2 | 6.45 | 54.84 |
| **No: Inappropriate to reward life science innovations** | 3 | 9.68 | 64.52 |
| **No: Invokes exclusive commercialization** | 3 | 9.68 | 74.19 |
| **No: Patented hSC** | 1 | 3.23 | 77.42 |

[23] As it was numbered in the questionnaire.

| | | | |
|---|---|---|---|
| **innovation is a form of commercialization of "Life"** | | | |
| **Other opinion** | 3 | 9.68 | 87.1 |
| **No: Inappropriate to reward life science innovations & patented hSC innovation is a form of commercialization of "Life"** | 1 | 3.23 | 90.32 |
| **No: Inappropriate to reward life science innovations & other opinion** | 1 | 3.23 | 93.55 |
| **No: Invokes exclusive commercialization & patented hSC innovation is a form of commercialization of "Life"** | 1 | 3.23 | 96.77 |
| **No: Uncertainty of enforcement, inappropriate to reward life science innovations & patented hSC innovation is a form of commercialization of "Life"** | 1 | 3.23 | 100 |
| **Total** | **31** | **100** | |

**Question: 7**

Table 9

| **Need for New Protection Framework** | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|
| **No** | 5 | 16.13 | 16.13 |
| **Yes: Can be** | 15 | 48.39 | 64.52 |
| **Yes: Should be** | 8 | 25.81 | 90.32 |

| | | | |
|---|---|---|---|
| **Other opinion** | 2 | 6.45 | 96.77 |
| **No: Other opinion** | 1 | 3.23 | 100 |
| **Total** | **31** | **100** | |

**Question: 8**

Table 10

| **Term of Protection for Commercial Exploitation Suggested for human Stem Cell based Invention/ Innovations** | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|
| **No protection** | 9 | 29.03 | 29.03 |
| **More than 20 years** | 1 | 3.23 | 32.26 |
| **20 years** | 9 | 29.03 | 61.29 |
| **15 years** | 1 | 3.23 | 64.52 |
| **10 years** | 7 | 22.58 | 87.1 |
| **5 years** | 3 | 9.68 | 96.77 |
| **20 or more than 20 years** | 1 | 3.23 | 100 |
| **Total** | **31** | **100** | |

**Question: 10**

Table 11

| **Entitlement of the IPR for human Stem Cell based Invention/Innovations** | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|
| **No one should own IPR** | 6 | 19.35 | 19.35 |
| **Scientist/Inventor** | 3 | 9.68 | 29.03 |
| **Employer organization/University/Assignee** | 1 | 3.23 | 32.26 |
| **Both scientist & employer organization** | 12 | 38.71 | 70.97 |
| **State: Through its health care department** | 4 | 12.9 | 83.87 |
| **Other opinion** | 3 | 9.68 | 93.55 |
| **Scientist/Inventor & patients** | 1 | 3.23 | 96.77 |
| **Scientist, employer organization & the State health care** | 1 | 3.23 | 100 |

| | | | |
|---|---|---|---|
| **department** | | | |
| **Total** | **31** | **100** | |

**Question: 12**

Table 12

| **Benefits of Imposing Legal Obligations (Cost Reduction & Incentives to Innovations)** | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|
| **Yes** | 8 | 25.81 | 25.81 |
| **Yes: If public health care sector involved** | 9 | 29.03 | 54.84 |
| **Yes: If licenses issued in favor of local manufacturers** | 2 | 6.45 | 61.29 |
| **Yes: But not sure** | 6 | 19.35 | 80.65 |
| **Other opinion** | 4 | 12.9 | 93.55 |
| **No: May benefit some impoverished countries but not required for every country** | 1 | 3.23 | 96.77 |
| **Yes: If public health care sector involved & licenses Issued in favor of local manufacturers** | 1 | 3.23 | 100 |
| **Total** | **31** | **100** | |

**Question: 13**

Table 13

| **Seeking Public Opinion: To Measure Post Marketing Impacts of IPR** | **Frequency** | **Percent** | **Cumulative %** |
|---|---|---|---|
| **No** | 7 | 22.58 | 22.58 |
| **Yes** | 7 | 22.58 | 45.16 |
| **Yes: Public opinion can be received online** | 11 | 35.48 | 80.65 |

| | | | |
|---|---|---|---|
| **Other Opinion** | 6 | 19.35 | 100 |
| **Total** | **31** | **100** | |

## IV. Key Findings and Observations

### A. Survey Numerical Summary

**Question 6:** Substantial number of respondents (41.94%) thought that the current patent system is working well to offer incentive to innovation for hSCI. The majority rejected the system on various grounds (approximately 49%). 9.68% of the respondents had different opinion.

**Question 7:** Despite substantial number of respondents (41.94%) thought that the patent system is working well for hSCI, approximately 75% of the respondents were interested to see an IPR protection framework separate from patent for those inventions/innovations that use biological materials of human origin[24] and targeted to health care.

**Question 8:** 29.03% of the respondents showed inclination towards the patent system, when it comes to the term of protection, as patent typically protects the invention for 20 years. An equal percentage (29.03%) of the respondents were also suggesting "no protection" for commercial exploitation; the mentality seems to be inclined to treat hSCI as "public good" or a freely available resource. A good number of respondents (35.49%) were in favor of endorsing a below 20 years' term of protection for commercial exploitation.

**Question 10:** 19.35% of the respondents were inclined to view IPR for hSCI as public good, as they did not favor the proprietary nature of the IPR for the hSCI. In question number 8, 29.03% of the respondents suggested "no protection" for those inventions/innovations. It can be observed that at least 19.35% of the respondents (between 19.35% (no one should own IPR

[24] The biological materials (in human) can be derived from the embryo, fetus or fully developed human being. Stem cell based inventions may require the use of human somatic cell, sperm, eggs and embryos for the product development. Although some of them are clearly "biological material of human origin" in the normal sense of the term, not all of them are accepted to be defined in such way by all the stakeholders. Whether, how and which of the stem cell based inventions encompasses the "biological material of human origin" can invite differing opinions. Another question (not included in this article) was asked to the respondents about "embryo destruction for research and invention/innovation" having one of the suggested options addressing the human embryos as the "biological material of human origin." 29.03% (9 out of the total 31) of the respondents treat the embryo as biological material of human origin.

These questions widely attempts to see if the stem cell based inventions, having encompassed the use of biological material of human origin, should be protected under a different IPR framework or not.

of hSCI) and 29.03% (no protection)) do not want that individual or organization should own the IPR of hSCI.

38.71% of the respondents supported the idea of IPR of hSCI being owned by the "scientist and employer organization" which at present happens mostly in the case of patent protection. 12.9% of the respondents supported the invention/ innovation to be owned by the "State: through its health care department" only. Ownership by State is feasible when the funding for research and investment comes from "public" sources. If the research and investment is conducted through "private" funding, exclusive ownership would be an obvious claim and seek justification as "incentive for innovation".

**Question 12:** At present compulsory licensing is not a precondition of obtaining/granting the patent. In some jurisdiction compulsory licensing can be done under the intellectual property law on certain grounds. There is a great diversity among the countries under which circumstances compulsory licenses can be issued. Article 31 of the TRIPS Agreement provides strict conditions under which "Use Without Authorization of the Right Holder" is possible.[25] It does not allow imposing the "compulsory licensing" on the will of the State authority where the patent is commercially exploited, as a precondition to patent. The affordability of the consumer in a particular territory is not a consideration of that provision. To remedy an anti-competitive effect, the "judicial or administrative" authority can be exercised under Article 31(k).[26] Such use can also be permitted under Article 31(b) for "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use" for a limited duration.[27] But an absence of *consideration of affordability of the consumer* in the legal framework, where public sector does not offer services in non-commercial manner, will not contribute to the wider access to the therapeutic applications of patented inventions. Determination of anti-competitive effects is also restricted to certain fixed criterion.

In this question, the examples of legal obligations were: (1) issuing licenses on easy terms, (2) compulsory licenses, and (3) technology transfer. This question explored if those legal obligations can be beneficial for wider accessibility of the medication in one hand and the intellectual property right of the IPR owner remains unaffected by them on the other hand. "No" and "other opinion" accounted for approximately 17%. However, 83.87%

[25] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter, "*TRIPS Agreement*"].

[26] *See id.*

[27] *See id.*

respondents supported that legal obligation may contribute to wider access to the therapy and will not harm the intellectual property right of the IPR owner. Reduced cost of the therapy is presumed to contribute to wider access to the treatment.

**Question 13:** 58.06 % of the respondents believed that public opinion can make a difference. There is post marketing surveillance by the U.S. Food and Drug Administration (U.S. FDA) that is concerned about the consumer responses to the drugs (regarding any adverse reactions) in post marketing months.[28] But the consumers are never informed about the production cost of the drug, the percentage charged for the present and future research and investment, IPR protection and marketing costs, when they are purchasing a drug. The consumer, if they are well informed, might generate sensible information about their affordability and practical implications of pricing on therapy, if such an opportunity is created. No doubt, that IPR protection contributes to enhanced cost of the drugs to a substantial extent. Monitoring and taking into account the public opinion will create an opportunity of people's participation in the cycle of biomedical research. For balancing the drug price, i.e., cost of the therapy and making it affordable to wider number of people, public opinion can be a good resource. It is debatable if the consumers possess enough information and knowledge to make sensible comments, but the patient who undergoes a treatment educate himself/ herself in that process and his/ her first hand experience can also be considered as a source of valuable information.

The above summary is a useful way to see the overall response pattern and also points to the direction subsequent statistical analysis needs to be carried out. However, the limitation of the findings and observations from the survey numerical summary lies in the fact that although the frequency and cumulative percentage in the numerical summary offered insight on how majority of the respondents answered to individual question, this does not necessarily indicate to any association between two variables to be statistically significant. Results derived from logistic regression analysis between different predictor and response variables reflect such associations.

### B. Logistic Regression Analysis Using STATA SE 13

A complete "Logistic Regression Analysis Table" and the corresponding "STATA Software Output" are not incorporated into the text of the writing. Only the tables with results showing "Significance" and the results showing "Trend" from those 6 questions have been inserted and interpreted in this

[28] *See* U.S. Food & Drug Admin., *Postmarketing Surveillance Programs*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm090385.htm (last visited Sept. 25, 2014).

writing. The p-value has to be less than 0.05 in order to be "significant" (95% significance with alpha level of 0.05). A p-value little more than 0.05 shows a "trend" towards significance.[29]

### 1. Logistic Regression Output (STATA SE 13): Results Showing Significance

Table 14

| Predictor | Response | P-value | Odds Ratio (OR) | 95% Confidence Interval (CI) |
|---|---|---|---|---|
| **professionb1** | q6b | 0.032 | 5.599999 | 1.158285 - 27.07451 |
| **Ageb3**[30] | q8b4 | 0.342 | 3.076923 | 0.3021829 - 31.33021 |
| | | 0.043 | 24 | 1.110724 - 518.5807 |
| **gnib1** | q7b | 0.043 | 7.6 | 1.067807 - 54.09217 |
| **q8b1** | q6b | 0.007 | 12.8 | 2.019838 - 81.11538 |
| **q10b1** | q8b1 | 0.036 | 5.833333 | 1.119237 - 30.40265 |
| **q10b4** | q8b4 | 0.009 | 0.046875 | 0.0047908 - 0.4586413 |
| **q13b** | q6b | 0.024 | 0.1442308 | 0.0268644 - 0.7743521 |

### 2. Logistic Regression Output (STATA SE 13): Results Showing Trend

Table 15

| Predictor | Response | P-value | Odds Ratio (OR) | 95% Confidence Interval (CI) |
|---|---|---|---|---|
| **professionb1** | q8b4 | 0.069 | 0.125 | 0.0132999 - |

[29] The soft copies of the complete "Logistic Regression Analysis Table" and the "STATA Software Output" are provided to the reviewer of the article.

[30] Ageb3 is a continuous predictor having three age groups (non-binary). Compared to the reference group (30 years or below), the change in other two groups are analyzed. Therefore, unlike other results, the change in increasing age is shown by a pair of results. For instance, even though the age group (31 to 50 years) shows a non-significant p-value of 0.342, the more elderly group (51 to 65 years) does show a significant p-value of 0.043.

| | | | | |
|---|---|---|---|---|
| | | | | 1.174819 |
| **Ageb2** | q8b3 | 0.097 | 6.666667 | 0.7084089 - 62.73841 |
| **Ageb3**[31] | q10b4 | 0.178 | 0.2857143 | 0.0461565 - 1.768608 |
| | | 0.094 | 0.0952381 | 0.0060564 - 1.497631 |
| **q6b** | q10b1 | 0.066 | 4.16 | 0.9092842 - 19.03211 |
| **q7b** | q13b | 0.091 | 5.333333 | 0.7668501 - 37.09256 |

### 3. Interpreting "Significance" and "Trend" in the Logistic Regression Analysis Output

While a statistically significant number of respondents (p-value = 0.007) opting for 20 years of protection for commercial exploitation were also more likely (OR= 12.8; 95% CI OR = 2.019838 - 81.11538) to consider the current patent system as the best way to provide incentive to human stem cell inventions/ innovations, the odds (p-value = 0.032) of preferring the existing patent system were 5.6 times higher (OR = 5.599999; 95% CI OR = 1.158285 - 27.07451) among the legal professionals compared to others. Respondents who opted for "no protection at all" were 95.31% less likely (OR = 0.046875; 95% CI OR = 0.0047908 - 0.4586413) to concur to the idea of entitlement of IPR to "scientists, organization (employer) or both" (p-value = 0.009). Compared to the respondents who belong to 30 years or below age group, those who are between 31 and 50 years old are 3.1 times (OR = 3.076923; 95% CI OR = 0.3021829 - 31.33021) and those who are between 51 and 65 years old are 24 times (OR = 24; 95% CI OR = 1.110724 - 518.5807) more likely (p-value = 0.043) to consider that "no one should own IPR of human stem cell inventions/innovations". Although a statistically significant (p-value = 0.032) result was observed in the case of the most elderly group (51-65 years), the p-value for the age group of 31-50 years (p-value = 0.342) was not significant at an alpha level of 0.05. On the other hand, those who found "20 years (term of protection for commercial exploitation) of protection"[32] appropriate were also 5.83 times (OR =

[31] Age is a continuous variable; therefore, unlike other results, the change in increasing age is shown by a pair of results.

[32] Patent is granted by a State in favor of the patentee/ assignee, empowering the owner (patentee/ assignee) the right (exclusive) to exploit the invention commercially throughout the period of term of protection, which is usually 20 years. Article 33 of the TRIPS Agreement, 1994 provides 20 years' term of protection for patents.

5.833333; 95% CI OR = 1.119237 - 30.40265) more likely (p-value = 0.036) to think that "both scientists and organizations (employer)" should be entitled to the IPR of human stem cell inventions/innovations. For the respondents from high economy country, the odds of favoring a "new protection mechanism/framework, separate from patent," for these innovations/inventions were 7.6 times higher (OR = 7.6; 95% CI OR = 1.067807 - 54.09217) compared to those from middle and low economy countries (p-value = 0.043). In addition, those who consider that "public opinion should be sought" in order to measure the impact of the IPR protected invention/innovation on the health care receiver were 85.57% less likely (OR = 0.1442308; 95% CI OR = 0.0268644 - 0.7743521) to think that the existing patent system are the best (p-value = 0.024).

Logistic regression analyses also revealed some promising associations although they were not significant at an alpha level of 0.05. For instance, the odds of concurring to "no IPR protection at all" for human stem cell inventions/innovations among the legal professionals were 87.5% less compared to those who belong to other professions (p-value = 0.069; OR= 0.125; 95% CI OR = 0.0132999 - 1.174819). In comparison to the respondents who belong to the age group 30 years or below, those who are between 31 and 50 years old have 71% (OR = 0.2857143; 95% CI OR = 0.0461565 - 1.768608) and those who are between 51 and 65 years old have 90.5% (OR = 0.0952381; 95% CI OR = 0.0060564 - 1.497631) less likelihood to consider that "only scientists or both scientists & organization (employer)" should own the IPR. Although the relation observed in the case of the most elderly group (51-65 years) showed a positive trend (p value = 0.094), the effect was statistically not "significant." For the respondents who opted for the existing patent protection, the odds of favoring entitlement of IPR to "both scientists and organizations (employer)" were 4.16 times higher than those who consider otherwise (p-value = 0.066; OR = 4.16; 95% CI OR = 0.9092842 - 19.03211). Interestingly, respondents aged 40 years or below were 6.7 times more likely to find "less than 20 years" of "term of protection for commercial exploitation" (IPR protection) appropriate compared to those who were above 40 years old (p-value = 0.097; OR= 6.666667; 95% CI OR = 0.7084089 - 62.73841). Also those who considered that a new protection mechanism/framework "can be"/"should be" developed were 5.3 times more likely to think that public opinion should also be sought to measure the post-marketing impacts of the IPR protected invention/ innovation on the health care receiver (p-value = 0.091; OR= 5.33; 95% CI OR = 0.7668501 - 37.09256).

## V. Conclusion and Recommendations

The survey numerical summary revealed several clear favorite options as chosen by the respondents. In a nutshell, the majority of the participating respondents did not consider that the current patent system offers the best incentive to hSCI on various grounds (approximately 49%); were highly supportive to the idea of a new protection framework (74.2%); did not support 20 years' term of protection (either against any type of protection or consider that less than 20 years of protection for commercial exploitation is appropriate for these type of inventions/innovations) (64.52%) [33]; and thought that imposing legal obligation is beneficial and simultaneously can serve the purpose of cost reduction and encouraging innovation (83.87%) and endorsed seeking public opinion to measure the post marketing impacts of IPR protection (58.06%). The current practice of entitlement of the IPR to both the scientists and organization (employer) was preferred by a substantial number of respondents (38.71%).

The logistic regression analysis reveals statistically significant relationship between:

- preference to the current patent system and supporting 20 years of IPR protection, with the legal professionals being the most prominent ones favoring the current system in place;
- residence in a high economy country and supporting development of a new protection framework;
- older age group (51 to 65 years) and predilection not to support entitlement of these inventions/innovations;
- inclination to opt for 20 years of protection and supporting the entitlement of the IPR (of human stem cell based inventions/innovations) to both the scientists and organizations (employer);
- aversion to the existing patent protection and preference to seeking public opinion in order to measure the post marketing impacts of the IPR protected invention/ innovation on the health care receiver.

In addition, several other promising associations showing positive trend were found.

The following conclusion by way of recommendations can be drawn after this empirical investigation. The numerical summary revealed that 41.94% of the respondents supported the patent system at present conditions and approximately 75% of the respondents will be interested to see a separate IPR protection framework for the inventions/innovations that use biological materials of human origin and has application in health care. This study revealed that the *legal professionals* consider the patent protection as it

[33] "No protection" + less than 20 years of protection = 29.03% + 3.23% + 22.58% + 9.68% = 64.52%.

exists today as the best way to provide incentive to hSCI.[34] Therefore, if we imagine that the patent continues to offer the IPR protection for the hSCI, there can be certain improvisations in the patent system that may contribute to the enhancing of the access to the stem cell based therapy at more affordable costs. 35.49% respondents suggested a *less than 20 years' term of protection* for commercial exploitation. 83.87% respondents thought that there will be benefits in terms of cost reduction and incentives to innovations, if *legal obligations* are imposed. Their choices supporting the legal obligation had additional suggestions such as "involvement of public health care sector (29.03%)" and "issuing license in favor of local manufacturers (6.45%)." 19.35% respondents supported legal obligation but they were *not sure* how it will benefit in "cost reduction and incentive to innovation."

Statistically, this study found that *residence in a high economy country* may prompt respondents to support development of a new protection framework.[35] The study also found that the respondents who are *disinclined to the current patent system*, will support seeking public opinion to observe the impact of the IPR protected invention on the health care receivers.[36] Public consultation may generate ideas to improve the means of accessing the therapy by the patients in respective countries. The study also found that, the respondents of older age group (51-65 years) did not support the entitlement, i.e., the proprietary nature of the IPR for hSCI.[37]

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[34] This conclusion is drawn from the regression analysis output: "a statistically significant number of respondents (p-value = 0.007) opting for 20 years of protection for commercial exploitation were also more likely (OR = 12.8; 95% CI OR = 2.019838 - 81.11538) to consider the current patent system as the best way to provide incentive to human stem cell inventions/ innovations, the odds (p-value = 0.032) of preferring the existing patent system were 5.6 times higher (OR = 5.599999; 95% CI OR = 1.158285 - 27.07451) among the legal professionals compared to others."

[35] Original interpretation: "Respondents belonging to high economy group country (with GNI >= $12,616) would think that a new protection mechanism/framework can/should be developed for the inventions/innovations using biological materials of human origin and directed to health care."

[36] This conclusion is drawn from the findings: "aversion to the existing patent protection and preference to seeking public opinion in order to measure the post marketing impacts of the IPR protected invention/ innovation on the health care receiver."

[37] This conclusion is drawn from the regression analysis output: "Compared to the respondents who belong to 30 years or below age group, those who are between 31 and 50 years old are 3.1 times (OR = 3.076923; 95% CI OR = 0.3021829 - 31.33021) and those who are between 51 and 65 years old are 24 times (OR = 24; 95% CI OR = 1.110724 - 518.5807) more likely (p-value = 0.043) to consider that 'no one should own IPR of human stem cell inventions/innovations'. Although a statistically significant (p-value= 0.032) result was observed in the case of the most elderly group (51-65 years), the p-value for the age group of 31-50 years (p-value = 0.342) was not significant at an alpha level of 0.05."

Offering the IPR protection for hSCI under the umbrella of supranational legal framework can be one way to offer protection. They are better suited for countries with similar socio-economic culture. There is need to have a uniformity in health care policies and similar ambitions in science and innovation among the States in order to enable a supranational legal arrangement to yield its best outcome. If the present scenario of patenting in the EU is taken into consideration, certain observations are worth mentioning. Despite cultural diversity, there are some coherence achieved through European community legislations and some differences remained when it comes to patenting life science based inventions. The feasibility of this recommendation in practical terms remains uncertain. The new Unitary Patent (UP)[38] protection for the EU countries is not accepted by all the States in the EU.[39] Spain has been continuously opposing the UP. As part of the opposition to this new EU initiative, two actions brought by Spain is pending before the CJEU, i.e., Case C-146/13 and Case C-147/13 (*Kingdom of Spain v. European Parliament and Council of the European Union*)[40] challenging the Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection.[41] In Europe, there remains the diverse approach of interpreting the ethical issues involved in hSCR and their patent protection. A new protection mechanism separate from patent under supranational legal framework shall also have to overcome the current obstacles of ethical issues in stem cell research and patenting. Because, the stem cell research as a basic research will remain the same, be it patented or not. Avoiding patent and offering a separate IPR protection will only change features of the commercial exploitation of the invention.[42] There can be meeting of minds between the States that have similar stem cell research policy. But they are going to be States from different continents. Therefore, could TRIPS Agreement offer any IPR protection of hSCI? A new section may be added in the TRIPS Agreement, which will be different from patent, utility model and trade secret protection. But that new provision will have to

[38] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, Dec. 17, 2012, 2012 O.J. (L 361) 1.

[39] 25 Countries are currently participating in this new EU patent except Croatia, Italy and Spain.

[40] Both actions brought on March 22, 2013.

[41] Dec. 17, 2012, 2012 O.J. (L 361) 1.

[42] Access to the therapy will largely depend on how the invention is commercially exploited. Stricter IPR may result in higher cost of the therapy. Therefore, the features of the IPR protection enabling the commercial exploitation is an important factor for cost reduction and promoting increased access to the therapy.

take into account the economic realities prevalent in developing countries with a goal to ensure wider access to the therapy. It will require lengthy consultation process and the challenges in reaching unanimity on the purview of legitimate stem cell research shall remain ahead.

Cited as:

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# Judicial Standard for the Well-Knownness of Trademarks in the Hotel Industry under the Case Law of the Taiwan Intellectual Property Court

Ping-Hsun Chen[*] & Ting-Wei Huang[†]

**Abstract**

This article is intended to explore the judicial standard for the well-knownness of trademarks in the hotel industry based on the decisions issued by the Taiwan Intellectual Property Court ("TIPC"). The decisions relate to two internationally-famous hotels: Amanresorts International Pte Ltd. and Four Seasons Hotels (Barbados) Ltd. While the trademarks of both hotels are considered as well-known in the hotel industry by the TIPC, Amanresorts acquires more extensive protection than Four Seasons. The key issue is whether the owner of a well-known trademark intends to enter the business sectors other than what the well-known trademark is designated to. In the Amanresorts case, Amanresorts successfully requested the TIPO to revoke one registered trademark which uses "aman." The revoked trademark was designated to architectural design services. The TIPC affirmed the TIPO's ruling because Amanresorts has used "AMAN" for its real estate business. Whereas, in the Four Seasons case, the TIPC affirmed the TIPO's denial of the revocation of a trademark requested by Four Seasons because the challenged trademark was designated to gardening services which Four Seasons was found to have no intent to enter into. Comparing both cases, the key implication could be that a hotel has to extend to other business sectors so as to acquire a well-protected well-known trademark.

Keywords: Well-known trademark, Trademark Act, Four Seasons, Amanresorts

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[*] Corresponding author. Assistant Professor, Graduate Institute of Intellectual Property, National Taipei University of Technology (Taiwan); J.D. 10' & LL.M. 08', Washington University in St. Louis School of Law; LL.M. 07', National Chengchi University, Taiwan; B.S. 97' & M.S. 99' in Chem. Eng., National Taiwan University, Taiwan. Contact email: cstr@mail.ntut.edu.tw. This article is a revision of a conference paper previously presented at the 2013 MCU Tourism International Conference, Mar. 16, 2013, Ming Chuan University, Taipei City, Taiwan.

[†] LL.M. in IP 13', Graduate Institute of Intellectual Property, National Taipei University of Technology (Taiwan).

## I. Introduction

Taiwan began to protect well-known trademarks (as well as marks) in 1998 even before entering into the World Trade Organization ("WTO") in 2002. The Trademark Act was amended in 1997 to satisfy the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") and Paris Convention for the Protection of Industrial Property ("Paris Convention"). In 2003, the Trademark Act was further amended to implement the protection on the dilution of well-known trademarks and to impose civil liabilities on a person who passes off well-known trademarks. While the governmental agency, Taiwan Intellectual Property Office ("TIPO"), has made the guidelines of well-known trademarks, it is necessary to look at the judicial branch because courts ultimately decide whether a trademark in question is a well-known trademark and to what extent the Trademark Act can protect such well-known trademark.

This article is intended to explore the judicial standard for the well-knownness of trademarks in the hotel industry. The study is based on the decisions issued by the Taiwan Intellectual Property Court ("TIPC"). Two internationally-famous hotels are involved in those decisions: Amanresorts International Pte Ltd. and Four Seasons Hotels (Barbados) Ltd. In both cases, the famous hotel tried to oppose a registered trademark that looks similar to its own well-known trademark. Amanresorts was troubled with one advertising company that registered a trademark "aman" and designated the trademark to architectural design services. There might be a scenario where that advertising company wanted to create an architectural design for commercial houses (or buildings) to mimic the style or image of Amanresorts. Four Seasons was also passed off by one advertising company that registered a trademark composed of "Four Seasons Villa&Resort" and designated the trademark to gardening services. While both Amanresorts' trademark and Four Seasons' trademark were considered well-known by the court, only Amanresorts successfully requested the TIPO to cancel the registration of "aman."

In this article, Part II discusses the trend of well-known mark protection under international law. Part III introduces the legislative history of the Trademark Act on the well-known trademark protection. Part IV analyzes the court decisions about Amanresorts and Four Seasons and summarizes the judicial standard for well-knownness. Part IV also explains the implications of those two decisions.

## II. Well-Known Mark Protection and International Law

The protection of well-known marks was first addressed internationally in Article 6*bis* of the Paris Convention for the Protection of Industrial

Property ("Paris Convention") at the Revision Conference in the Hague in 1925.[1] Article 6*bis* includes three clauses[2]:

> (1) The countries of the Union undertake, ex officio if their legislation so permits, or at the request of an interested party, to refuse or to cancel the registration, and to prohibit the use, of a trademark which constitutes a reproduction, an imitation, or a translation, liable to create confusion, of a mark considered by the competent authority of the country of registration or use to be well known in that country as being already the mark of a person entitled to the benefits of this Convention and used for identical or similar goods. These provisions shall also apply when the essential part of the mark constitutes a reproduction of any such well-known mark or an imitation liable to create confusion therewith.
>
> (2) A period of at least five years from the date of registration shall be allowed for requesting the cancellation of such a mark. The countries of the Union may provide for a period within which the prohibition of use must be requested.
>
> (3) No time limit shall be fixed for requesting the cancellation or the prohibition of the use of marks registered or used in bad faith.

Article 6*bis* mandates each treaty member to permit the owner of a well-known mark to oppose or request to cancel a registered trademark that is similar to such well-known mark and that may cause confusion to the extent where customers may associate such registered trademark with the source of such well-known mark. Article 6*bis*(3) specifically requires the unlimited period against bad-faith users of a well-known mark or trademark.

Near the end of the twenty century, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") spoke about the well-known mark issue again in Article 16.[3]

Article 16(2) recites, "Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to services. In determining whether a trademark is

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[1] *See* Leah Chan Grinvald, *A Tale of Two Theories of Well-Known Marks*, 13 VAND. J. ENT. & TECH. L. 1, 19 (2010).

[2] *See* World Intellectual Property Organization [WIPO], *Paris Convention for the Protection of Industrial Property*, http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html (last visited Nov. 7, 2014).

[3] *See* Martin R.F. Senftleben, *Keyword Advertising in Europe-How the Internet Challenges Recent Expansions of EU Trademark Protection*, 27 CONN. J. INT'L L. 39, 65 (2011).

well-known, Members shall take account of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Member concerned which has been obtained as a result of the promotion of the trademark."[4] While Article 6*bis* of the Paris Convention addresses well-known marks in goods, Article 16 of the TRIPS extends the protection to well-known marks in services.[5]

Article 16(3) recites, "Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to goods or services which are not similar to those in respect of which a trademark is registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use."[6] While Article 6*bis* of the Paris Convention applies to "identical or similar" goods, Article 16 of the TRIPS applies not only to "identical or similar" goods or services, but also to "dissimilar" goods or services.[7]

The TRIPS became effective on January 1, 1995.[8] In 1999, the WTO and WIPO reached a Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks (hereinafter, "Recommendation").[9] The Recommendation specifically addressed the issues of dilution of well-known marks. The drafting process of the Recommendation began in 1995 and went through three yearly sessions managed by the WIPO Committee of Experts on Well-Known Marks by the end of 1997.[10] Later, the drafting process was

[4] World Trade Organization [WTO], *PART II — Standards Concerning the Availability, Scope and Use of Intellectual Property Rights*, http://www.wto.org/english/tratop_e/trips_e/t_agm3_e.htm#2 (last visited Nov. 7, 2014) [hereinafter, WTO, *PART II*].

[5] *See* Latha R. Nair, *Tracking the Protection of Well-Known Marks in India: A Befuddled Path to Nirvana?*, 101 TRADEMARK REP. 1419, 1421(2011).

[6] WTO, *PART II*, *supra* note 4.

[7] *See* Eugene C. Lim, *Dilution, the Section 22 Debacle, and the Protection of Business Goodwill in Canada: Some Insights from U.S. Trademark Law and Policy*, 101 TRADEMARK REP. 1232, 1242-43 (2011).

[8] *See* WTO, *Overview: The TRIPS Agreement*, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 8, 2014) [hereinafter, WTO, *Overview*].

[9] *See* Lisa P. Ramsey, *Free Speech and International Obligations to Protect Trademarks*, 35 Yale J. Int'l L. 405, 432 (2010).

[10] *See* WIPO, *Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks: Preface*, http://www.wipo.int/about-ip/en/development_iplaw/pub833.htm (last visited Nov. 8, 2014) [hereinafter, WIPO, *Joint Recommendation*].

continued by the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications from 1998 to 1999.[11]

The Recommendation provides guidelines for determining whether a mark is well known. Article 2(1)(b) provides six necessary factors: "1. the degree of knowledge or recognition of the mark in the relevant sector of the public; 2. the duration, extent and geographical area of any use of the mark; 3. the duration, extent and geographical area of any promotion of the mark, including advertising or publicity and the presentation, at fairs or exhibitions, of the goods and/or services to which the mark applies; 4. the duration and geographical area of any registrations, and/or any applications for registration, of the mark, to the extent that they reflect use or recognition of the mark; 5. the record of successful enforcement of rights in the mark, in particular, the extent to which the mark was recognized as well known by competent authorities; 6. the value associated with the mark."[12] Such six factors are not exclusive.[13] According to Article 2(1)(a), a member state can consider additional factors.[14] In terms of weighing of different factors, Article 2(1)(c) requires a case-by-case standard.[15]

Specifically for Factor 1, Article 2(2)(a) defines the factors for determining "relevant sector of the public": "(i) actual and/or potential consumers of the type of goods and/or services to which the mark applies; (ii) persons involved in channels of distribution of the type of goods and/or services to which the mark applies; (iii) business circles dealing with the type of goods and/or services to which the mark applies."[16] But, these three factor are not a factor which must be considered according to Article 2(2)(a). Furthermore, Article 2(3)(a) excludes some factors from consideration[17]:

> (i) that the mark has been used in, or that the mark has been registered or that an application for registration of the mark has been filed in or in respect of, the Member State;
>
> (ii) that the mark is well known in, or that the mark has been registered or that an application for registration of the mark has

[11] *See id.*

[12] WIPO, *Publication 833: Part I (Determination of Well-Known Marks)*, http://www.wipo.int/about-ip/en/development_iplaw/pub833-02.htm#P90_4657 (last visited Nov. 8, 2014) [hereinafter, WIPO, *Publication 833: Part I*].

[13] *See id.*

[14] *See id.*

[15] *See id.*

[16] *Id.*

[17] *Id.*

> been filed in or in respect of, any jurisdiction other than the Member State; or
>
> (iii) that the mark is well known by the public at large in the Member State.

But, particularly for Factor (ii), according to Article 2(3)(b), "a Member State may, for the purpose of applying [Article 2(2)(d)], require that the mark be well known in one or more jurisdictions other than the Member State."[18]

One scenario where a mark must be considered well-known is vested in Article 2(2)(b) reciting, "Where a mark is determined to be well known in at least one relevant sector of the public in a Member State, the mark shall be considered by the Member State to be a well-known mark."[19] There are two guidelines that limit the holding of "not well-known." Article 2(2)(c) states, "Where a mark is determined to be known in at least one relevant sector of the public in a Member State, the mark may be considered by the Member State to be a well-known mark."[20] Article 2(2)(d) states, "A Member State may determine that a mark is a well-known mark, even if the mark is not well known or, if the Member States applies [Article 2(2)(c)], known, in any relevant sector of the public of the Member State."[21]

## III. Taiwan's Legislation on the Protection of Well-Known Trademarks

### A. 1997 Amendment

The Trademark Act (*shang biao fa*, in Mandarin) did not include any provisions specifically for protecting well-known trademarks until 1997. The 1997 amendment dealt with the issues of conflicting marks. The main purpose of the amendment was to fulfill the requirements of Taiwan's accession to the WTO.[22] Taiwan had to amend IP laws to comply with the TRIPS because protecting well-known marks was one obligation under the TRIPS.

The 1997 amendment added one condition of ineligible registration into Article 37.[23] The newly-added condition was that a trademark cannot be registered if it is the same as, or similar to, other's well-known trademark or mark to cause likelihood of confusion to the public. The new clause gave the

[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *See* LEGISLATIVE YUAN OF TAIWAN, LI FA YUAN GONG BAO (VOL. 86 NO. 6) 238 (Taipei City, Taiwan, Legislative Yuan of Taiwan 1997).
[23] *See* LEGISLATIVE YUAN OF TAIWAN, LI FA YUAN GONG BAO (VOL. 86 NO. 7) 267 (Taipei City, Taiwan: Legislative Yuan of Taiwan 1997).

TIPO the authority to cancel or deny the registration of a trademark that is the same as, or similar to, a well-known trademark or mark.

### B. 2003 Amendment

The 2003 amendment introduced the protection against the dilution of a well-known trademark. Article 37 was amended and renumbered as Article 23. [24] The purpose of the amendment was to comply with the Recommendation.

The condition newly added by the 1997 amendment was revised again to extend "the public" to "the relevant public," so the determination of likelihood of confusion is based on the view of the relevant public. In addition, Article 23 further provided another condition where a trademark cannot be registered if it is the same as, or similar to, other's well-known trademark or mark so as to likely dilute the distinctiveness or reputation of such well-known trademark or mark.

Moreover, the 2003 amendment added Article 62 to provide one cause of action for the owner of a well-known registered trademark to stop an infringing use. [25] Under Article 62, a person is liable for trademark infringement if, without a trademark owner's consent, he knows other's well-known registered trademark and uses the words in that well-known trademark as a name of his own company, a trade name, a web address name, or other mark that represents a business entity or source so as to dilute the distinctiveness or reputation of such well-known trademark or mark. The clause requires actual dilution.[26]

### C. Current Law

The Trademark Act was amended again in 2011, and the provisions related to well-known trademarks or marks remained unchanged except for the civil liability clause. Article 23 of the 2003 amendment is now Article 30, while Article 62 of the 2003 amendment is now Article 70. The clause against an infringing use of a well-known trademark does not require "actual dilution." Only likelihood of dilution is required.[27]

## IV. Analysis of Judicial Decisions regarding Well-Known Trademarks in the Hotel Industry

[24] *See* LEGISLATIVE YUAN OF TAIWAN, LI FA YUAN GONG BAO (VOL. 92 NO. 23) 239-44 (Taipei City, Taiwan: Legislative Yuan of Taiwan 2003).

[25] *See id.* at 296-97.

[26] *See id.* at 296-97.

[27] *See* LEGISLATIVE YUAN OF TAIWAN, LI FA YUAN GONG BAO (VOL. 100 NO. 45) 315 (Taipei City, Taiwan: Legislative Yuan of Taiwan 2011).

**A. General Standard for the Well-Knownness of a Trademark**

In Part IV, two cases are analyzed: Administrative Decisions 2011 Xing Shang Su Zi No. 73 (Taiwan Intellectual Property Court 2011) (hereinafter, "Amanresorts court") [28] and 2008 Xing Shang Su Zi No. 83 (Taiwan Intellectual Property Court 2008) (hereinafter, "Four Seasons court").[29] The standard elaborated here relates to how the TIPC determines the likelihood of confusion and the dilution of distinctiveness and reputation caused by opposed trademarks.

The Amanresorts court held that Amanresorts' "AMAN" (Fig. 1(a)) and "AMANRESORTS" (Fig. 1(b)) are well-known registered trademark. The holding was based on three pieces of evidence. First, the court found that Amanresorts had filed trademark applications in several countries (e.g., Tailand, Malaysia, Australia, German, and European Union) and acquired registered trademarks in those countries. Second, the court found the business record provided by Amanresorts proved that Amanresorts had a successful business in the hotel industry. Amanresorts provided its hotel booking records, revenue records, award records, and publications and also demonstrated that it had established hotels or resorts in several countries (e.g., Tailand, Indonesia, Bhutan, India, Sri Lanka, Morocco, and United States). Third, the court relied on two authors' travel articles that show Amanresorts is famous in the hotel industry.


（a） （b）

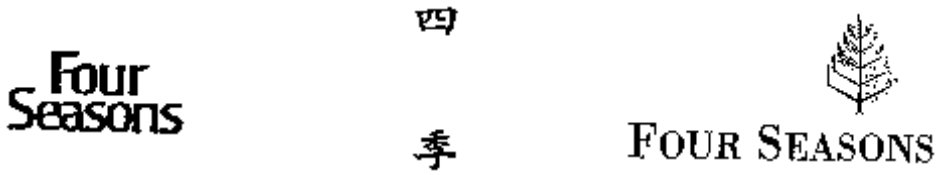
Figure 1: Amanresorts' well-known trademarks.

The Four Seasons court held that Four Seasons' trademarks, "FOUR SEASONS" (Fig. 2(a)), "四季" (*si ji*, in Mandarin) (Fig. 2(b)), and Four Seasons-figure mark (Fig. 2(c)), are well-known. The decision was based on three reasons. First, Four Seasons had filed trademark applications in our country and several other countries (e.g., United States, China, European Union, Canada, Australia, German, Japan, and Korea). It also acquired trademark rights. Second, Four Seasons had established 4 hotels and 31 resorts around the World. In addition, several locations (e.g., Bangkok, Chiang Mai, Hong Kong, Shanghai, and Tokyo) where Taiwan travelers

[28] Administrative Decision 2011 Xing Shang Su Zi No. 73 (Taiwan Intellectual Property Court 2011) [智慧財產法院行政判決 100 年度行商訴字第 73 號].

[29] Administrative Decision 2008 Xing Shang Su Zi No. 83 (Taiwan Intellectual Property Court 2008) [智慧財產法院行政判決 97 年度行商訴字第 83 號].

often visit had Four Seasons' hotels. Travel agencies in Taiwan often promoted travel plans that feature a stay in a Four Seasons' hotel. Third, Four Seasons had launched a series of commercial advertising in one Taiwan magazine since 1999.




(a) (b) (c)

Figure 2: Four Seasons' well-known trademarks.

The evidence adopted to demonstrate that both Amanresorts and Four Seasons owned well-known trademarks is similar in those two courts. To prove well-knownness of a trademark or mark, it is sufficient for the owner to show trademark applications and registrations, business activities, or travel articles. So, the determination of a well-known mark under the Taiwan Intellectual Property Court's jurisprudence may comply with Taiwan's duties under the international IP treaties.

To recognize either of those trademarks as a well-known trademark is not enough, whether the law can stop others from imitating those trademarks is more important to the owners. Under Article 3(1) of the Recommendation, a "Member State shall protect a well-known mark against conflicting marks, business identifiers and domain names, at least with effect from the time when the mark has become well known in the Member State."[30] Article 4(1)(a) defines one category of conflicting trademarks as a "mark, or an essential part thereof, constitutes a reproduction, an imitation, a translation, or a transliteration, liable to create confusion, of the well-known mark, if the mark, or an essential part thereof, is used, is the subject of an application for registration, or is registered, in respect of goods and/or services which are identical or similar to the goods and/or services to which the well-known mark applies."[31] This category focuses on identity or similarity of the goods and/or services between a conflicting mark and a well-known mark.

Article 4(1)(b) defines a second category of conflicting trademarks as a "mark, or an essential part thereof, constitutes a reproduction, an imitation, a

[30] WIPO, *Publication 833: Part II (Scope of Protection)*, http://www.wipo.int/about-ip/en/development_iplaw/pub833-03.htm#TopOfPage (last visited Nov. 8, 2014) [hereinafter, WIPO, *Publication 833: Part II*].

[31] *Id.*

translation, or a transliteration of the well-known mark, and where at least one of the following conditions is fulfilled: (i) the use of that mark would indicate a connection between the goods and/or services for which the mark is used, is the subject of an application for registration, or is registered, and the owner of the well-known mark, and would be likely to damage his interests; (ii) the use of that mark is likely to impair or dilute in an unfair manner the distinctive character of the well-known mark; (iii) the use of that mark would take unfair advantage of the distinctive character of the well-known mark."[32]

Article 4(1)(b) disregards identity or similarity of the goods and/or services between a conflicting trademark and a well-known trademark.[33] Rather, it recognizes three kinds of conflicting trademark.[34] The first type is a trademark which causes the association between it and the goods and/or services provided by the owner of an infringed well-known trademark so that such owner's interests are likely damaged.[35] The second type is a trademark which causes the impairment or dilution of the distinctive character of a well-known trademark.[36] Whether the impairment or dilution is done by an unfair manner is a matter of degree.[37] Last, the third type is a trademark which takes advantage of the distinctive character of a well-known trademark. Again, whether the advantage taken is unfair is a matter of degree.[38]

The Recommendation provides three measures for the owner of a well-known trademark to knock out a conflicting mark. Article 4(2) provides to well-known trademark owners the right to oppose a conflicting trademark in an opposition procedure if the opposition procedure is available in such a country.[39] The opposition procedure is a forum for the public to oppose the registration of a trademark application before such registration if such registration will cause the harm of the opposer's interests.[40] If the opposer succeeds, then the trademark agency will withdraw or cancel the registration of the conflicting mark. The second measure is vested in Article 4(3) which

[32] *Id.*
[33] *See id.*
[34] *See id.*
[35] *See id.*
[36] *See id.*
[37] *See id.*
[38] *See id.*
[39] *See id.*
[40] *See* Ethan G. Zlotchew, *"Scandalous" or "Disparaging"? It Should Make a Difference in Opposition and Cancellations Actions: Views on the Lanham Act's Section 2(a) Prohibitions Using the Example of Native American Symbolism in Athletics*, 22 COLUM.-VLA J.L. & ARTS 217, 222-23 (1998).

provides the right to invalidate a conflicting trademark.[41] An invalidation decision may be made by a competent authority, either a court or a trademark agency.[42] Last, the third measure is the right to prohibit the use of a conflicting trademark and is vested in Article 4(4).[43]

The two cases analyzed in this paper are related to the second measure. In each case, the well-known trademark owner initiated an invalidation request in the TIPO. The conflicting trademark uses all or part of the features of the well-known trademark. In the next two sections, two cases will be analyzed in terms of why the TIPC did or did not invalidate the disputed trademark.

**B. Amanresorts International Pte Ltd.**

In the Amanresorts case, the opposed trademark was "aman" (Fig. 3). The Amanresorts challenged the disputed trademark because it caused likelihood of confusion with Amanresorts' well-known trademarks.


Figure 3: The disputed trademark.

The TIPC agreed with Amanresorts. First, Amanresorts' well-known trademarks were quite distinctive, while the disputed trademark was less distinctive. Second, Amanresorts' trademarks were more well-known than the disputed trademark because Amanresorts had used its trademarks for a very long time. Third, while the disputed trademark was designated to "rental and sale of various kinds of building, real estate transactions, lease brokers, real estate management services" and Amanresorts' trademarks were designated to hotel services and hostel services, the use of Amanresorts' trademarks was not limited to hotel services and hostel services because Amanresorts had begun its real estate business with its trademarks. So, the TIPC concluded, "Objectively, relevant consumers are likely to misunderstand that the services offered under the disputed trademark and [Amanresorts' trademarks] are from the same source or that the user of the disputed trademarks is an affiliation [of Amanresorts], or has a licensing relationship, franchise relationship, or any other similar relationship with [Amanresorts]." The similarity between the disputed

[41] *See* WIPO, *Publication 833: Part II*, *supra* note 30.
[42] *See id.*
[43] *See id.*

trademark and Amanresorts' trademarks would result in the likelihood of confusion.

**C. Four Seasons Hotels (Barbados) Ltd.**

In the Four Seasons case, Four Seasons challenged the disputed trademark (Fig. 4), the combination of Mandarin characters ("四季山莊") and English characters ("Four Seasons Villa&Resort"), because the disputed trademark had caused likelihood of confusion with Four Seasons' well-known trademarks and likelihood of dilution of the distinctiveness or reputation of Four Seasons' trademarks.


Figure 4: The disputed trademark.

Although recognizing the high similarity between Four Seasons' trademarks and the disputed trademark, the TIPC held no likelihood of confusion or dilution.

Regarding the issue of likelihood of confusion, the TIPC considered four factors: (1) "the degree of relevancy between the services as designated by both trademarks," (2) "the situation of the diversity of the plaintiff's businesses," (3) "circumstances of actual confusion," and (4) "the degree of how relevant consumers get familiar with the later registered trademark."

Because of two main reasons, the TIPC concluded no confusion between the uses of the disputed trademark and Four Seasons' trademarks. First, the service as designated by the disputed trademark is dissimilar from the Four Seasons' service. The service of the disputed trademark covers "gardening and landscaping, turf care, weed removal, garden design, landscape design, and garden landscaping," while Four Seasons' service covers "hotels, hostels, real estate, and rental services of various kinds of building." The TIPC held that those two services are less commercially relevant because "the nature of each service is different, the needs or purposes of the customers in those services are different, the markets of those services are obviously separate and non-competing."

Second, the TIPC held that "the protective scope depends on the degree of the well-knownness of the well-known trademark and degree of the diversity of the owner's businesses." The protection for Four Seasons cannot extend to the gardening service because the well-knowness of Four Seasons' trademarks is "limited to hotels, hotel service industry, tourism, and relevant consumers, but not to the general public." The use of Four Seasons' trademarks is in the area of "hotels, hostels, residential apartments, and hotel houses." The intent to diversify the owner's businesses is not shown. Therefore, it cannot be concluded that the protective scope can be extended to the field that is less relevant to the hotel industry.

Regarding the dilution issue, the TIPC held that the applicable standard is to consider (1) "the degree of inherent distinctiveness and well-knownness of the well-known trademark," (2) "the degree of similarity between the trademarks [of both parties]," and (3) "the uses of the [well-known] trademark by third parties to associate with different goods or services." Because the distinctiveness of Four Seasons' well-known trademarks was weak, the TIPC held no dilution. The main reason for such holding was that "FOUR SEASONS" or "四季" is suggestive and indicates the service provided by hotel in all four seasons. Additionally, there had existed prior uses of "FOUR SEASONS" or "四季" as trademarks by others, either foreign or domestic trademark owners in other products or services. Thus, the TIPC held there was no dilution of the distinctiveness or reputation of Four Seasons' trademarks.

**D. Implications**

Drawing from those two decisions, some implications can be concluded. First, international trademark filing, publications about the hotel, advertisements in magazines or journals, worldwide establishments of hotel business, and business records are those factors which help define the well-knownness of a trademark or mark in the hotel industry.

Second, the similarity factor is not an ultimate factor for a well-known trademark owner to invalidate a conflicting trademark under Article 4(1)(b) of the Recommendation.

Third, the protective scope of a well-known mark with respect to conflicting trademarks depends on the degree of the well-knownness of a well-known trademark in the fields other than what such well-known trademark is designated to.

Finally, the degree of diversity of the businesses of a well-known trademark holder helps enlarge the protective scope of such well-known trademark.

## V. Conclusion

While the trademarks of both Amanresorts and Four Seasons are considered as well-known in the hotel industry by the TIPC, Amanresorts acquires more extensive protection than Four Seasons. The key issue is whether the owner of a well-known trademark intends to enter the business sectors other than what the well-known trademark is designated to. In the Amanresorts case, Amanresorts successfully requested the TIPO to revoke one registered trademark which uses "aman." The revoked trademark was designated to architectural design services. The TIPC affirmed the TIPO's ruling because Amanresorts has used "AMAN" for its real estate business. Whereas, in the Four Seasons case, the TIPC affirmed the TIPO's denial of the revocation of a trademark requested by Four Seasons because the challenged trademark was designated to gardening services. Four Seasons argued that it did provide gardening services because its hotels were famous of its garden decors, but the TIPC disagreed by stating that the garden decors were only part of the hotel services and that it did not show that Four Seasons intends to enter into the gardening business. Comparing both cases, the key implication could be that a hotel has to extend to other business sectors so as to acquire a well-protected well-known trademark.

Cited as:

Bluebook Style: Ping-Hsun Chen & Ting-Wei Huang, *Judicial Standard for the Well-Knownness of Trademarks in the Hotel Industry under the Case Law of the Taiwan Intellectual Property Court*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 164 (2014).

APA Style: Chen, P.-H. & T.-W. Huang. (2014). Judicial standard for the well-knownness of trademarks in the hotel industry under the case law of the Taiwan Intellectual Property Court. *NTUT Journal of Intellectual Property Law & Management, 3*(2), 164-177.

OSCOLA Style: PH Chen & TW Huang, 'Judicial Standard for the Well-Knownness of Trademarks in the Hotel Industry under the Case Law of the Taiwan Intellectual Property Court' (2014) 3 NTUT Journal of Intellectual Property Law & Management 164.

# Federal Circuit Blocks Trademark for Being Disparaging to Muslims

Mark Bartholomew[1]

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## Quick View

Section 2 of the Lanham Act contains a variety of limitations on trademark registration.[2] Some are widely used—for example, the prohibition on merely generic marks. Others rarely come into play, including a registration bar for any mark containing "matter which may disparage."[3] In its first ever interpretation of this statutory provision, the Federal Circuit in *In re Geller* affirmed a decision of the Trademark Trial and Appeal Board (TTAB) that denied federal registration to the mark STOP THE ISLAMISATION OF AMERICA. The Federal Circuit agreed with the TTAB that the mark would be disparaging to a substantial composite of the American Muslim community. The stakes are high here because the Federal Circuit is the typical route for appeals of TTAB decisions, and a highly anticipated decision from the TTAB on disparagement involving the WASHINGTON REDSKINS mark is due soon.

Pamela Geller and Robert Spencer tried to register their STOP THE ISLAMISATION OF AMERICA mark in connection with services of "understanding and preventing terrorism." Geller and Spencer are known for their criticism of Islam, particularly their opposition to the construction of a mosque and Islamic Center near the former site of the World Trade Center. Organizations started by Geller and Spencer, including Stop the Islamisation of America, have been designated as hate groups in the United Kingdom and attracted widespread criticism in this country. This background appeared to influence the Federal Circuit's view as to whether Geller and Spencer's mark was disparaging.

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[1] Professor, SUNY Buffalo Law School; B.A., Cornell University; J.D., Yale Law School. Contact email: bartholo@buffalo.edu. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/05/circuit-trademark-disparaging.html.

[2] *See* 15 U.S.C § 1052.

[3] *See id.* § 1052(a) ("No trademark by which the goods of the applicant may be distinguished from the goods of others shall be refused registration on the principal register on account of its nature unless it—(a) Consists of or comprises immoral, deceptive, or scandalous matter; or matter which may disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs, or national symbols, or bring them into contempt, or disrepute ….").

The Federal Circuit began its analysis by endorsing the TTAB's two-prong test for disparagement inquiries. Under the first prong of that test, a court must determine the likely meaning of the mark in question. Under the test's second prong, the court examines whether the likely meaning refers to an identifiable group and, if so, whether that meaning is disparaging to a substantial composite of that group. The Federal Circuit spent most of its time on the first prong, examining the evidence for the TTAB's finding that "Islamisation" has a public meaning referring to conversion or conformance to Islam. It endorsed the TTAB's use of online dictionaries, but also ratified its consideration of essays posted by Geller and Spencer on their own website as well as anonymous reader comments posted on the same website. With regard to the essays, the Federal Circuit read them as advocating suppression of the entire Islamic faith, rather than merely critiquing particular political groups like the Muslim Brotherhood. The essays called for opposing mosque-building, which the Federal Circuit implied was tantamount to an attack on Islam itself. With regard to the website comments, the TTAB cited posts like "Islam is evil" and "There's only one thing you can do and that's say no to Islam and the Islamization of America." Geller said that these were "cherry-picked anonymous comments" deserving of no evidentiary weight. Nevertheless, the Federal Circuit affirmed the use of such evidence in determining the likely meaning of the applicants' mark. From there, it was not surprising that the court, in evaluating the test's second prong, found that STOP THE ISLAMISATION OF AMERICA refers to American Muslims and that this group would be offended by a mark associating Islam with terrorism.

In many ways, the Federal Circuit's opinion is not surprising. The reported decisions evaluating whether marks are disparaging or "scandalous" (another registration prohibition under Section 2) reveal longstanding concern over marks that can offend the sensibilities of particular religious or ethnic groups. For example, a 1938 case heard by the Federal Circuit's predecessor, the Court of Customs and Patent Appeals, involved the mark MADONNA in connection with wine. Denying registration, the CCPA relied on its own intuition that intoxicating liquors like wine cause various "evils" while the Madonna in Christianity "stands as the highest example of the purity of womanhood, and the entire Christian world pays homage to her as such."[4]

What In re Geller suggests, however, is current judicial discomfort with the disparagement provision of the Lanham Act and an attempt to build a larger doctrinal edifice to justify its existence. The two-prong test endorsed by the Federal Circuit looks like scaffolding meant to make the

[4] In re Riverbank Canning Co., 95 F.2d 327 (C.C.P.A. 1938).

disparagement analysis seem more rigorous than it really is. After all, once the court determined the likely definition of STOP THE ISLAMISATION OF AMERICA, it seems like the determination that the mark was disparaging to American Muslims was pretty obvious. The Geller decision also authorizes an expansion in the amount of evidence that should be brought to bear in determining whether a particular group is being disparaged. Do we really want examiners at the PTO building lengthy cases regarding the likely interpretation of a potentially disparaging term by doing things like sifting through anonymous reader comments? It might be better to simply rely on dictionary definitions, which in this case would have been enough to conclude that the applicant's mark was meant to "stop" an entire religion.

In a recent article, I maintain that judges frame trademark decisions (and intellectual property law decisions in general) in the seemingly neutral language of efficiency and economic analysis but, beneath the surface, there are often hotly contested moral considerations that drive judicial outcomes. Today, it is not considered appropriate for judges to apply moral intuition to their decisions, particularly in the utilitarian-based world of intellectual property law. But this happens all the time in trademark law, from findings of infringement to mark validity to geographic restrictions. But it is usually done behind the scenes. Section 2(a)'s prohibition on disparagement, however, offers a seemingly blank check for judges to engage in just this sort of unfettered analysis of right and wrong. The legalistic approach adopted in Geller shows that the Federal Circuit is nervous about cashing this blank check. Disparagement issues will continue to appear, but it is likely that courts will decide these issues only reluctantly and with a preference for anchoring determinations in seemingly neutral doctrinal frameworks and comprehensive sources of "likely meaning."

Cited as:

Bluebook Style: Mark Bartholomew, *Federal Circuit Blocks Trademark for Being Disparaging to Muslims*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 178 (2014).

APA Style: Bartholomew, M. (2014). Federal Circuit blocks trademark for being disparaging to muslims. *NTUT Journal of Intellectual Property Law & Management*, *3*(2), 178-180.

OSCOLA Style: M Bartholomew, 'Federal Circuit Blocks Trademark for Being Disparaging to Muslims' (2014) 3 NTUT Journal of Intellectual Property Law & Management 178.

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# The Pragmatic Approach: The Myriad Gene Patents Before the Australian Courts

Benjamin McEniery[1]

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## Quick View

The Full Court of the Federal Court of Australia in D'Arcy v Myriad Genetics Inc [2014] FCAFC 115[2] recently upheld the validity of Myriad Genetics' Australian BRCA1 gene patent over isolated DNA sequences.

The five judges who constituted the court in a joint judgment unanimously held that isolating a DNA sequence from its surrounding genetic material involves more than simply taking the nucleic acid out of the cell, and instead involves structural and functional changes that create a new composition of matter. The court thus took the view that the patent in question claims something other than subject matter that had previously existed in nature, and as such, the isolated nucleic acid, including cDNA, constitutes patentable subject matter.

The expressly court rejected the conclusion reached last year by the US Supreme Court in AMP v Myriad Genetics that isolated genes and the information they encode are not patent eligible. Instead, it adopted the reasoning of Judges Lourie and Moore in the Federal Circuit below, finding that isolated genes are not naturally-occurring substances but are "the products of man." At paragraph [212] the court said that:

> What is being claimed is not the nucleic acid as it exists in the human body, but the nucleic acid as isolated from the cell. The claimed product is not the same as the naturally occurring product. There are structural differences but, more importantly, there are functional differences because of isolation.

Although the court characterised isolated DNA as material derived from

[1] Senior Lecturer in Law, Queensland University of Technology; Doctor of Philosophy, Queensland University of Technology; Master of Laws, Queensland University of Technology; Bachelor of Laws (Hons), University of Queensland, Bachelor of Arts in Computer Science, University of Queensland; Barrister-at-Law. Contact email: b.mceniery@qut.edu.au. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/09/australia-myriad-patents.html.

[2] D'Arcy v Myriad Genetics Inc [2014] FCAFC 115 (5 September 2014), http://www.austlii.edu.au/au/cases/cth/FCAFC/2014/115.html.

naturally occurring material, it held that this is not a reason for it to be excluded from patentability. In this regard, the court by reference to precedent explained the distinction between a discovery (and an idea in the abstract) and an invention at paragraphs [111] to [113]. The court thus took the view that in determining whether an invention is patentable subject matter, there is no requirement for a consideration of whether a claimed composition of matter is a "product of nature" or whether a microorganism is "markedly different" from something that already exists in nature. The court also noted at paragraph [155] that "the analysis should focus on differences in structure and function effected by the intervention of man and not on the similarities [with what is found in nature]."

The court, for the purposes of Australian law, sought to delineate patentable and non-patentable subject matter by stating that, "[a] mere discovery is not patentable and an idea is not patentable, but a "manner of manufacture," as that term has been developed, is." In doing so, the court rejected any suggested that there is a "product of nature" subject matter exclusion in Australian law.

Unlike the US Supreme Court, the Full Federal Court considered that the correct approach when determining patentable subject matter is to focus on the products of human ingenuity claimed (in this instance being the isolated nucleotide sequences) and not on the information that they contain. In this regard, the court criticised the US Supreme Court noting at paragraph [215] that:

> It is difficult to reconcile that Court's endorsement of the reasoning in Chakrabarty, with its rejection of isolated nucleic acid as eligible for patentability. With respect, the Supreme Court's emphasis on the similarity of 'the location and order of the nucleotides' existing within the nucleic acid in nature before Myriad found them is misplaced. It is the chemical changes in the isolated nucleic acid which are of critical importance, as this is what distinguishes the product as artificial and economically useful.

Unlike in places such as the United States and Canada where subject matter eligibility is defined by reference to enumerated classes of subject matter, the scope of patentable subject matter in Australia is defined by reference to whether an invention is a "manner of manufacture" of the kind envisaged by s 6 of the Statute of Monopolies 1623.

While it is difficult to fault the Full Federal Court's reasoning, it is unlikely that this will be the final chapter in Myriad's defense of its Australian patent. Rather, it is likely that the unsuccessful applicant in this instance will appeal to the High Court of Australia, Australia's final court of

appeal, and that that the High Court will give leave (a statutory equivalent to certiorari) to hear the appeal given the importance of the subject matter concerned.

Cited as:

Bluebook Style: Benjamin McEniery, *Australia: Myriad Gene Patents Look Good*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 181 (2014).

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OSCOLA Style: B McEniery, 'Australia: Myriad Gene Patents Look Good' (2014) 3 NTUT Journal of Intellectual Property Law & Management 181.

# Akamai: Is the Answer in the Common Law?

Lynda J. Oswald[1]

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## Quick View

In its recent decision in *Limelight Networks Inc. v. Akamai Techs., Inc.*,[2] the U.S. Supreme Court decided the easy question—whether inducement must be supported by direct infringement—on precedent grounds, yet avoided the much more difficult question of how the courts should deal with multi-actor infringement of a method or process patent.

Precedent is indeed clear that direct infringement is a predicate to indirect infringement, and the Court's decision on this question was exactly right. The interesting questions remaining, however, are *why* did the Federal Circuit attempt to rewrite precedent in this manner and *what* should the Federal Circuit do with multi-actor infringement doctrine on remand?

The answer to the *why* question is driven by the courts' fundamental discomfort with strict liability. The Federal Circuit's inartful attempt in its en banc decision in *Akamai*[3] to move multi-actor infringement from direct infringement to inducement was an effort to relocate such infringement from the harsh rules of strict liability to the more forgiving rules of intent-based indirect liability. Justice Kagan highlighted this at oral argument:

> But the reason [the Federal Circuit] put this under 271(b) rather than 271(a) is because of what Justice Scalia said, that 271(b) is not a strict liability offense . . . . [T[hey thought they were being very clever by putting it into a 271(b) box and avoiding the strict liability consequences of what they were doing, but also avoiding the possibility of an end run of the patent law.[4]

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[1] Professor of Business Law, Area Chair of Business Law, University of Michigan Ross School of Business; J.D. 86' & M.B.A. 86', University of Michigan; A.B. 82', University of Michigan. Contact email: ljoswald@umich.edu. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/06/akamai-answer-common.html.

[2] Limelight Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111 (2014).

[3] Akamai Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301 (Fed. Cir. 2012).

[4] Oral Argument Transcript at 23, Limelight Networks, Inc. v. Akamai Techs., Inc., 134 S. Ct. 2111 (2014), *available at* http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-786_i4dj.pdf.

As I explore in a work-in-progress,[5] the courts similarly attempt to avoid the strictures of strict liability in other IP contexts such as imposition of officer liability in patent and copyright cases. Although strict liability is antithetical to the notions of fault-based liability that permeate most of American law, the courts are bound by the statutory language and the Supreme Court's rejection of the Federal Circuit's attempt to circumvent direct infringement's strict liability requirement was spot-on.

The *what* question is harder to answer. The Supreme Court expressed significant skepticism about the *Muniauction Inc. v. Thomson Corp.*[6] test, appearing, in fact, to characterize any current doctrinal difficulties as self-inflicted by the Federal Circuit:

> [R]espondents, like the Federal Circuit, criticize our interpretation of § 271(b) as permitting a would-be infringer to evade liability by dividing performance of a method patent's steps with another whom the defendant neither directs nor controls. We acknowledge this concern. Any such anomaly, however, would result from the Federal Circuit's interpretation of § 271(a) in *Muniauction.* A desire to avoid *Muniauction*'s natural consequences does not justify fundamentally altering the rules of inducement liability that the text and structure of the Patent Act clearly require—an alteration that would result in its own serious and problematic consequences . . . .[7]

The Court viewed the Federal Circuit's multi-actor infringement precedent too narrowly, however. To adequately address the multi-actor infringement issue on remand, the Federal Circuit needs to reexamine not just *Muniauction*, but two additional decisions as well: *BMC Resources, Inc. v. Paymentech*[8] and the panel decision in *Akamai*.[9]

*BMC Resources* provided the foundation of the Federal Circuit's current multi-actor infringement doctrine by stating that: (1) for inducement to exist, some other single entity must be liable for direct infringement but (2) a mastermind who controls or directs the activities of another party incurs vicarious liability for the actions of that other party such that the combination of acts would be deemed the act of a single actor for purposes of establishing

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[5] Lynda J. Oswald, *The Divergence of Corporate Officer Liability Doctrine Under Patent and Copyright Law* (Nov. 29, 2014), *available at* SSRN: http://ssrn.com/abstract=2448697 or http://dx.doi.org/10.2139/ssrn.2448697.

[6] Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008).

[7] *Limelight Networks, Inc.*, 134 S. Ct. at 2120.

[8] BMC Res., Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007), *overruled* by Akamai Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301 (Fed. Cir. 2012).

[9] Akamai Techs., Inc. v. Limelight Networks, Inc., 629 F.3d 1311, 1314 (Fed. Cir. 2010).

liability. *Muniauction*'s contribution was to refine the *BMC Resources* test by identifying a "spectrum" of relationships: at one pole is "mere arms-length cooperation," which does not lead to liability; at the other is "control or direction over the entire process such that every step is attributable to the controlling party, i.e., the mastermind."[10] The panel decision in *Akamai* attempted to further clarify the standard by setting up two-pronged test of the type that the Federal Circuit seems to prefer these days: multi-actor infringement occurs only when the parties involved are in either (1) in an agency relationship or (2) contractually obligated to each other.

Perhaps it is a function of its narrow jurisdiction, but the Federal Circuit often misses the opportunity to apply traditional common law doctrines in a manner that would reconcile statutory language with the policies underlying the statute. As I discuss in a recent article,[11] the Federal Circuit could resolve much (but not all—some aspects of this issue are amenable only to legislative resolution) of the confusion surrounding multi-actor infringement by explicitly invoking common law doctrines of tort and agency. The panel decision in *Akamai* got much of this right by looking at agency and contractual relationships. However, the *Akamai* panel decision ignored the possibility that there could be co-equals involved in the infringement, not bound by contract or agent-principal relationships but acting in concert in a joint tortfeasorship relationship. Early (pre-Federal Circuit) cases did recognize the role that joint torts can play in establishing multi-actor liability but that relationship was lost in the *BMC Resources* single-entity rule.

The *Akamai* Court issued a clear call to the Federal Circuit to revisit (and revamp) its troublesome multi-actor infringement standard. Judge Newman provided an elegant statement of how the court should approach this issue in her dissent in the *Akamai* en banc decision:

> The court should simply acknowledge that a broad, all-purpose single-entity requirement is flawed, and restore infringement to its status as occurring when all of the claimed steps are performed, whether by a single entity or more than one entity, whether by direction or control, or jointly, or in collaboration or interaction.[12]

On remand, the Federal Circuit will have the opportunity to articulate liability rules that are more principled, more grounded in traditional legal doctrine, and more consistent with the general patent law scheme; Judge

[10] *Muniauction, Inc.*, 532 F.3d at 1329.

[11] Lynda J. Oswald, *Simplifying Multiactor Patent Infringement Cases Through Proper Application of Common Law Doctrine*, 51 AM. BUS. L.J. 1 (2014), *available at* http://onlinelibrary.wiley.com/doi/10.1111/ablj.12024/pdf.

[12] *Akamai Techs., Inc.*, 692 F.3d at 1326 (Newman J., dissenting).

Newman's characterization provides an excellent starting point for that analysis.

Cited as:

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APA Style: Oswald, L. J. (2014). Akamai: Is the answer in the common law?. *NTUT Journal of Intellectual Property Law & Management, 3*(2), 184-187.

OSCOLA Style: LJ Oswald, 'Akamai: Is the Answer in the Common Law?' (2014) 3 NTUT Journal of Intellectual Property Law & Management 184.

[2014] Vol. 3 No. 2 NTUT J. of Intell. Prop. L. & Mgmt.

# Tesla Motors and the Rise of Non-ICT Patent Pledges

Jorge Contreras[1]

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## Quick View

This week, electric car developer Tesla Motors made news by publicly announcing that it will no longer "initiate patent lawsuits against anyone who, in good faith, wants to use our technology."[2] Tesla's pledge has met with both praise and cynicism, with some applauding the company's ostensible desire to spur the development of eco-friendly technology, while others have dismissed the announcement as a mere publicity stunt lacking in real effect.

Whatever the merits of Tesla's patent pledge, it is only the most recent in a growing series of voluntary public commitments made by patent holders to refrain from exercising their patent rights to the fullest extent of the law. To date, most of these pledges have been made by companies in the information and communications technology ("ICT") sector. For example, in 2004-05, a handful of firms publicly announced that they would not assert patents against use of the open source Linux operating system.[3] Some large patent holders have issued blanket assurances covering substantial portfolios of patents and products, including IBM's public commitment not to assert approximately 500 patents against open source software products,[4] and Google's more recent "Open Patent Non-Assertion Pledge."[5] As I have written elsewhere,[6] these pledges are intended to assure the market that the pledged patents will not be used to disrupt or hinder the adoption of

[1] Associate Professor, University of Utah College of Law; J.D. 91', Harvard Law School; B.S.E.E. 88' and B.A. 88' in English, Rice University. Contact email: jorge.contreras@law.utah.edu. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/06/motors-patent-pledges.html.

[2] Elon Musk, *All Our Patent Are Belong To You*, http://www.teslamotors.com/blog/all-our-patent-are-belong-you.

[3] Legally Binding Commitment Not to Assert Nokia Patents against the Linux Kernel, http://web.archive.org/web/20051229190243/http:/www.nokia.com/iprstatements.

[4] IBM, IBM STATEMENT OF NON-ASSERTION OF NAMED PATENTS AGAINST OSS, *available at* http://www.ibm.com/ibm/licensing/patents/pledgedpatents.pdf.

[5] Google, *Open Patent Non-Assertion Pledge*, http://www.google.com/patents/opnpledge/pledge/.

[6] *See, e.g.*, Jorge L.Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, UTAH L. REV. (forthcoming Spring 2015), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_ id=2309023; *Patent Pledges*, *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2525947.

market-wide interoperability standards or open technology platforms.

But, as the Tesla pledge demonstrates, patent pledges are also becoming popular outside the ICT sector. Below are examples of a few recent patent pledges made by companies in non-ICT industries ranging from GM seeds to household electrical meters.

| Company | Patents | Pledge |
|---|---|---|
| Monsanto | Patents claiming genetically-modified seeds | "It has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seed or traits are present in farmer's fields as a result of inadvertent means." |
| Myriad Genetics | Genetic diagnostic patents | Myriad will not "impede non-commercial, academic research that uses patented technology licensed or owned by us… Myriad will continue its practice of not interfering with laboratories conducting genetic testing on patients for the purpose of confirming a test result provided by Myriad.. Myriad will continue to offer financial assistance programs and free testing to help patients with the greatest need." |
| Southern California Edison | US 11/626,810 (Method of communicating between a utility and | SoCal Ed will grant anyone a non-exclusive royalty-free license under any patent |

| | | |
|---|---|---|
| | its customer locations) | issuing from this application covering basic "smart metering" technology. |
| Tesla Motors | All patents | Tesla will not "initiate patent lawsuits against anyone who, in good faith, wants to use our technology." |

The full text of (and hyperlinks to) these commitments, as well as patent pledges from many companies in the ICT sector, can be found in the Non-SDO patent pledge database [7] maintained by the Program on Information Justice and Intellectual Property ("PIJIP" [8]) at American University's Washington College of Law. As always, we welcome additional contributions to the database.

Cited as:

Bluebook Style: Jorge Contreras, *Tesla Motors and the Rise of Non-ICT Patent Pledges*, 3 NTUT J. OF INTELL. PROP. L. & MGMT. 188 (2014).

APA Style: Contreras, J. (2014). Tesla Motors and the rise of non-ICT patent pledges. *NTUT Journal of Intellectual Property Law & Management, 3*(2), 188-190.

OSCOLA Style: J Contreras, 'Tesla Motors and the Rise of Non-ICT Patent Pledges' (2014) 3 NTUT Journal of Intellectual Property Law & Management 188.

[7] http://www.pijip.org/non-sdo-patent-commitments/.
[8] http://www.pijip.org/.

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# The Proper Role for the Presumption of Validity

Derek Dahlgren[1]

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## Quick View

In 2011, the Supreme Court addressed the presumption of validity in *Microsoft Corp. v. i4i Ltd. P'ship*.[2] It confirmed that the standard of proof for invalidity is clear and convincing evidence. Initially, this opinion was seen by many as preserving the strength of patents. But closer scrutiny reveals that the Supreme Court's analysis does not extend to all invalidity defenses. According to Justice Breyer's concurrence, joined by Justices Scalia and Alito, the presumption of validity only provides protection against factual elements of an invalidity challenge. That concurrence, and the Supreme Court's recent opinion in *Nautilus, Inc. v. Biosig Instruments, Inc.*,[3] suggest that the presumption of validity has no application to purely legal bases for invalidity.

A brief discussion of *i4i* and *Nautilus* is instructive. In *i4i*, Microsoft appealed a jury decision finding that it had not proven invalidity due to the on-sale bar, a purely factual inquiry, by clear and convincing evidence. On appeal, Microsoft argued that a defendant to an infringement action need only persuade the jury of an invalidity defense by a preponderance of the evidence. The Supreme Court rejected that argument.

Instead, the Supreme Court concluded that the presumption of validity codified the pre-1952 standard set forth in opinions such as *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*[4] The Supreme Court stated that by the time Congress enacted 35 U.S.C. § 282, "the presumption encompassed not only an allocation of the burden of proof but also an imposition of a heightened

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[1] Associate, Rothwell, Figg, Ernst & Manbeck, P.C.; B.S. in Chemical Engineering, Bucknell University; M.S. in Biotechnology, Johns Hopkins University; J.D., Georgetown University Law Center. Contact email: ddahlgren@rfem.com. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/06/proper-presumption-validity.html. The opinions expressed are those of the author and do not necessarily reflect the views of Rothwell, Figg, Ernst & Manbeck, P.C. or its clients. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[2] Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238 (2011).

[3] Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014).

[4] Radio Corp. of Am. v. Radio Eng'g Labs., Inc., 293 U.S. 1 (1937).

standard of proof."[5] The Supreme Court then upheld the Federal Circuit's articulation that "a defendant seeking to overcome [the presumption of validity] must persuade the factfinder of its invalidity defense by clear and convincing evidence."[6]

Justice Breyer wrote a separate concurrence. There, he stated "I believe it worth emphasizing that in this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law."[7] He also noted:

> Many claims of invalidity rest, however, not upon factual disputes but upon how the law applies to facts as given . . . Where the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today's strict standard of proof has no application.[8]

In *Nautilus*, the same issue—the application of the presumption of validity—arose at oral argument. During the argument, Justice Kennedy pressed Nautilus' counsel on how the presumption of validity applies to indefiniteness. Nautilus' counsel conceded that the presumption of validity would accord deference to the U.S. Patent & Trademark Office's ("PTO") fact-finding.[9] But he stated that since there were no fact-findings at issue in this case, the presumption did not apply.[10] At Justice Kennedy's prompting, he also agreed that the PTO's legal decisions are not accorded any deference.[11]

On June 2, 2014, the Supreme Court issued its opinion in *Nautilus*, and again touched on the issue. In footnote 10, the Supreme Court rejected the idea that a permissive definiteness standard accords with the presumption of validity.[12] To the contrary, it stated that the presumption does not alter the degree of clarity that 35 U.S.C. § 112, ¶2 requires.[13] That said, the Supreme Court ultimately did not address the parties' dispute as to whether subsidiary

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[5] *i4i*, 131 S. Ct. at 2246.

[6] *Id.* at 2243.

[7] *Id.* at 2253 (Breyer J., concurring).

[8] *Id.*

[9] *See* Oral Argument Transcript at 19:22 – 21:8, Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014), *available at* http://www.supremecourt.gov/oral_arguments/argument_transcripts/13-369_4oc4.pdf

[10] *See id.*

[11] *See id.* at 21:4-8.

[12] *See Nautilus, Inc.*, 134 S. Ct. at 2130 n.10.

[13] *See id.*

factual issues trigger the clear-and-convincing evidence standard.[14] Because the Federal Circuit treated indefiniteness as a legal issue reviewed without deference, and the parties had not identified any contested factual matter, Supreme Court concluded the question could be settled another day.[15]

So where does that leave us? While the Supreme Court has not expressly held that the presumption of validity has no role in purely legal validity challenges, it certainly makes sense. According to *i4i*, the presumption of validity serves two functions: allocating the burden of proof and imposing the standard of proof.[16] For a purely legal question, however, there is nothing to prove by clear and convincing evidence. Furthermore, to apply the presumption for a legal challenge would give deference to the PTO's legal conclusions. The Federal Circuit does not do that. And the PTO lacks substantive rule-making authority, at least with respect to defining the metes and bounds of invalidity defenses. Thus, there does not appear to be any basis for according deference to the PTO's legal conclusions. Consequently, for pure questions of law, it seems reasonable to conclude that the presumption of validity has absolutely no bearing. And as a result, invalidity challenges based on purely legal grounds may be much more powerful.

Nonetheless, while the Supreme Court may have circumscribed the application of the presumption of validity, it now has the opportunity to reject the assertion that claim construction is a pure question of law.[17] The Supreme Court hinted in Nautilus that factual questions permeate claim construction when it cited to *Markman* and stated that claim construction "may turn on evaluations of expert testimony."[18] Should that become settled law after *Teva*, one likely consequence would be a resurgence of the presumption in areas previously considered purely legal domains. Generally, the pure legal bases for invalidity are premised on the notion that claim construction is a pure question of law. Therefore, while the Supreme Court may have given patent challengers a gift in *i4i* and *Nautilus*, it could be short-lived to a certain degree.

Cited as:
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[14] *See id.*
[15] *Id.*
[16] *See i4i*, 131 S. Ct. at 2246.
[17] *See* Teva Pharms. USA, Inc. v. Sandoz, Inc., No. 13-854, 134 S.Ct. 1761 (2014).
[18] *Nautilus, Inc.*, 134 S. Ct. 2130.

[2014] Vol. 3 No. 2 NTUT J. of Intell. Prop. L. & Mgmt.

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OSCOLA Style: D Dahlgren, 'The Proper Role for the Presumption of Validity' (2014) 3 NTUT Journal of Intellectual Property Law & Management 191.

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# How the DMCA's Online Copyright Safe Harbor Failed

Eric Goldman[1]

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## Quick View

## I. Introduction

In 1998, Congress enacted the Digital Millennium Copyright Act ("DMCA"). One of its provisions, 17 U.S.C. § 512, gave online service providers a safe harbor from liability for user-caused copyright infringements. The web hosting safe harbor's structure was relatively simple: copyright owners assume the burden of notifying service providers when their users are committing copyright infringement, at which point the service providers are expected to intervene if they want to avoid being liable. This system, called "notice-and-takedown," has served the Internet well enough to create many interesting and important user-generated content websites.

Unfortunately, 15 years of relentless litigation by the copyright industry has created a number of cracks in the notice-and-takedown system. As a result, the notice-and-takedown system is failing as a safe harbor, progressively undermining the safe harbor's ability to foster entrepreneurship in the user-generated content industry. This Essay explains how cracks in the safe harbor are rendering it useless.

## II. Background

Copyright law is a strict liability tort. That means a person is liable for copyright infringement if their actions violate a copyright owner's rights, even if they had no idea they were doing so. In the mid-1990s, a few cases suggested that online service providers could be strictly liable for user-caused copyright infringement, even if the service providers didn't know that its users were doing so.[2]

These cases prompted the DMCA safe harbor codified in 17 U.S.C. §

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[1] Professor of Law and Co-Director of the High Tech Law Institute, Santa Clara University School of Law; J.D./M.B.A., University of California, Los Angeles; B.A., University of California, Los Angeles. Contact email: egoldman@gmail.com. This article (without footnotes) was originally published at http://blog.ericgoldman.org/archives/2014/06/how-the-dmcas-online-copyright-safe-harbor-failed.htm.

[2] *See, e.g.*, Playboy Enterprises, Inc. v. Frena, 839 F. Supp. 1552 (M.D. Fla. 1993); Playboy Enterprises, Inc. v. Russ Hardenburgh, 982 F. Supp. 503 (N.D. Ohio 1997).

512(c), which created the notice-and-takedown system. Its key innovation is that online service providers aren't strictly liable for user-caused copyright infringement; service providers should be liable only if they get a takedown notice from copyright owners and then fail to respond quickly. Indeed, the statute spells out what information needs to be in a takedown notice before it creates the obligation for service providers to act.[3] Thus, it's clear Congress wanted to override copyright law's strict liability default rule for online service providers and require copyright owners to take affirmative steps outside the courtroom before they ran to the courtroom to sue user-generated content websites.

From the beginning, copyright owners quickly realized that sending takedown notices was a chore.[4] As a result, copyright owners have repeatedly sued service providers for user-caused copyright infringement even where the copyright owners haven't sent takedown notices.[5] Naturally, if copyright owners could establish service provider liability without the need to send takedown notices, it would effectively render Section 512(c)'s notice-and-takedown scheme moot.

## III. Undermining the Safe Harbor

Through aggressive litigation in court, copyright owners have made substantial progress in eviscerating the notice-and-takedown system, especially in the past two years or so. Some of the ways they have done so:

### 1. Pre-1972 Sound Recordings

In the *GrooveShark* case,[6] the court held that pre-1972 sound recordings–which are governed by state copyright law, not federal copyright law–are not covered by the notice-and-takedown scheme. Because a service provider allowing users to post sound recordings has no reliable automated way of distinguishing pre- and post-1972 works, service providers cannot rely on the notice-and-takedown for any sound recordings.[7]

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[3] 17 U.S.C. § 512(c)(3).

[4] *See, e.g.*, ALS Scan v. Remarq Communities, Inc., 239 F.3d 619 (4th Cir. 2001)

[5] *See, e.g.*, UMG Recordings, Inc. v. Shelter Capital Partners LLC, 667 F.3d 1022 (9th Cir. 2011); Viacom Int'l Inc. v. YouTube, Inc., 676 F.3d 19 (2d Cir. 2012) (Viacom sued YouTube even though Viacom waited some time to send 100,000 takedown notices and YouTube immediately processed them).

[6] UMG Recordings, Inc. v. Escape Media Group, Inc., 107 A.D.3d 51, 964 N.Y.S.2d 106 (N.Y.A.D. 1 Dept. 2013).

[7] *See* Eric Goldman, *More Evidence That Congress Misaligned the DMCA Online Copyright Safe Harbors (UMG v. Grooveshark)*, http://www.forbes.com/sites/ericgoldman/2013/04/24/more-evidence-that-congress-misaligned-its-online-copyright-safe-harbors-umg-v-grooveshark/ (last visited Dec. 2, 2014).

**2. Knowledge Requirement**

Courts have established two ways that service providers can "know" about their users' infringing behavior even if copyright owners don't send takedown notices. First, courts have added a new safe harbor exclusion called "willful blindness." [8] This exclusion doesn't have a rigorous definition–courts are still trying to figure out what it means[9]–and the courts created this exclusion even though the statute specifically described what types of information about user conduct could foreclose the safe harbor.

Second, the courts have said that "inducing" infringement also likely forecloses the safe harbor.[10] We have clearer definitions of what constitutes inducement, though inducement arguments have rarely succeeded outside the peer-to-peer file sharing context. Nevertheless, lawsuits against user-generated content websites routinely allege inducement, consuming substantial litigation expenses for both parties.

**3. Investors' Liability**

Courts have indicated that investors in online service providers aren't covered by Section 512[11]–leading the potentially anomalous conclusion that investors may be liable for copyright infringement even when the companies they've invested in aren't. Naturally, exposing investors to personal risk for making investments in user-generate content websites is a pretty effective way of discouraging those investments.

* * *

These three exclusions undermine the safe harbor in two ways. First, they prevent user-generated content websites from relying on the notice-and-takedown system. Simply responding to copyright owner takedown notices isn't enough to keep a service provider out of court.

Second, more problematically, copyright owners can drain defendants' coffers of lots of money seeking evidence to support these exceptions,[12]

[8] *See* Viacom Int'l Inc. v. YouTube, Inc., 676 F.3d 19 (2d Cir. 2012); UMG Recordings, Inc. v. Shelter Capital Partners LLC, 718 F.3d 1006 (9th Cir. 2013).

[9] *See, e.g.*, the Ninth Circuit's baffling quadruple-negative articulation of the doctrine: "the DMCA recognizes that service providers who do not locate and remove infringing materials they do not specifically know of should not suffer the loss of safe harbor protection." UMG Recordings, Inc. v. Shelter Capital Partners LLC, 718 F.3d 1006 (9th Cir. 2013).

[10] Columbia Pictures Industries, Inc. v. Fung, 710 F.3d 1020 (9th Cir. 2013).

[11] UMG Recordings, Inc. v. Shelter Capital Partners LLC, 718 F.3d 1006 (9th Cir. 2013).

[12] For example, YouTube spent $100M just to file its summary judgment motion in the Viacom case. Erick Schonfeld, Google Spent $100 Million Defending Against Viacom's $1 Billion Lawsuit, http://techcrunch.com/2010/07/15/google-viacom-100-million-lawsuit/ (last

even if the copyright owners ultimately lose in court. This ensures that well-funded copyright owners can drive entrepreneurs out of business simply through aggressive litigation, regardless of the merits;[13] and it substantially raises the amount of cash required to enter the user-generated content business, as a portion (effectively, the first funds raised) must be set aside for the seemingly inevitable and quite expensive ligation that will surely ensue.

## IV. Implications

For all of the angst about SOPA's evisceration of notice-and-takedown,[14] it's clear that the notice-and-takedown system is dying without any legislative intervention. Congress attempted to articulate a pretty clear rule: users who upload infringing files are liable; their web hosts aren't unless they ignore takedown notices. Somehow, the courts have gotten far enough away from this basic proposition that now copyright owners have plenty of leverage over user-generated content websites without ever sending them takedown notices at all. Perhaps Section 512's failure isn't surprising; in retrospect, it's pretty clear Congress misarchitected Section 512.[15] Despite that, Congress isn't likely to consider meaningful defendant-favorable reform any time soon.

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OSCOLA Style: E Goldman, 'How the DMCA's Online Copyright Safe Harbor Failed' (2014) 3 NTUT Journal of Intellectual Property Law & Management 195.

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visited Dec. 2, 2014).

[13] The most obvious example is Veoh, which won its Ninth Circuit case after it had gone bankrupt. Eric Goldman, *UMG v. Shelter Capital: A Cautionary Tale of Rightsowner Overzealousness*, http://blog.ericgoldman.org/archives/2011/12/umg_v_shelter_c.htm (last visited Dec. 2, 2014).

[14] *See* Eric Goldman, *Celebrating (?) the Six-Month Anniversary of SOPA's Demise*, http://www.forbes.com/sites/ericgoldman/2012/07/18/celebrating-the-six-month-anniversary-of-sopas-demise/ (last visited Dec. 2, 2014).

[15] *See* Eric Goldman, *Want to End the Litigation Epidemic? Create Lawsuit-Free Zones*, http://www.forbes.com/sites/ericgoldman/2013/04/10/want-to-end-the-litigation-epidemic-create-lawsuit-free-zones/ (last visited Dec. 2, 2014).

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# The Rise of the End User in Patent Litigation and Attorney Fee Shifting

Gaia Bernstein[1]

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## Quick View

We usually think of two players in the patent system: the patentee and its competitor. Increasingly, however, end users – who are neither patentees nor competitors – are playing a significant role in the patent system. The attention of the press has recently turned to patent assertion entities who are suing vast numbers of customers using patented technologies in their everyday businesses. For example, one patent assertion entity has sued individual podcasters, including the Comedian Adam Carolla. End users were also principal players in some of the recent patent cases before the Supreme Court. In *Bowman v. Monsanto*,[2] Monsanto sued a farmer for re-using its patented seed technology. End users also appear as patent challengers: in *Ass'n for Molecular Pathology v. Myriad Genetics*,[3] patients and physicians sued to invalidate breast cancer gene patents. And patients and drug stores repeatedly challenge pay-for-delay agreements between patentees and competitors, claiming they undermine patients' interests in access to generic drugs. This is only the beginning: end users are likely to become even more prevalent in patent litigation, as 3D printers become more popular, making it more likely that an individual or a small business will make an infringing item that will expose them to patent liability.

All of this begs the questions what is an "end user" and how well is patent law suited to deal with this new player? In *The Rise of The End User in Patent Litigation*, which was published in the Boston College Law Review,[4] I define end users as people and companies that use a patented technology for personal consumption or in their business. I emphasize that

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[1] Professor of Law, Seton Hall University School of Law; J.S.D.. New York University School of Law; LL.M., Harvard Law School; LL.M., Tel-Aviv University; J.D., Boston University; B.A., Tel-Aviv University. Contact email: bernstga@shu.edu. This article (without footnotes) was originally published at http://patentlyo.com/patent/2014/06/litigation-attorney-shifting.html.

[2] Bowman v. Monsanto, 133 S. Ct. 1761 (2013).

[3] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[4] *See* Gaia Bernstein, *The Rise of the End User in Patent Litigation*, 55 B.C.L. REV. 1443 (2014), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2440914.

they are strictly users. Even if they incorporate the patented technology into a product or service they offer their customers, they do not make or sell the technology standing by itself. I explain that end users differ from competitors in three respects. First, end users usually lack technological sophistication – they are generally not technological companies and do not produce and supply the allegedly infringing technology. Second, end users usually become involved in the patent conflict relatively late in the life of the patent, after the patented technology enters the market and achieves widespread adoption. Third, end users are typically one-time players. In most cases the technology is ancillary to their business and they do not have a long-term stake.

Patent litigation is exorbitantly expensive. It is all the more expensive for end users who lack the technological expertise to challenge validity and infringement claims and cannot rely on in-house technological expertise. Because end users are often one-time players, they prefer to avoid the expense of patent litigation and settle even strong cases, making them a particularly lucrative target for patent owners. Unfortunately, even the most recent substantive patent law legislation, the America Invents Act ("AIA") fails to address the growing role of end users. I show that while the AIA attempts to address the needs of small entities, mainly by adding and changing procedures to challenge patents in the patent office, thus providing a cheaper and faster forum for contesting validity, those same novel procedures are largely unsuitable for end users because they permit expansive challenges mostly early in the life of the patent before end users are likely to be involved in the patent dispute. The procedures that allow challenges later in the life of the patent limit the grounds available for challenging the patent. Thus, unlike even small competitors of the patent holder, end users are unlikely to benefit from the enhanced patent office proceedings put in place in the AIA. The effect of this is to leave them without the very same tools that were implemented to protect small entities.

Ultimately, the rise of the end user is a complex phenomenon that needs to be addressed by a series of reforms, which I am addressing in other works in progress. Here, however, I focus on the role that fee shifting of attorney fees and litigation expenses to the prevailing party can play in end user cases because a modest change could contribute toward leveling the footing of end users in all type of end user-patentee disputes.

Fee shifting in patent litigation has been a hot topic this year. Recently, the Supreme Court decided two fee shifting cases: *Highmark Inc. v. AllCare Health Mgmt. Sys., Inc.*[5] and *Octane Fitness, LLC v. ICON Health & Fitness,*

[5] Highmark Inc. v. AllCare Health Mgmt. Sys., Inc., 134 S.Ct. 1744 (2014).

*Inc.*[6] In *Octane Fitness*, the Court lowered the standard for awarding fee shifting in patent litigation. Congress is also considering multiple bills advocating different versions of fee shifting. The problem is that although some of the congressional bills address PAE's suits against customers, neither these bills nor the Supreme Court decisions address the broader role that end users are now playing in our patent system. In the article, I argue that the case for fee shifting is strong where end users are implicated particularly because of the great inequality in technological sophistication between end users and patentees and because end users frequently represent many other parties who are not before the court. For these reasons, end user status should be considered as a factor that weighs in favor of fee shifting, particularly when the end user fits the paradigmatic form of a classic end user.

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[6] Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S.Ct. 1749 (2014).

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# Review of the CJEU Judgment on the Application of Site Blocking Order

Ya-Chi Chiang[1]

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## Quick View

### I. Background of *UPC v. Constantin* Case

To tackle rampant copyright piracy in the digital world, in the past decade copyright holders have relied more and more on the contribution from the private third parties.[2] The technical powers owned by Internet Service Providers ("ISP") have never been underestimated in the fight against copyright infringers.[3] The growing demand of ISP technical obligations has posed many legal challenges to the legislators and courts. Among various technical obligations imposed on ISP, and one of the most widely-used is to demand ISP to block copyright infringing sites.[4] Leaning against the backdrop, in March 2014, the Court of Justice of European Union ("CJEU") has made a judgment interpreting the justification and appropriateness of site blocking orders of EU Copyright Directive under the request of Austrian Supreme Court.[5]

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[1] Assistant Professor, Graduate Institute of Intellectual Property, National Taipei University of Technology. Ph.D, University of Durham (UK); LL.M., University of Leeds (UK); LL.B., National Taiwan University (Taiwan). Contact email: christy@mail.ntut.edu.tw.

[2] *See* Ellen Marja Wesselingh, *Website Blocking: Evolution or Revolution? 10 Years of Copyright Enforcement by Private Third Parties* (July 03, 2014), *in* INTERNET, LAW AND POLITICS. A DECADE OF TRANSFORMATIONS, PROCEEDINGS OF THE 10TH INTERNATIONAL CONFERENCE ON INTERNET, LAW & POLITICS, Universitat Oberta de Catalunya, Barcelona, July, 3-4, 2014, *available at* http://ssrn.com/abstract=2464969.

[3] *See* Ebenezer Duah, *Internet Service Provider's Monitoring Obligations: Recent Developments*, 6 MASARYK U. J.L. & TECH. 207, 208-21 (2012).

[4] *See* Faye Fangfei Wang, *Site-blocking Orders in the EU: Justifications and Feasibility*, *in* 14TH ANNUAL INTELLECTUAL PROPERTY SCHOLARS CONFERENCE (IPSC), Boalt Hall School of Law, University of California, Berkeley, Aug. 7-8, 2014, *available at* https://www.law.berkeley.edu/files/Wang_Faye_Fangfei_IPSC_paper_2014.pdf.

[5] *See* UPC Telekabel Wien GmbH v Constantin Film Verleih GmbH,Wega Film produktionsgesellschaft mbH, Case C‑314/12, Mar. 27, 2014, http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d0f130d55af5f05befec41e9873ff77df482333f.e34KaxiLc3eQc40LaxqMbN4Obh4Me0?text=&docid=149924&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=722256 (hereinafter, "Case C‑314/12").

Briefed in a press release of CJEU,[6] a Germany company Constantin Film Verleih and an Austrian company Wega Filmproduktionsgesellschaft noted that their films could be viewed or downloaded from the website "kino.to"without their consent. In 2011, these two companies later requested the Austrian courts to order UPC Telekabel Wien, an Austrian ISP, from providing its customers with access to that site. UPC Telekabel argued that such an injunction to it was not justified, because it did not have any business relationship with the operators of kino.to and it was never established that its own customers acted unlawfully. In addition, UPC Telekabel argued that the site blocking measures could be technically circumvented, not to mention it was not fair for it to bear the costs of those measures. By order of 27 October 2011,[7] the Oberlandesgericht Wien (Higher Regional Court, Vienna) (Austria), as an appeal court, partially reversed the order of the court of first instance in so far as it had wrongly specified the means that UPC had to introduce in order to block the website at issue and thus execute the injunction. In order to reach that conclusion, the Oberlandesgericht Wien held that Austrian laws must be interpreted in the light of Article 8(3) of Directive 2001/29. UPC Telekabel then appealed on a point of law to the Oberster Gerichtshof (Supreme Court) (Austria).

Because the arguments made by UPC involved the interpretation of Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society[8] (hereinafter referred to as Directive 2001/29), the Austrian Supreme Court referred the case to CJEU, and CJEU made the subsequent judgment which further clarified the justification and the appropriateness of argued Articles of EU Copyright Directive.

This request of Austrian Supreme Court concerns the interpretation of Article 5(1) and (2)(b) and Article 8(3) of Directive 2001/29.[9] The main issues including whether the UPC qualified as "intermediaries" in Article 8(3) while making access to infringing sites available to customers, and how to balance fundamental rights in an event of issuing a site blocking order by the courts.

In summary, regarding the first issue, CJEU ruled against UPC and

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[6] *See* Court of Justice of the European Union, *An Internet Service Provider May Be Ordered to Block its Customers' Access to a Copyright-Infringing Website*, Press Release No 38/14, Mar. 27, 2014, *available at* http://curia.europa.eu/jcms/upload/docs/application/pdf/2014-03/cp140038en.pdf.

[7] *See* Case C‑314/12, *supra* note 5, at para.14.

[8] The English version of the Directive 2001/29 is available at: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0029&from=EN.

[9] *See* Case C‑314/12, *supra* note 5, at para. 1.

decided it is an "intermediary" which falls within the scope of Article 8(3). Regarding the second issue, CJEU weighed the conflicts between the freedom to conduct a business, the freedom of information of internet users and the copyright protection, finally decided that a site blocking order is justified and proportionate on various grounds.

## II. Justification of Site Blocking Order in *UPC v. Constantin* Case

The Oberster Gerichtshof (Austrian Supreme Court) decided to stay the proceedings and to refer the following questions to the CJEU for a preliminary ruling[10]:

> 1. Is Article 8(3) of Directive 2001/29 … to be interpreted as meaning that a person who makes protected subject-matter available on the internet without the right holder's consent [for the purpose of Article 3(2) of Directive 2001/29] is using the services of the [internet] access providers of persons seeking access to that protected subject-matter?
>
> If the answer to the first question is in the negative:
>
> 2. Are reproduction for private use [within the meaning of Article 5(2)(b) of Directive 2001/29] and transient and incidental reproduction [within the meaning of Article 5(1) of Directive 2001/29] permissible only if the original of the reproduction was lawfully reproduced, distributed or made available to the public?
>
> If the answer to the first question or the second question is in the affirmative and an injunction is therefore to be issued against the user's [internet] access provider in accordance with Article 8(3) of [Directive 2001/29]:
>
> 3. Is it compatible with Union law, in particular with the necessary balance between the parties' fundamental rights, to prohibit in general terms an [internet] access provider from allowing its customers access to a certain website (thus without ordering specific measures) as long as the material available on that website is provided exclusively or predominantly without the right holder's consent, if the access provider can avoid incurring coercive penalties for breach of the prohibition by showing that it had nevertheless taken all reasonable measures?
>
> If the answer to the third question is in the negative:

[10] *Id.* at para. 17.

> 4. Is it compatible with Union law, in particular with the necessary balance between the parties' fundamental rights, to require an [internet] access provider to take specific measures to make it more difficult for its customers to access a website containing material that is made available unlawfully if those measures require not inconsiderable costs and can easily be circumvented without any special technical knowledge?

The CJEU has answered the first and the third questions with a thorough reasoning process. The judgment of these two questions will be discussed in the following sections.

## III. Article 8(3) of EU Directive 2001/29

The first question raised in this case was about whether Article 8(3) of Directive 2001/29 must be interpreted as meaning that a person who makes protected subject-matter available to the public on a website without the agreement of the right holder, for the purpose of Article 3(2) of that directive, is using the services of the internet service provider of the persons accessing that subject-matter, which is to be regarded as an intermediary within the meaning of Article 8(3) of Directive 2001/29.

First of all, the CJEU confirmed that given that right holders have the exclusive right to authorize or prohibit any act of making available to the public, making protected subject-matter available to internet users without the consent of the right holders in Article 3(2) of Directive 2001/29 infringes copyright and related rights.[11]

Subsequently the CJEU confirmed[12] that to remedy such a situation of copyright, Article 8(3) of Directive 2001/29 provides for the possibility for right holders of member states to apply for an injunction against intermediaries whose services are used by a third party to infringe one of their rights.[13]

The CJEU further cited Recital 59 of Directive 2001/29 to stress the role of intermediaries to bring infringements to an end.[14] Recital 59[15] reads as

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[11] *See id.* at para. 23-25.

[12] *See id.* at para. 26.

[13] Article 8(3) of the Directive 2001/29 provides, "Member States shall ensure that rightholders are in a position to apply for an injunction against intermediaries whose services are used by a third party to infringe a copyright or related right."

[14] *See* Case C‑314/12, *supra* note 5, at para. 27.

[15] *See* Directive 2001/29, http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0029&from=EN.

"In the digital environment, in particular, the services of intermediaries may increasingly be used by third parties for infringing activities. In many cases such intermediaries are best placed to bring such infringing activities to an end. Therefore, without prejudice to any other sanctions and remedies available, rightholders should have the possibility of applying for an injunction against an intermediary who carries a third party's infringement of a protected work or other subject-matter in a network. This possibility should be available even where the acts carried out by the intermediary are exempted under Article 5. The conditions and modalities relating to such injunctions should be left to the national law of the Member States."

According to Recital 59, intermediaries are in best position to bring copyright infringements to an end especially in the digital environment, which provided a legal ground to impose technical obligations on intermediaries.

Nonetheless, UPC Telekabel disputed it was not an "intermediary" of Article 8(3), even though the infringers used its services to make access of unauthorized content available to the public. UPC argued that there's no business relation between copyright infringers and it, furthermore, no evidence shown that its customers actually accessed those unauthorized content on the internet.

The CJEU ruled that given that the internet service provider is an inevitable actor in any transmission of an infringement over the internet between one of its customers and a third party, since, in granting access to the network, it makes that transmission possible, it must be held that an ISP which allows its customers to access protected subject-matter made available to the public on the internet by a third party is an intermediary whose services are used to infringe a copyright or related right within the meaning of Article 8(3) of Directive 2001/29.[16] Accordingly, for Article 8(3) of Directive 2001/29 to be applicable, it is not necessary to establish there's a contractual link between the ISP and the copyright infringer.[17]

Regarding the evidence of customers' actual behaviors, the CJEU decided that neither the wording of Article 8(3) nor any other provision of Directive 2001/29 indicates that a specific relationship between the person infringing copyright or a related right and the intermediary is required.[18] Furthermore, the Court emphasized that to add such requirement which not specified in the Directive would diminish the legal protection promised to the copyright holders which is state in the objective of the directive.[19]

[16] *See* Case C‑314/12, *supra* note 5, at para. 32.
[17] *See id.* at para. 34.
[18] *See id.* at para. 35.
[19] *See id.*

The CJEU further took previous cases as examples to stressed that Directive 2001/29 requires that the measures which the Member States must take in order to conform to that directive are aimed not only at bringing to an end infringements of copyright and of related rights, but also at preventing them.[20] Such a preventive effect presupposes that the holders of a copyright or of a related right may act without having to prove that the customers of an internet service provider actually access the protected subject-matter made available to the public without their agreement.[21]

In brief, it is important that the CJEU clarified that for ISP to be qualified as an intermediary does not require any business links with copyright infringers, nor does it need evidence of customers' actual behaviors for ISP to be held responsible to bear technical obligations. From the wording of the judgment, this answer was made on grounds of high legal protection to copyright holders promised by the Directive and preventive steps are allowed to tackle copyright infringements.

**IV. Non-Specific Injunction**

If the CJEU's answer to the first question confirmed the justification of site blocking order to an ISP under the Directive 2001/29, the third question is essentially about whether a non-specific injunction order is allowed. From the perspective of ISP, a non-specific injunction which does not specify the measures an ISP must take and when that ISP can avoid incurring coercive penalties for breach of that injunction by showing that it has taken all reasonable measures, would inevitably lay heavy burden on its own discretion and costs concerning what measures to take.

The CJEU firstly cited Recital 59 of Directive 2001/29 which states, that "The conditions and modalities relating to such injunctions should be left to the national law of the Member States" and confirmed that it's a matter of national law to decide the appropriateness of the injunction. Nonetheless, the CJEU's responsibility is to examine the application of national law is consistent with EU law, therefore necessary to take account whether it is consistent with the protection of the applicable fundamental rights, and to do so in accordance with Article 51 of the Charter of Fundamental Rights of the European Union (hereinafter referred to as the Charter).[22]

The CJEU pointed out that In this case, the injunction at issue might conflict with the following fundamental rights[23]: (i) copyrights and related

[20] *See id.* at para. 37 (citing Case C‑70/10 Scarlet Extended [2011] ECR I‑11959, paragraph 31, and Case C‑360/10 SABAM [2012] ECR, paragraph 29).

[21] *See id.* at para. 38.

[22] *See id.* at para. 45.

[23] The English version of the Charter of Fundamental Rights of the European Union is

rights, which are intellectual property and are therefore protected under Article 17(2) of the Charter, (ii) the freedom to conduct a business, which economic agents such as internet service providers enjoy under Article 16 of the Charter, and (iii) the freedom of information of internet users, whose protection is ensured by Article 11 of the Charter.

Regarding the protection of copyright, Article 17(2) of the Charter assures that intellectual property shall be protected, this raised the question whether an injunction would be justified by protecting intellectual properties. In this respect, this question is the same as the first question which examines the justification of an site blocking order. The CJEU reiterated an injunction might not cease copyright infringements but it would have preventive effects. While Article 17(2) implies Implementing that injunction must be sufficiently effective to ensure genuine protection of the fundamental right at issue, that is to say that they must have the effect of preventing unauthorised access to the protected subject-matter or, at least, of making it difficult to achieve and of seriously discouraging internet users who are using the services of the addressee of that injunction from accessing the subject-matter made available to them in breach of that fundamental right.[24]

Article 16 of the Charter states, “The freedom to conduct a business in accordance with Community law and national laws and practicesis recognized.”

The CJEU explained that the freedom to conduct a business under Article 16 includes the right for any business to be able to freely use, within the limits of its liability for its own acts, the economic, technical and financial resources available to it.[25]

The CJEU recognizes that an injunction in this case would inevitably restricts the free use of the resources because the injunction obliges an ISP to take measures which may have significant cost to it,[26] yet such such an injunction does not seem to infringe the very substance of the freedom of an ISP to conduct a business.[27]

There are two reasons provided by the CJEU that an injunction does not violate the substance of freedom to conduct a business.[28] First, a non-specific injunction such as the injunction in this case leaves the ISP to determine what measures to take, an ISP has the freedom to decide how to best dispose its resources. Secondly, an ISP can avoid possible penalties by

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available at http://www.europarl.europa.eu/charter/pdf/text_en.pdf.

[24] *See* Case C‑314/12, *supra* note 5, at para. 62.

[25] *See id.* at para. 49.

[26] *See id.* at para. 50.

[27] *See id.* at para. 51.

[28] *See id.* at paras. 52-54.

proving that it has taken all reasonable measures, therefore it is not an unbearable sacrifices and seems justified.

Regarding the freedom of expression enshrined by Article 11 of the Charter,[29] the CJEU emphasized in the judgment that the injunction measures adopted must comply with the rights of internet users' freedom of information.[30] To ensure the protection, the ISP must not affect the internet users' lawful access to information while taking reasonable measures. Despite the CJEU notes that, if the internet service provider adopts measures which enable it to achieve the required prohibition, the national courts will not be able to carry out such a review at the stage of the enforcement proceedings if there is no challenge in that regard, It is also important for national courts to check that is the case. Accordingly, in order to prevent the fundamental rights recognised by EU law from precluding the adoption of an injunction, the national procedural rules must provide a possibility for internet users to assert their rights before the court once the implementing measures taken by the internet service provider are known.

In brief, to justify the adoption non-specific injunction and reconcile the conflicts between copyright protection, rights to conduct a business and right to information, the CJEU ruled that as long as the measures proved to have preventive effects to copyright infringement, it is not necessary to prove to be able to fully cease infringing activities. Furthermore, a non-specific injunction does not violate the very substance of ISP's freedom to conduct a business, conversely, it assures freedom to some extent for an ISP to decide how to best place its resources to achieve the goal. Lastly, The adoption of any reasonable measures to prevent copyright infringements should assures the lawful access to information of internet users at the same time. It is also required to allow internet users to challenge that point in the court.

## V. Summary

In the judgment, the CJEU reiterated that an injunction in this case is justified in light of copyright protection, and in accordance with the trend of urging more cooperation from the private third parties to fight against digital piracy, the CJEU highly recognized the role of an ISP as intermediary without the requirements of proving actual links between ISP and copyright infringers. While it is not surprising that the Court emphasized the importance to protect internet users' freedom of information, it is worth

[29] Article 11 of the Charter provides, "1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. 2. The freedom and pluralism of the media shall be respected."

[30] *See* Case C‑314/12, *supra* note 5, at para. 55-57.

attention that the CJEU considered that a non-specific injunction provides more freedom to conduct a business rather than curbs it. The judgment could be problematic while there are limited legal methods of blocking sites and lays the burden of solution finding to the ISP.

**A. Disparities of Site Blocking Order Application in Member States**

Although the CJEU confirmed that application of non-specific site blocking order in this case, courts in member states have adopted different attitudes towards site blocking order. For example, courts in Germany, Netherlands and Ireland rejected to issue site blocking injunctions.[31] In comparison, Belgium, UK and Denmark have been issuing site blocking injunctions with specific technical measures.[32]

In the *Sabam v. Netlog* case, the Belgian court initially ordered an injunction of more general nature, stating that an ISP shall stop copyright infringements by disabling file sharing through P2P without giving technical specifications.[33] While the case was referred to the CJEU,[34] the Court ruled that no Deep Packet Inspection shall be ordered in this type of case.[35] It is because the CJEU decided that DPI system would filter all traffic files and performs a general monitoring function without prejudice to all users, which would be in conflict with human rights protected in the Charter of Fundamental Rights of the EU, most notably the freedom to do business, privacy of individual customers and freedom of expression.

In UK, a site-blocking injunction which specifying several technical measures seems to be widely adopted by the court. For example, in July 2011, the court ordered the ISP (British Telecom) to block the website Newzbin2.[36] In April 2012, several internet service providers were ordered to block the Pirate Bay.[37] In February 2013, the same providers were ordered to block different websites.[38]

In the ruling of *Fox v. BT* case in 2011, the High Court stated two specific technical measures to block the site at issue[39]:

> The technology to be adopted is:

[31] *See* Wang, *surpa* note 4, at 8.
[32] *See id.*
[33] *See* Wesselingh, *surpa* note 2, at 66.
[34] Case C-360/10, 16 February 2012.
[35] *See* Wesselingh, *surpa* note 2, at 66.
[36] Fox v. BT, [2011] EWHC 1981.
[37] Dramatico v. B Sky B, [2012] EWHC 268.
[38] EMI v. B Sky B, [2013] EWHC 379.
[39] Fox v. BT, [2011] EWHC 1981, para.12.

> (i) IP address blocking in respect of each and every IP address from which the said website operates or is available and which is notified in writing to the Respondent by the Applicants or their agents.
>
> (ii) DPI based blocking utilising at least summary analysis in respect of each and every URL available at the said website and its domains and sub domains and which is notified in writing to the Respondent by the Applicants or their agents.

Notably that in Newzbin ruling the UK High Court still recognized the application of DPI method to be one of the acceptable technical measures. Shortly after the Newzbin ruling, the CJEU ruled in the Scarlet v Sabam case and excluded the DPI on the ground of fundamental rights protection. Therefore in the case Dramatico v B Sky B, the High Court stated the technical means to be adopted should be[40]:

> (i) IP blocking in respect of each and every IP address from which the said website operates and which is:
>
> (a) notified in writing to the Respondent by the Applicants or their agents; and
>
> (b) in respect of which the Applicants or their agents notify the Respondent that the server with the notified IP address blocking does not also host a site that is not part of the Newzbin2 website.
>
> (ii) IP address re-routing in respect of all IP addresses that provides access to each and every URL available URL available from the said website and its domains and sub-domains and which URL is notified in writing to the Respondent by the Applicants or their agents; and
>
> (iii) URL blocking in respect of each and every URL available from the said website and its domains and sub-domains and which is notified in writing to the Respondent by the Applicants or their agents.

Considering different methods of site blocking measures are subject to the review of CJEU and might be excluded under EU laws, the non-specific injunction adopted by the Austrian Court in the first place seems to be a solution to balance the freedom of business and avoid the possibility of being ruled out later by the CJEU.[41] Nonetheless, a non-specific injunction has raised legal insecurity to ISP and may require a more careful examination by

[40] Dramatico v. B Sky B, [2012] EWHC 268, para. 3.

[41] *See* Wesselingh, *surpa* note 2, at 70.

the court to weigh on different values in conflict.

**B. Conclusion Remarks**

Copyright holders, intermediaries, users and website operators each have different interests, it is impossible to satisfy all of them.[42] To issue a site blocking injunction order, the national courts must follow the guidance set by the CJEU precedents and establish the proportionality analysis to weigh on various interests in conflict.[43] In the case of *UPC v. Constantin*, the CJEU affirmed a non-specific site blocking order is not only lawful under EU laws but also better protects freedom of conduct a business. For national courts which intend to adopt site blocking method to protect copyright, it may be time not to specify any technical measures on the order but leave the question to the discretion of the enterprise at issue.

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[42] *See* Pekka Savola, *Proportionality of Website Blocking: Internet Connectivity Providers as Copyright Enforcers*, 5 J. INTELL. PROP., INFO. TECH. & E-COM. L. 116, 130 (2014), *available at* http://www.jipitec.eu/issues/jipitec-5-2-2014/4000/savola.pdf.

[43] *See id.*

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# Copyright Protection on Pornography in Japan

Student Note

Yasuto Shirae*

**Abstract**

Most courts in Taiwan have denied legal redress in infringement suits to holders of copyrights on immoral or obscene works by applying judicially-created doctrines. These judgments were based on the Supreme Court held that adult films are not copyrightable because these films are against social order or public interest, and in no way promoted social development in 1999. However, the Taiwan Intellectual Property Office ("TIPO") has tended to recognize porn films as copyrightable works. In an administrative letter of explanation issued in 2008 (Zhi-Zhu-Zi No. 09700025950), TIPO stated that if adult films are original, they are covered by copyright regardless of whether they are also categorized as obscene material. Porn isn't an object of copyright protection until the IP Court in 2014 held that a pornographic work is entitled to copyright protection as long as it meets the originality requirement. Contrary to individual opinions in Taiwan, porn is taken it for granted that AV can be protected under Copyright Act in Japan.

Keywords: Japan, copyright, porn film, pornography

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* LL.M. Student, Graduate Institute of Science and Technology Law, National Kaohsiung First University of Science and Technology; M.S. in IP, Osaka Institute Technology (Japan); B.A. in IP, Osaka Institute Technology (Japan). Contact mail: resource.world.0922@gmail.com.

## I. Introduction

Adult entertainment companies in Japan have focused on Taiwan where websites openly sell their videos and TV channels air their content without permission. For many years, Japanese porn producers tried to seek copyright infringement lawsuits against Taiwanese pirates in the hope of holding them accountable for profiting from their content. The adult producers claimed that the pirates were spreading obscene material and damaging children didn't gain any ground either. The prosecutors decided that since the pirate sites displayed warnings and blocked minors from accessing their websites then there was no case to answer there either.

Nevertheless, the Supreme Court in Taiwan denied the originality of adult videos,[1] they hold that because copyright which aims at "protecting the rights and interests of authors with respect to their works, balancing different interests for the common good of society, and promoting the development of national culture." Nevertheless, porn films are against social order or public interest, and in no way promoted social development. According to the court, porn is not included, and can't be copyrighted for a long time.

For years producers of porn movies in Japan have bemoaned the lack of protection their content has received in Taiwan. However, on February 20, 2014, the Intellectual Property Court affirmed that the originality of adult videos.[2] It has become the first judgment held that adult videos can be copyrighted and the new standard for the other courts to hear and decide similar cases in the future.

## II. Legal Protection of Adult Videos in Japan

Under Japanese Copyright Act, Article 1 provides that the purpose of this Act is to provide for, and to secure protection of, the rights of authors, etc. and the rights neighboring thereto with respect [copyrightable] works as well as performances, phonograms, broadcasts and wire-broadcasts, while giving due regard to the fair exploitation of these cultural products, and by doing so, to contribute to the development of culture. In short, copyright is to protect and promote the development of national culture.

"Work" means a production in which thoughts or sentiments are expressed in a creative way and which falls within the literary, scientific, artistic or musical domain.[3] Article 10 provides the Illustrations of works.

However, do adult videos belong to works under Japanese Copyright Act? In light of Article 2, Para. 1, Subpara. 1, it can't be inferred that Congress

[1] *See* Supreme Court Criminal Decision No. 1999- Tai-Shang-250.
[2] *See* Intellectual Property Court criminal decision No. 2014- Xing Zhi Shang Yi Zi -74.
[3] *See* Art. 2, Para. 1, Subpara. 1 of the Japanese Copyright Act.

intended that obscene materials could not be copyrighted. In general, porn films are deemed a kind of cinematographic works[4], the reason is in light of Article 2, Para.3 which provides that "cinematographic work" includes a work which (i) is expressed through a process producing visual or audio-visual effects similar to those of cinematography, and (ii) is fixed in an object. All of porn videos can meet the factors of this article.[5]

Furthermore, they are found as a creation in which thoughts or sentiments with "originality" by a human mind and can be copyrighted under Article 2. Thus, to protect adult videos could apply the regulatory purposes of copyright- contribute to the development of culture in Japan.

Although porn films are recognized as copyrightable works, these work often face statutory limitations with respect to their distribution. Due to obscene materials of porn films, spreading obscene materials may damage the health of teenagers and children.

So the main regulation of porn is Article 175 of Japanese Penal Code, it provides, "A person who distributes, sells or displays in public an obscene document, drawing or other objects shall be punished by imprisonment with work for not more than 2 years, a fine of not more than 2,500,000 yen or a petty fine. The same shall apply to a person who possesses the same for the purpose of sale."

We can find that whether porn is in violation of the above article, the point is porn can't be distributed, sold or displayed in public an obscene document, drawing or other objects. However, how to define "an obscene document?" In Japan, there is a general opinion that was made by the Supreme Court of Judicature,[6] which was the highest judicial body in the Empire of Japan. The Court defined an obscene document as one that text or pictures and any other items can excite sexual desire; to make general people feel shame and disgust. The definition is remained ever since in Japan.

## III. The Judgment of Adult Videos in Japan

The following context I'll introduce a case how to find the protection of adult videos under the Copyright Act in Japanese courts.

In Japan, if someone sells unauthorized copies of AV (so-called bootleg) or, the copyright owner has a right to seek injunction.[7] I'll introduce a case

[4] *See* Art. 10, Para. 1, Subpara. 7 of the Japanese Copyright Act.

[5] Based on Article 2, Para. 1, Subpara. 1 of the Japanese Copyright Act, we can extend to explain the copyright protection for pornography, including even obscene materials.

[6] It existed from 1875 to 1947. The court was composed of 120 judges in both civil and criminal divisions. Five judges would be empaneled for any given case. *See* http://www.geocities.jp/since7903/kantyou/daishinin.htm (last visited June 20, 2014).

[7] Article 112 of the Japanese Copyright Act provides:

(1) The author, the copyright holder, the holder of the right of publication, the

about possession or distribution of unauthorized video tapes.

Whether an AV is a cinematographic work , the Tokyo District Court held, "Porn is a plaintiff work which falls within a cinematographic work."[8] Adult videos are a cinematographic work in the precedent of many other.

**A. The brief of the judgment**

Plaintiffs, Athena video Inc., F E. Metal Corporation, Cinemagic Corporation, Japan Home Video Inc., Max-et Inc., Media Station Ltd., which were adult entertainment companies and the copyright holders of porn films. These companies provided video tapes to the dealers of adult video franchise system, which are entitled 日本ビデオ販売 Inc.

The defendant, 日本ビデオ販売 Inc., which obtained legal copies of the porn movies from plaintiffs and sold pornographic video tapes. However, the defendant reproduced pornographic videos without plaintiffs' permission and sold the porn video tapes and supplied pirated editions to its own franchise system.

One of the plaintiffs was a member of the Nihon Ethics of Video Association[9] ("NEVA"), which was a Japanese video rating organization. NEVA found the defendant sold unauthorized duplication of plaintiffs' works. Later, plaintiffs wrote attestation letters to request the defendant to destruct the illegal copies and stop infringing; otherwise, they would bring an action against the defendant. However, the defendant refused to stamp or sign the letters. Therefore, plaintiffs asserted that the defendant violated Article 175 of the Japanese Penal Code and Copyright Act and sued for an injunction at the Tokyo District Court.

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performer, or the holder of neighboring rights may demand that persons infringing, or presenting a risk of infringing, on his moral rights of author, copyright, right of publication, or moral rights of performer or neighboring rights, as applicable, cease the infringement or not infringe, as the case may be.

(2) When making the demand provided for in the preceding paragraph, the author, the copyright holder, the holder of the right of publication, the performer or the holder of the neighboring rights may [also] demand the taking of measures necessary to effect the cessation or prevention of the infringement, such as the destruction of objects constituting the acts of infringement, objects made by acts of infringement, and/or machines and tools used exclusively for acts of infringement.

[8] Tokyo District Court in Year 1996 (Wa) No. 1590 (no copyright infringement injunction).

[9] It was a voluntary organization to ensure adherence to Japanese obscenity laws, which prohibit any display of genitals. This is accomplished by a mosaic pixilation that is applied to videos for sale in Japan, and the NEVA seal is placed on all videos produced by member studios, which included the larger and older adult video studios in Japan.

The Tokyo District Court found that plaintiffs had issued 169 attestation letters to notice the defendant and there had discovered 582 unauthorized porn films in the defendant's directly-managed stores. The judgment didn't explain why porn films are cinematographic works, the judges indicated that due to the defendant's unreasonable action and possession of unauthorized copies, we can assume the infringer's attempt to immunize their illegal acts and cause damage to plaintiffs' cinematographic works. The defendant was obviously violate the purpose of the Japanese Copyright Act.

**B. Comments of the judgment**

The Tokyo District Court ruled that the defendant infringed plaintiffs' "cinematographic works" but didn't illustrate why porn films belonged to cinematographic works. The reasons are quite simple, the Japanese Copyright Act doesn't exclude porn from protection objects. There is no denying that porn is expressed through a process producing visual or audio-visual effects similar to those of cinematography, and is fixed in an object.

There was another famous judgment[10] about a video rental store bought the products of Soft On Demand Inc. ("SOD") which is a Japanese adult video group of companies and illegally duplicated the products, so that the store could provide the unauthorized copies for people to rent. The judgment hold that porn films were cinematographic works, hence the producers enjoyed rights of distribution under Article 26 of the Japanese Copyright Act.[11]

**IV. Conclusion**

In Japan, adult entertainment has become just like "adult industry." Despite the Copyright Act contains the goal of efficiently utilizing and allocating the social resources so as to optimize the total social benefit. To recognize porn as a copyrightable object is different from to control obscenity. Moreover, denying copyright protection to works adjudged obscene by the standards of one era would frequently result in lack of copyright protection and it will be lack of financial incentive to create.

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[10] *See* 東京地裁　平成 10 年(ワ)第 17625 号.

[11] Article 26 of the Japanese Copyright Act provides:
(1) The author of a cinematographic work shall have the exclusive right to distribute his work by distributing reproductions of said cinematographic work.
(2) The author of a work reproduced in a cinematographic work shall have the exclusive right to distribute his work by distributing reproductions of the same.

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# Editorial Note on the Volume 3 Number 2 Issue of 2014

Ping-Hsun Chen[1]

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## Editorial Note

In this issue, we change the title of the "Research Article" section to "Regular Articles" to separate articles in this section from Quick View articles. In addition, we open a "Student Note" section to encourage LL.M. students to submit their ideas to our journal. Another important step is that our journal is now indexed in Scopus. This major step helps our journal exposed to more scholars.

## Appendix

(June 17, 2014 Letter from Scopus Title Evaluation Team )

Title: NTUT Journal of Intellectual Property Law and Management
ISSN / E-ISSN: 2226-6771 /
Publisher: National Taipei University of Technology

Dear Prof. Ping-Hsun Chen,

The title mentioned above has been evaluated for inclusion in Scopus by the Content Selection & Advisory Board (CSAB). The review of this title is now complete and the CSAB has advised that the title will be **accepted** for inclusion in Scopus. For your information, the reviewer comments are copied below:

Useful journal in English for those interested in intellectual property law in Taiwan

If necessary, our Source Collection Management department will contact the publisher in order to set up the content feed for Scopus. The title will be loaded in Scopus as soon as we have access to the title and the content has

[1] Assistant Professor, Graduate Institute of Intellectual Property, National Taipei University of Technology (Taiwan); J.D. 10' & LL.M. 08', Washington University in St. Louis School of Law; LL.M. 07', National Chengchi University, Taiwan; B.S. 97' & M.S. 99' in Chem. Eng., National Taiwan University, Taiwan. Corresponding email: cstr@mail.ntut.edu.tw.

been processed for indexing. At this moment, there is no further action required from your end.

Yours sincerely,

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