

## Biomedical Patent Securitization In Taiwan

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### Abstract

*Funding institutions such as Banks are currently hesitant to undertake lending to businesses on the basis of pledges of intellectual property. This is due to a variety of factors, such as the difficulty in maintaining the value of the intellectual property (“IP”), the imperfections in the method of valuing IP, a lack of confidence in IP, an overestimation of the degree of risk associated with IP and the inefficiency in realizing on pledged intellectual property assets. In this article, cases on intellectual property securitization from around the world are examined, together with the factors which make them successful. In addition, issues and suggestions for future legislation are reviewed, as are applications of the current forms of asset securitization to provide for private fundraising and the commercial issues that arise after patent securitization legislation is introduced. Finally, suggestions on biomedical patent securitization legislation are presented and the properties that intellectual property should possess in order to be useable as security for fundraising are explained. The foreign examples of fundraising and lending institutions are presented as demonstrative as to how the mechanism and framework for implementation of biomedical patent securitization would operate. It is hoped this article will contribute to future legislation on intellectual property securitization, starting with biomedical patent securitization.*

### 1. History of Patent Securitization

Patent securitization is a form of intellectual property-based assets securitization which started in United States in the 1970s. The earliest cases of intellectual property securitization involved copyrights in the musical and digital-rights fields by entertainers, such as David Bowie, James Brown, Ashford & Simpson, the Isely Brothers, and Iron Maiden. Other examples include the Italian film maker Cecchi Gori (securitization of future movie income in 1999), fashion designer Bill Blass (trademark securitization) and Formula 1 (securitization of trademark, copyright and royalties).

The first example of patent securitization is that which was underwritten by Royalty Pharma in 2000. The securitized asset was “Zerit,” an anti HIV medicine that raised 115 million U.S. dollars for Yale University. In 2003, Royalty Pharma again involved in

an important securitization, this time involving 13 medicines from several companies raising 225 million U.S. dollars. These two cases reveal the potential of, and demonstrate the successful models for, biomedical patents securitization.

Patent securitization offers new sources of funding for patented technology while providing tax offset and investment protection. The patent owner does not need to lose the whole patent right or accept unfavorable conditions simply due to a lack of funding. Patent securitization also offers the following additional advantages for the capital markets:

#### (1) A new financial

**product:** a new option for investors to broaden options for their investment portfolios.

(2) **A simplified asset:** investors only need to focus on the securitized patent, patent pool or royalty stream; there is less need to worry about the credit record, financial performance, operation or management of the IP owner.

(3) **An asset with a risk management mechanism:** the system provides a vehicle that shields the IP assets which have been securitized from the bankruptcy of the IP owner. The securitized IP is isolated from the owner, and there is a credit-enhancement mechanism.

### 2. Special Characteristics of Biomedical Patents

Due to profound scientific hurdles and regulatory requirements of, for example, the U.S. Food and Drug Administration office and related medicine laws, the entry barrier into this business is rather high and the funding required to validate the quality of the patented technology is much larger than can normally

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1. [http://www.cpmda.org.tw/file/e\\_news/037/d/037.pdf](http://www.cpmda.org.tw/file/e_news/037/d/037.pdf), 28 Apr 2012 visited.

be expected. The application fee alone for U.S. FDA can cost from 20 to 30 million NT dollars,<sup>1</sup> not to mention the cost and expense of drug discovery, pre-clinical trials, phase I, II, III a, b, and phase IV trials, good manufacture practice, good laboratory practice, etc. In addition the patent securitization process is a highly complex and technical one, requiring the parties involved, such as the inventor, the patent holder, the investor, special purpose vehicle, issuer, underwriter, buyer, bond holder, etc., to be highly trained. These reasons all point to the importance of appropriate statutory mechanisms and government involvement in the process to provide for protection for all parties involved.

Unlike other industries, if a patent expires, many biomedical technologies can still profitably be on the market for patient use, although the price will drop to a certain extent. Drugs, such as aspirin, penicillin, etc., demonstrate that products normally need not completely disappear from the market, but rather, can continue to generate relatively steady profits.<sup>2</sup> This is typically achieved, for example, by the use of the drug for new indications. An example of this is, lamivudine<sup>3</sup> which was originally developed for the treatment of hepatitis B, but which is now also approved for use in HIV combination treatment. Another example is Quinine,<sup>4</sup> which was originally developed for treating malaria, but which now is approved for the treatment of Lupus (systemic Lupus Erythematosus, SLE).<sup>5</sup> Biomedical patent securitization is a kind of new investment choice for the general public to participate in the business of saving lives, but for those parties involved in the securitization mechanism, it can be a far more complicated one than exists with other technologies.

In addition, biomedical patents have relatively higher development and commercialization costs than those usually associated with other types of intellectual property. In order to manage the risks

and uncertainty, the securitization process must be carefully and professionally handled to maximize the commercial benefits that securitization can bring via such strategies as patent life cycle management and patent enforcement.

### 3. Legislation on Biomedical Securitization in Taiwan

Traditional assets securitization is a creative financial product used to attract investors. Biomedical patents are intellectual properties that can be securitized for cash flow as long as accounting concerns relating to the unique features from the intellectual properties (*i.e.*, the uncertainty of forecasting cash flow precisely) can be understood and managed. According to traditional accounting principles, expenses and costs should be able to be listed on the balance sheet, however, Article 60 of the Taiwanese Income Tax Act clearly states that "... Business rights, trademarks, copyrights, patents and other franchises are assets only if they are acquired by purchase...",<sup>6</sup> meaning that patents developed internally can only be listed as research expenses and cannot be considered as assets on a company balance sheet, while the other assets with an objective value can.<sup>7</sup> Therefore, how to amend the traditional accounting principle for asset definition is certainly one of the directions for legislation in order to promote biomedical patent securitization in Taiwan.<sup>8</sup>

Another area in Taiwanese law that is ripe for legislation is how to place a financial value on the intellectual property being securitized. In Taiwan, the Enforcement Rules of the Estate and Gift Tax Act, Article 35 states that: "Unless otherwise provided for under other relevant acts or regulations, for the valuation of intangible assets, the provisions under the preceding article [Article 34] shall apply *mutatis mutandis.*," while Article 34 elaborates "The value of...rights shall be determined according to the years remaining.

"...For mining and fishing rights, the estate and gift tax shall be levied only in accordance with the provisions set forth under the two preceding

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2. See John S. Hillery, "Securitization of Intellectual Property: Recent Trends from the United States," *Washington Core*, March 2004, p23; [www.iip.or.jp/summary/pdf/WCORE2004s.pdf](http://www.iip.or.jp/summary/pdf/WCORE2004s.pdf), 20 June, 2007 visited, at 14.

3. <http://en.wikipedia.org/wiki/Lamivudine>, 28 Apr 2012 visited.

4. [http://zh.wikipedia.org/wiki/percentE5\\_percentA5\\_percent8E\\_percentE5\\_percentAF\\_percentA7](http://zh.wikipedia.org/wiki/percentE5_percentA5_percent8E_percentE5_percentAF_percentA7), 28 Apr 2012 visited.

5. [http://translate.google.com.tw/translate?hl=zh-TW&sl=en&tl=zh-TW&u=http%2F%2Fwww.medicinenet.com%2Fsystemic\\_lupus%2Farticle.htm&anno=2](http://translate.google.com.tw/translate?hl=zh-TW&sl=en&tl=zh-TW&u=http%2F%2Fwww.medicinenet.com%2Fsystemic_lupus%2Farticle.htm&anno=2), 28 Apr 2012 visited.

6. <http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=G0340003>, 28 Apr 2012 visited.

7. See Liu C-C, "Accounting Measure on Intangible Assets," *Security and Future Journal*, Vol. 24, No. 12, p4, Dec 2006.

8. See "Accounting Standard Measurement and Principle for Intangible Assets" in the no. 37, *Standard Report for Finance and Accounting*, p4, announced by Taiwan Accounting Research and Development Foundation on 20 July 20006, based on International Accounting Standard no. 38 (IAS 38), effective from 1 Jan 2007.

paragraphs. The trade name carried on by the business established thereunder shall no longer be subject to estate or gift tax payment.”<sup>9</sup>

Those provisions also provide examples as to how to calculate the value of the patent rights within limited periods of time and instruct that intangible assets shall follow these principles if there are no other laws or regulations to be followed. In addition, the ShiZi no 563 comments from Taiwan grand judges meeting on 28 Dec 2001 on this subject states that: “...the calculation for the stocks from the non-listed or over-the-counter companies are involved in the tax burdens on people, therefore, it shall be legislated according to the law...,”<sup>10</sup> thereby further demonstrating the legislatures power to provide guidance on asset valuation. These examples can be relied upon to provide the legislature with a framework by which it can value intangible assets, like biomedical patents.

#### 4. Parties, Processes and Legal Design Involved in Legislation of Biomedical Patent Securitization

There are several factors involved in the intellectual property securitization process, including originators, the credit enhancement mechanism, credit evaluation agencies, consulting and investment institutes, security underwriters and agencies, bonds underwriters and agencies, assets services institutes, and others, all of whom play their particular role in making the securitization process a success.

##### 4.1 Parties Involved in Legislation of Biomedical Securitization

Securitization is a process wherein assets are turned into securities, and relies on the participation of parties with various professions to be successful. Briefly, the parties involved are:

**(1) The Debtor(s)/Borrower(s):** the debtor(s) or borrower(s) apply for the loan from the originator to generate the creditor’s right. Thereafter, the debtor/borrower pays the originator principal and interest based on a cash flow that the patent rights can be expected to provide.

**(2) The Originator:** the originator is the owner of the securitized asset(s). In return for capital, all or part of the rights from the securitized assets are transferred to a special purpose vehicle for initiating and maintaining the securitized intellec-

tual property as a pledge for a specified period of time. There is no recourse against the securitized asset(s)<sup>11</sup> and the conveyance process shields them from bankruptcy. The securitized asset(s) may be partitioned and pooled according to similarities to permit stable forecasting and management of risks and to maximize profit generation. The originator is allowed to be the service provider for managing the securitized asset(s) in exchange for a service charge.

**(3) The Special Purpose Vehicle (SPV) or issuer:** the special purpose vehicle is the entity that takes over control of the securitized asset(s) to shield them from bankruptcy and that issues the securities (for example, a subsidiary company or the institute of underwriters). The special purpose vehicle can be a trust, a company or any other legal entity and depends on the local law or regulation governing the situation, and the relevant tax offsets.<sup>12</sup> In addition, its business scope should be limited in order to simplify risk control.

**(4) The Investors:** the investors are the final purchasers of the securities, such as the bank, insurance company, pension funds, investing company or corporate treasuries, and sometimes retail investors.

**(5) The Trustee:** the trustee represents the investors in their negotiations with the credit enhancers, service providers, issuers, etc. Normally the bank or trust will play this role. The issuer will entrust the security interest to the trustee.<sup>13</sup> In Taiwan, the Financial Securitization Act, Article 77 states: “When issuing Asset-Backed Securities, in order to protect the rights and interests of the Asset-Backed Security holders, the special purpose company (SPC) shall appoint a Supervisory Institution and shall enter into a supervision agreement with the Supervisory Institution in compliance with the asset securitization plan; provided, that the SPC shall not appoint the Originator or Servicer set forth in the asset securitization plan as the Supervisory Institution.”<sup>14</sup> The supervisory institute protects the rights for the investors.

9. <http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=G0340072>, 28 Apr., 2012 visited.

10. <http://law.moj.gov.tw/LawClass/ExContent.aspx?ty=C&K1=&K2=&K3=&CC=D&CNO=536>, 28 Apr., 2012 visited.

11. See Steven L. Schwarcz, “The Alchemy of Asset Securitization,” *1 Stanford Journal of Law, Business & Finance* 133, 135 (1994).

12. See Chen W-D, Lee A-Y, Lia S-S, “Principle and Practice on Asset Securitization,” *ZhiOShan Cultural publisher*, Aug 2002, p24.

13. See Diane Audino, “Securitization: The Rating Agency Approach to Credit Risks,” *Euromoney*, 1996, p 21.

14. <http://eng.selaw.com.tw/FLAWDAT0202.asp>, 28 Apr, 2012 visited.

**(6) The Credit Enhancer:** in order to manage the credit risk, the credit enhancement mechanism is often applied to raise the credit rating and encourage investment. There are two types of credit enhancement mechanisms: (i) internal credit enhancers; and (ii) external credit enhancers. These are applied according to the request from the credit rating agency to provide the credit enhancement measures requested by the credit rating agency to maintain the desired credit rating.

**(7) The Credit Rating Agency:** the credit rating agency is the party who provides the credit rating for the securitized asset(s) and suggestions for the risk control management thereof,<sup>15</sup> as well as the rating report used as a reference for the investors to judge whether the particular pledge is secure to pay for the principal and interest.<sup>16</sup> The credit rating agency reviews the qualities of the securitized asset(s), the abilities of the service provider, the financial performance of the originator, the infrastructure of the securitization, the securitization process itself, how the credits, etc., may be enhanced, and provides investors with all the information thereon for their references when examining their desire to invest in the securitization. Example of such rating agencies with internationally esteemed reputation, are Moody's Investor Services, Standard & Poor's Corporation, Duff & Phelps and Fitch IBCA. The rating examples from Standard & Poor's Corporation or Moody's Investor Services can be something like AAA (S & P) or Aaa (Moody's). The minimum recommended investing ratings are BBB (S & P) or Baa (Moody's). According to the Taiwan Finance Asset Securitization Act, Article 102: "The Asset-Backed Securities or Beneficial Securities issued through public offerings to non-specific people by the SPC or the Trustee pursuant to this Act shall be rated by a credit rating institution with the recognition of the competent authority."<sup>17</sup> Any legislation on biomedical patent securitization should, in a similar fashion, mandate the inclusion of ratings by such credit rating agencies in a similar fashion.

**(8) The Underwriters/Placement Agents:** the underwriter is often a security corporation and its duties are to analyze the market, recommend

the infrastructure, price the securities and suggest a public offerings or private placements for the securities for the investors. The underwriter may promote the trading and act as an arranger to integrate the comments from various professions including legal, financial, tax and government policy, etc.<sup>18</sup>

**(9) The Servicer or Backup Servicer:** the special purpose vehicle is to shield the securitized assets from bankruptcy of the owner or originator, and it will not necessarily have the ability to manage or operate the securitized asset(s). Therefore, the servicer/back-up servicer will serve the role of managing and operating the securitized asset(s) and allocating profits to the investors according to the securitization contract. In case the unexpected situation happens, such as poor management or bankruptcy of the servicer's core business, which hinders the servicer to perform in the securitization, a backup servicer will take over the duties in the securitization.

If patents are involved in the securitization, the servicer monitors the patent licensor to insure fulfillment of the obligations and duties and to update the technology information in order to sustain the securitization operation, as royalties are often the main cash flow that warrants the particular intellectual property securitization. Where the securitization of biomedical patents are concerned, licensors often have to meet milestones for the securitized biomedical patent (such as to pass the review of FDA or accomplishing a specific stage of clinical trial or the development of dosage form or even better, a new indication which implies a brand new market) to use this securitized patent for an additional cash flow. The stability of the cash flow from the securitized patent will affect the credit rating, and if the servicer is able to not only sustain the cash flow from existing patent licensing, but also to develop new licensing for the securitized patent, the cash flow performance will be better than stable, which is beneficial for the credit rating during the periods of securitization.<sup>19</sup>

The concept mentioned above can also be seen in the Taiwan Finance Asset Securitization Act, in chapter 2: special purpose trust, section 5 (Articles

15. See *supra* note 19, p25.

16. See Teresa N. Kerr, Bowie Bonding in "the Music Biz: Will Music Royalty Securitization Be the Key to the Gold for Music Industry Participants?," 7 *UCLA Ent. L. Rev.* 367, 377 (Spring 2000).

17. <http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=G0380122>, 28 Apr 2012 visited.

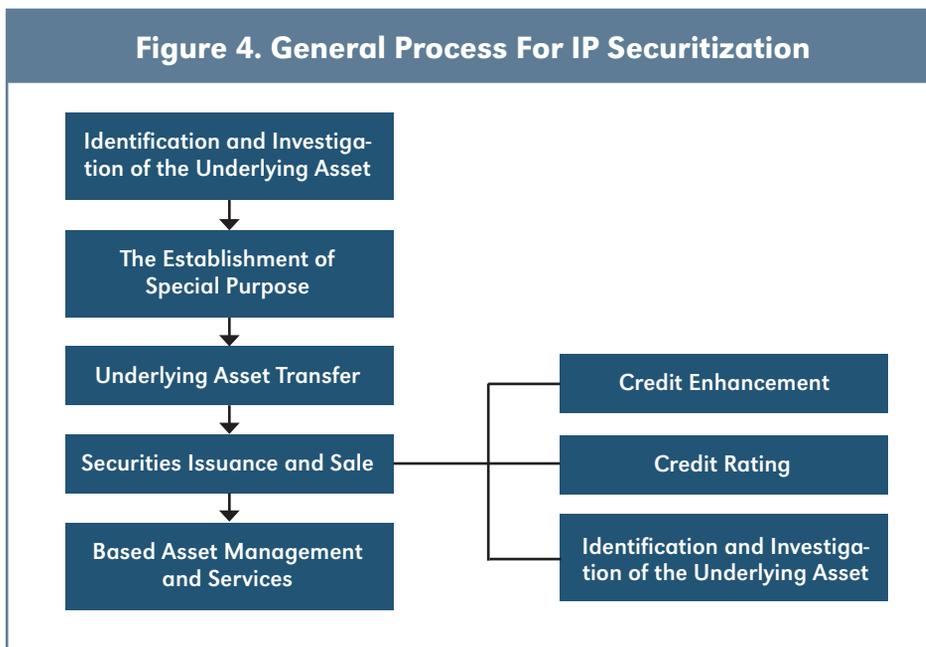
18. See Chou Y-B, "Study Report for Basel International Convergence of Capital Measurement and Capital Standards and Assets Securitization," *Central Deposit Insurance*, 2003, p53.

19. See Wang J-C, "Financial Assets Securitization," Wu-Nan publisher, Mar 2005, p12.

34-36): rights and duties for the trustee, and section 6 (Articles 37-42): calculation, tax and related issues for the special purpose trust.<sup>20</sup>

**(10) The Professional Advisers:** the professional advisers are the experts from those professions that are needed to conduct due diligence and auditing. Examples of such people include legal counsel to draft the legal documents, financial experts, accounting advisers and patent experts experienced with biomedical patent(s).

## 4.2 Processes Involved in Legislation of Biomedical Securitization



The general process of intellectual property securitization can be summarized in the above flow chart.

The securitization includes several steps that more or less run simultaneously, however, the logical order is:

**(1) Identify the securitization target(s) and the process for the preliminary analysis of the asset(s).**

The originator has to identify the needs for the asset(s) which may possibly undergo securitization and preliminarily analyze them to decide whether the securitization can be successful, and thereafter, to design the best infrastructure for the securitization according to the needs from the asset(s).

**(2) Invite professional advisors and parties to be involved in securitization process.**

It is impossible to have all the experts and parties from the very beginning of the securitization planning, however, the core members involved in securitization should be invited to form a team early, on which can support the design of infrastructure and arrange the deal with legal documents.

**(3) Information analysis.**

While, initially, there will be a preliminary analysis as to whether the securitization can be successful, at this stage, a thorough analysis is made of the

decision to initiate the securitization process. The historical analysis of the securitized asset(s), the environmental analysis of the target market and the whole economic situation are all taken into account for detailed calculation, so as to provide as precise a forecast as possible.

**(4) Refine the identified assets for securitization and process the auditing.**

In general, only an asset that can generate stable cash flow or can be converted into predictable amount of cash is allowed

for securitization. The securitized asset(s) must be able to generate sufficient cash flow to cover not only the principal but also any interest and services charges and credit rating agency charges and the credit enhance mechanism adjustments as may be required during securitization. Decisions are also made as to whether it is better to pool the assets at issue with other assets to diversify the holding and lower the risks involved therewith. If so, after refining the securitized assets, the originator will pool and partition the assets according to similarity and process due diligence, reviewing documents to determine the intellectual property rights of the pooled asset(s), auditing their administration and related security interest and other obligations for the creditors. In any event, the predictable cash flow income must be greater than the overall costs to pay, including the principal, interest, services charges and related expenses.

20. <http://law.moj.gov.tw/LawClass/LawAll.aspx?PCode=G0380122>, 29 Apr 2012 visited.

## **(5) Set up special purpose vehicle and perform true-sale.**

In order to shield the securitized assets from bankruptcy, a true-sale of the assets is a must to separate the securitized asset(s) from the originator. In the United States, this special purpose vehicle can be a trust, a corporation, a limited liability partnership, or any other legal entity, as long as it can perform the fundraising purpose. In the end, the final choice will be determined mainly by the needs of the originator, whether the tax off-set can be achieved and the purpose of this trading. Furthermore, the special purpose vehicle must meet the requirement of being out of the control of the originator or the patent(s) owner to shield them from creditors in the case of bankruptcy to protect investors.

## **(6) Take care of the trading structure and audit from time to time internally.**

The special purpose vehicle and the originator will enter into a service contract whereby the originator is to take care of the securitized asset(s), a trustee (*i.e.* a bank) is to be assigned to represent the investors, an underwriter agreement is prepared, and a credit rating agency is hired to evaluate the designed infrastructure for the securitization. Similar requirements can be found in the Taiwan Financial Asset Securitization Act, chapter 3: special purpose company, section 8, Articles 85-89<sup>21</sup> for the business scope of the special purpose companies in patent securitizations.

## **(7) Credit enhancement and circulation improvement.**

In order to improve the credit rating and attract more investors, the special purpose vehicle can undergo the credit enhance mechanism to improve the credit rating or the issuing conditions based on the advice from the credit rating agency. These measures are to ensure liquidation of the debts. In case there may be temporary cash shortfalls from the securitized asset(s), the third party (such as a bank or an insurance company) provides liquidity as a contingency, or a back-up arrangement for the special purpose vehicle to cash out for paying the investors.

## **(8) Process the credit evaluation and issue the securities.**

After credit enhancement, the special purpose vehicle hires a credit rating agency to provide an

evaluation of the securitized asset(s) and announce the credit rating to be applied thereto by the Agency for the investors' reference. Thereafter, the underwriter arranges the sale of these securities to investors for public or private placements.

## **(9) Obtain income from the issued securities and pay the originator the agreed price.**

The special purpose vehicle receives income from the underwriter and pays the originator the agreed price for its fundraising purpose.

## **(10) Manage the assets with payment for the principal and interest.**

The servicer manages the pooled asset(s) and bookkeeping profits from the securitized asset(s), sometimes even to pursue legal action if payment is delayed. The profits are saved in an account established by the special purpose vehicle for this purpose. Upon maturity, the special purpose vehicle pays investors the principal and interest then due.

## **5. Legislation Among Countries on Patent Securitization**

In Taiwan, patent securitization has not yet been legislated and the related legal issues can only apply under the "Company Act," the "Securities and Exchange Act," the "Financial Asset Securitization Act" and the "Clauses of the Real Estate Securitization Act."

Based on the custom in Taiwan, a specific law and regulation on patent securitization is highly recommended for facilitating fundraising needed for the development of patented technologies.

Like Taiwan, there is no specific law or regulation in the United States specifically concerning patent securitization, with resort being made instead to the Uniform Commercial Code and the Securities and Exchange Act being the primary legal bases currently used. Nonetheless, the registration of the transfer of the intellectual property rights and of the securitization interest are recommended as stated in the 35 U.S.C. 261 Ownership and Assignment:<sup>22</sup>

"An assignment, grant or conveyance shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it is recorded in the Patent and Trademark Office within three months from its date or prior to the date of such subsequent purchase or mortgage."

In addition, each of the individual states that make

21. <http://law.moj.gov.tw/LawClass/LawAll.aspx?PCode=G0380122>, 29 Apr 2012 visited

22. [http://www.uspto.gov/web/offices/pac/mpep/documents/appxl\\_35\\_U\\_S\\_C\\_261.htm](http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_261.htm), 26 Apr 2012 visited.

up the United States has its own law and regulation concerning registration and its effects.

Japan is similar to the United States in that a registration system for assets conveyance is also applied.<sup>23</sup> There are several theories discussing how to define the assets conveyance in Japan. A registration system with a public announcement is preferred to protect an innocent third party from double selling. There are several research companies receiving funding from the Japanese Policy Investment Bank by providing intellectual property rights as financial guarantees,<sup>24</sup> which indicates that intellectual property securitization is already being used in the Japanese capital market. Japanese trust law was amended to accommodate intellectual property rights in 2004. The other laws and regulations relating to application of securitization in Japan are the Japanese Patent Act,<sup>25</sup> the Japanese Bankruptcy Act (specifically Article 53: Bilateral Contract) and Civil Law Section IV Assignment of claims in Japanese civil law (specifically Articles 466-473), which, in Article 469 states that:

“The assignment of any debt payable to order may not be asserted against the relevant obligor or any other third party unless the certificate representing such claim is tendered to the assignee with the endorsement of the relevant assignment.”<sup>26</sup>

*Which is reinforced by 466 (2) which states that:*

“... where the parties have manifested their intention to the contrary; provided, however, that such manifestation of intention may not be asserted against a third party without knowledge.”

In Taiwan, for the time being, the applicable law and regulation to be applied for the issues involved in securitization are the Patent Act, the Civil Act, the Company Act, the Securities and Exchange Act, the Trust Act, the Financial Asset Securitization Act, Clauses of the Real Estate Securitization Act and the Bankruptcy Act. According to Article 6 of the Taiwan Patent Act, the:

“...patent right are both assignable and inheritable...In the case of taking a patent right as the

subject of a pledge, the pledgee shall not be allowed to put the patent under pledge into practice, unless otherwise provided for as a covenant in an agreement.”

*Furthermore, Article 59 states that:*

“The assignment, trust or licensing made by the patentee of the patent right of an invention to another person to practice the invention, or the pledge created on the patent by the patentee shall not be asserted against any third party, unless it has been registered with the Patent Authority.”

*And Article 74 provides that:*

“The grant, alteration, extension, prolongation, assignment, trust, licensing, compulsory licensing, revocation, extinguishments or pledging of an invention patent right as well as other matters which should be published, the Patent Authority shall effect such publication in the Patent Gazette.”<sup>27</sup>

Article 62 extends that principle to joint owners of patent rights (“A joint-owner of an invention patent shall not assign or entrust his/her share thereof to another person or create a pledge on the same patent, without the consent of all the other joint-owners.”)

The above mentioned articles in Taiwan show that the law in individual countries is becoming internationally harmonized, since the concepts and principles in the existing law and regulations are somehow similar to that in the United States, Japan and Taiwan, although the applicable laws were legislated in different acts or chapters with minor differences to cope with local environment. Regarding the conveyance of the intellectual property rights, registration with the patent and trademark office is recommended and the protection for the innocent third party should be maintained, in view of the complicated patent right assignment involved.

## 6. Overseas Biomedical Securitization Cases Studies

There have been several successful cases involving securitization of biomedical patents that can provide models for us to refer to when examining different scenarios involving this type of instrument.

### 6.1 Case I: Securitization for Investment in Development

The first case study we shall examine is a traditional one involving a large pharmaceutical company: the Eli Lilly securitization of Semagacestat for raising funds needed for clinical trials.

23. See Huang M-J, “Basic Principle on Securitization,” *Financial Law*, Yuan-Jau publisher, 2007, pp239-243, 249.

24. See “Dynamic Fundraising on Intellectual Property,” in the *Investigation Report of Intellectual Property Circulation and Fundraising Cases Studies*, by Economic and Industry Department, Dec 2007, p45.

25. See Nahoko Ono, “Intellectual Property as Guarantee-Current Issues in Japanese Intellectual Property Law,” PhD thesis from Hitotsubashi University Law school, Nov 2011, p 4.

26. <http://ishare.iask.sina.com.cn/jf/12992168.html?from=like>, 28 Apr 2012 visited.

27. <http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=J0070007>, 28 Apr 2012 visited.

Eli Lilly, one of the top ten pharmaceutical companies in the world, securitized Semagacestat for U.S. \$300 million through TPG-Axon Capital Management, LP and NovaQuest in order to raise funds for paying Quintiles, a world class clinical trial organization, to perform clinical trials for two candidate drugs. For 300 million U.S. dollars, TPG-Axon provided 90 percent of development funding while NovaQuest provided 10 percent, backed by royalties and milestone fees from three of Lilly's Alzheimer's drug candidates, including Semagacestat.

TPG-Axon Capital Management, LP (TAC) is a globally famous private hedge fund, providing services to high tech individuals, pension funds, and banking institutions; its main interests are healthcare, pharmaceuticals, financial services, technologies, new energies, and basic materials and retails.

NovaQuest is a unique value-added-reseller (VARs) and distributor. The NovaQuest business is focused on small-to-medium enterprises, providing expertise in industrial equipment, life sciences, consumer goods, high-tech, CPG, and apparels.

This case study shows that, even with a world class organization, knowledge experience and expertise, the securitizations are not guaranteed for, according to a 17 August 2010 official announcement on Eli Lilly's website:<sup>28</sup> Lilly has since halted further development of Semagacestat for Alzheimer's Disease based on the preliminary results of the Phase III Clinical Trials. This Semagacestat case thus also demonstrates the need for various mechanisms used in securitization, such as vehicles to shield the asset from bankruptcy and the pooling of assets to provide greater security and higher guarantees for the buyer.

## 6.2 Case II: Single Technology From University and Marketer

The second case study we shall examine, that of the securitization of "Zerit" by Yale University, points out the difficulties encountered with properly evaluating the royalty and income streams of drug and other biomedical products and the problems that can arise when this evaluation is not properly made.

BioPharma Royalty Trust structured a securitization of "Zerit" (Stavudine; 2'-3'-dideoxy-2'-3'-dideoxythymidine, d4T), which was protected by a patent from Yale University and licensed to Bristol-Myers Squibb Co., who were to pay royalties as a guarantee for the securitization of 115 million U.S.

dollars, including 57.15 million U.S. dollars in senior debt, 22 million U.S. dollars in mezzanine debt and 22.16 million U.S. dollars in equity, for securities that were awarded a single A rating by Standard & Poor's in October 2000.

The transaction was completed based on the track record of royalties from 1992 to 2000, which had shown that such compounds had a 24 percent compound annual growth rate. Biopharma Royalty Trust's senior notes were due quarterly beginning from 6 Sept. 2000 to 6 June 2006, supported by a strong legal structure, that segregated the revenue stream, from the credit support provided by subordinate debt and equity investors, and the strength of the historical and projected royalty revenues provided by the Zerit patent. In addition, the excellent AAA credit rating of Bristol-Mayers Squibb Co.—a leading international pharmaceutical company—itsself. The underwriter/issuer of Biopharm Royalty Trust was Royal Pharma AG and the senior holder was Westdeutsche Landesbank Girozentrale in London.

Nonetheless, because this securitization was based on a single product (Zerit), it carried an inherently higher risk than in cases where several products are involved. This is because market conditions and assumptions of compound rates (and market share that a drug will achieve) can never be predicted with absolute certainty, and errors in the process become much more pronounced.

In the case of Zerit, this turned out to be the case due to the following reasons:

- (1) Zerit was indicated for acquired immune deficiency syndrome (so called "AIDS"), and the majority of patients suffering from AIDS are from the developing countries who are normally unable to pay for the treatment—a factor that was not properly accounted for in the valuation;
- (2) Health reimbursement systems are different in every country and medications for AIDS are often too expensive to be covered by public reimbursement systems—again a factor that was not properly accounted for in the valuation; and
- (3) Although the prevalence or incidence of the patient pool was large, the available patient pool who could afford the drug was difficult to achieve based the health reimbursement system worldwide—once again, a factor that was not properly accounted for in the valuation.

While, for Yale University, this was a successful securitization as Bristol-Mayers Squibb Co. paid royalty based on the licensing agreement, and the funding raised from this particular securitization was then

28. [http://www.aidsinfonet.org/fact\\_sheets/view/414](http://www.aidsinfonet.org/fact_sheets/view/414), visited on 9 Dec 2012.

used for its intended purpose. However, from the investors point of view, the Zerit securitization was not able to deliver the expected financial benefits due to various factors, one of which was an overly optimistic assumption of 24 percent compound growth rate. Fortunately, this securitization period was only from 2000-2006, otherwise, there would have been additional downside for investors as the World Health Organization subsequently announced a recommendation that Zerit was not suitable for initial treatment of HIV infection in 2009, which further limited its market size. Furthermore, certificates permitting the introduction of generic competition were granted by United States Food and Drug Administration in the U.S. market further negatively impacting the drugs market share.<sup>29</sup>

### 6.3 Case III: Pooled Assets From Leading Biotechnology and Pharmaceutical Companies

The third case study we shall examine points out the advantages of pooling assets to be securitized in providing security and advantages for investors and to avoid the problems that were encountered in the Zerit securitization discussed in the previous case study.

The current trend is towards the securitization of preferred pooled assets in order to prevent intentional or unintentional mistakes or forecasting errors, such as those that were seen in the Zerit case. An example of such a securitization was the Royalty Pharma Finance Trust's 225 million U.S. dollar securitization of variable funding notes, structured by Credit Swiss First Boston in 2003 with AAA rating by Moody's and Standard & Poor's for a pool of drugs from various companies. The insurance company was MBIA Insurance Group, which was involved in the insurance of this securitization, and the trustee was Deutsche Bank Trust Co. America.

This securitization involved a three-year revolving borrowing period with a seven-year expected maturity, in combination with quarterly amortization. The special purpose vehicle involved with this transaction issued securities for a pool of 13 drugs from various companies, such as, Genetech's and Biogen Idec's Rituxan®, Celegen's Thalomid®, PrePro® from Eli Lilly and Johnson & Johnson/Centocor, Centocor's Retavase®, Chiron's TOBI®, Novartis' Simulect®, Roche's Zenapax®, Ligand's Targretin® Capsules, Memorial Sloan Kettering's Neupogen/Neulasta®, Organon's Variza®, Glaxo Smith Kline and Adolor's Entereg®, Pfizer's lasofoxifene® and Wyeth's Bazedoxifene®.

29. [http://www.aidsinfonet.org/fact\\_sheets/view/414](http://www.aidsinfonet.org/fact_sheets/view/414), visited on 9 Dec 2012.

In January 2004, a portion of the royalty interest in Neupogen/Neulasta®, which belonged to the Memorial Sloan Kettering Cancer Center, added a further U.S. \$263 million into the bankruptcy-protection vehicle and the investor insisted that there also be a U.S. \$7 million dollar investment in Royal Pharma. At the start of this transaction, the royalty assets were owned by the offshore company Royalty Pharma AG, while, at closing, the assets were sold on to an Irish Trust, which was a newly formed Delaware business trust established for the purpose of providing the securitization with a shield from bankruptcy claims.

Nine of the drugs were launched in the market within 5 years, with the patents involved having expiration dates that fell between 2005 to 2015. Performance of this portfolio generated 4.4 billion U.S. dollars in sales, about 49 million U.S. dollars in royalty and contingent payment rights to Royalty Pharma AG in a calendar year. The licensees of the contingent payment rights were owned by a diverse group of investment trade companies.

### 6.4 Case IV: Securitization Through Litigated Assets

The fourth case study involves a case where funding was sought for the IP assets in question, in order to enforce the very IP assets that were the subject of the securitization: thus meaning that the very assets that were securitized were being put at risk by their use.

Emtricitabine (FTC), a fluorinated version of lamivudine (3TC), was discovered and patented by Emory University, and subsequently licensed to Triangle Pharmaceuticals in 1996. Later, Triangle Pharmaceuticals was acquired by Gilead Sciences, who completed development and secured market authorization for the drug from the FDA on 2 July 2003. Therefore, the right to market FTC was owned by Gilead Sciences.

Lamivudine (3TC) was marketed by Glaxo, which had obtained it when Glaxo acquired Burroughs-Wellcome. Both FTC and 3TC were produced by a process for the synthesis of BHC-189, this process had been previously licensed by Emory to Burroughs Wellcome prior to its acquisition by Glaxo. However, Emory claimed that Glaxo has improperly obtained the rights to the synthesis patent and to 3TC itself.

Emory University filed an action against Glaxo for the rights to the BHC-189 synthesis patent on the grounds that Wellcome had misappropriated the intellectual property of Emory's inventors, and that the intellectual property and patents covering FTC were originally from Emory University. In addition, Emory University demanded the rights to the clinical trial data that had been generated relating to FTC.

Emory also faced patent challenges on other fronts with challenges having also been launched by Shire Pharmaceutical and BioChem Pharmaceutical.

In the end, Emory University was able to maintain the rights for both 3TC and FTC. The FTC monetized securitization by Emory University was conducted during the ongoing litigation:

1. February—September 2004: Emory University held internal discussions to monetize FTC and/or 3TC royalty streams for securitization;
2. October 2004—February 2005: Emory University employed an experienced financial advisor Citigroup and Covington & Burling as outside legal counsel;
3. March—June 2005: Due Diligence process was conducted with various parties;
4. July 2005: Emory University conducted final negotiations in New York, and sale contracts with an Amended and Restated License Agreement were executed;
5. At the close of the transaction, Gilead and Royalty Pharma paid Emory University 525 million U.S. dollars for all FTC royalties. In addition, Gilead paid 15 million U.S.D. for amending and restating the license agreement to Emory University;
6. Regarding the 525 million U.S. dollars, it was agreed that Gilead and Royalty Pharma would pay 65 percent and 35 percent, respectively, to Emory University and the Inventors within 30 days of the closing date- July 21, 2005;
7. Emory University and the inventors acquired an interest from Royalty Pharma approximating 25 percent of the proceeds paid by Royalty Pharma during the transaction; and
8. Gilead was obligated to pay to Royalty Pharma royalty revenue based on future FTC net sales.

This case was the largest sale of royalty interests to date in the pharmaceutical sector, with significant interest from investors, sponsors and hedge funds. Based on the Citigroup's profound knowledge for asset management and potential buyers assisted valuation, significant interest in the securitization was generated, which created competition to expedite signing and closing. Gilead's stock went up about 3 percent (about 625 million U.S. dollars) on the announcement day. Considering that Gilead's costs was only 65 percent out of the 525 million U.S. dollars (341.25 million U.S. dollars), Gilead was able to realize a profit of 283.75 million U.S. dollars on the transaction.

Lamivudine (3TC) is the only oral medication for hepatitis B, and there are more than 130 million people in China that still suffer from hepatitis B. In this case, 3TC was demonstrated to be useful for a new indication (to treat AIDS) which greatly increased the cash flow. We learn from this case how fierce competition can be in the pharmaceutical industry and how the value of the innovation can be greatly compensated. Emory University was able to raise funds permitting it to carry on for 6 years in litigation and received quite a payoff in return. However, dangers still exist as China launched a compulsory licensing amendment effective on 1 May, 2012, and Lamivudine (3TC) was the first drug to be possibly granted compulsory licensing, which further enhanced the importance of FTC.

## 7. Recommendations

Biomedical (including pharmaceutical) technologies require a huge amount of resources and time to maintain the intellectual property and fund the technology until it reaches the market.<sup>30</sup> Securitization is an innovative financial tool that offers a mechanism to link capital markets with intellectual property rights in such a manner that IPRs are accepted as pledges for fundraising.<sup>31</sup> Adoption of characteristics of the current Financial Asset Securitization Act for future legislation permitting intellectual property rights to serve as a basis for financial securitization for biomedical technologies is recommended.

However, governance to insure proper financial control is crucial, as it can be recklessly used and can trigger economic crises. Certainly, it is unforgettable regarding the catastrophic recession caused by Lehman Brothers years ago, which caused tens of trillions of U.S. dollars lost and doubled the American national debt with 30 million people out of jobs worldwide. However, the deregulation of the financial industry in United States for over 30 years gave opportunities for the system to be misused, something which needs to be safeguarded against if biomedical patent securitization is to be successful.

### 7.1 Overseas Fundraising and Guarantor Institutions

In Japan, Tetsuya Komuro securitized the future royalties of his 806 songs from his music CDs in exchange for 1 billion Japanese yen from Fujitsu Bank<sup>32</sup>

30. See Adam Grant, "Ziggy Stardust Reborn: A Proposed Modification of the Bowie Bond," 22 *Cardozo L. Rev.* 1291, 1296 (2001).

31. See David Edwards, "Patent Backed Securitization: Blueprint for a New Asset Class," [http://www.securitization.net/pdf/gerling\\_new\\_0302.pdf](http://www.securitization.net/pdf/gerling_new_0302.pdf), 18 May 2007 visited.

in order to buy digital music equipment and recording facilities needed to produce yet more songs and, presumably, more revenue.<sup>33</sup> Fuji Bank required Tetsuya Komuro to sign the rights in the assets to an asset management company to manage the royalties for these songs in the securitized CD.

In the United States, companies like IP Innovations Financial Services, Inc. (IPI), exist whose core business specialized on intellectual properties evaluation and the raising of funds using this IP as security. As an off-shore company, Royal Pharm, also specializes in the securitization of biomedical patents, with several successful cases like Yale University on Zerit and many others biomedical patents.

There is also the need to execute Technology Escrow Contracts for intellectual property to be accepted as a mortgage guarantee, in which the targeted intellectual property is transferred to a custodian company under the terms of an escrow contract, which the company verifies and evaluates and manages the assets.<sup>34</sup> The true example of such an agreement was Norand—a software company with many valuable patents and copyrights, which was acquired by a biotech company through the help of the custodian company in 1988<sup>35</sup> by offering funding and deposit verification for the secured intellectual properties and accounting status reports of Norand.<sup>36</sup>

In Taiwan, the government supports and provides trust funds for small and medium size enterprises to pledge their intellectual property.<sup>37</sup> Considering the great expectation on biomedical patent securitization, even though it can be a sophisticated and costly mechanism, it is one that offers enormous benefits and protection for the parties involved.

## 7.2 Opinions from Scholars

There are differing opinions as to whether legislation on patent securitization is a must or whether the application of the current laws and regulations

is sufficient, since neither the United States nor European countries have specific legislation on patent securitization. Therefore, the following scenarios were reviewed to try to resolve these differences.

### 7.2.1 Application of the Current Financial Assets Securitization Act in Taiwan

Adoption of the current Finance Asset Securitization Act is one of the suggestions for biomedical patent securitization: the related monitoring from the government can be provided for under Article 9 (apply, approval and registration); creditor right transfer and notification can all be provided for under Articles 5 and 6; and rules regarding fees and tax off-sets are all provided for under Articles 38-41. Furthermore, securities offerings can apply special rules and risk management control and the trading expenses discount can apply, in a fashion similar to those applied to financial asset securities. However, there are some limitations in these extensions of the law and regulations and so-called “grey areas” would remain, such as the scope of the rights of the originator, how to define assets, capital restrictions, and operation models.

Nonetheless, many scholars do not agree that intellectual property rights should be qualified as the securitized assets. According to the Financial Asset Securitization Act, the definition of assets includes such things as rent, credit card debt, payment receivable or other moneywise creditor’s right in Article 4 (paragraph 2, part 3). Thus, it would appear that intellectual property may be qualified as a payment receivable or other moneywise creditor’s right. However, if that is not the case, then consideration should be given to amending part 5 in Article 4-paragraph 2 of the Financial Asset Securitization Act, to provide that intellectual property rights can be an option.

Again, there are scholars who worry whether “future debt” can be adopted into the Financial Asset Securitization Act as the assets mentioned in Article 4, paragraph 2 (car mortgage, house mortgage, rent, credit card debt or payment receivable, etc.) presently exist at the moment that the credit is extended as a creditor’s right. However, the cash flow to be securitized is the anticipated royalty from the licensed contract or the future licensing contract that is based on the intellectual property right. Thus, it is not present and certain. This raises the issue as to whether the future creditor’s right can be applied to the current Financial Asset Securitization. Therefore, if the biomedical patents are to be covered in the current Financial Asset Securitization, then an amendment of Part 5, Paragraph 2 in Article 4 must be made before

32. <http://www.fujibank.co.jp/>, 4 May 2012 visited.

33. See Liu H-D, “Current Situation and the Future for Financial Institutes to Handle the Intellectual Property Fundraising,” master thesis from graduate school of Management in National ChengChi University, p35, Dec 2004.

34. See Jeremy Lewis, Andrew Moore, “Ensuring IP Protection Through Escrow,” *21 Entertainment and Sports Lawyer* 8 (spring 2003).

35. See Liu J-B, Yan R-C, King T-L, Shi J-F, “Study on the Intellectual Property as Guarantee, Protection and Application of Intellectual Property in China and Taiwan,” Yuan-Jau publisher, July 2002, p148.

36. See Jeremy Lewis, Andrew Moore, *supra* note 36, p8.

37. See Chen W-L, “Introduction of Evaluation and Fundraising on Intangible Assets in Taiwan,” *National Lawyer*, Vol. 10, no. 1, 32-34, Jan 2006.

implementation.

## 7.2.2 An Independent Legislation on Biomedical Patent Securitization

For better implementation and to better encourage the capital market, the establishment of legislation on biomedical patent securitization is highly recommended.<sup>38</sup> This new law can follow the framework of the existing Financial Asset Securitization Act and incorporate useful concepts of the Trust Act. While it is inevitable that people will debate whether or not the unique features of intellectual property right and future royalties from the existed licensing and future licensing means that biomedical patents should not be considered as financial assets, it is indisputable, that there are similarities between intellectual properties and financial assets which should justify their being able to be used as collateral for the securing of funding.<sup>39</sup>

## 7.2.3 Author's View on Biomedical Patent Securitization Legislation

To provide better protection and safeguards for patent and other intellectual property-based asset securitization, a registration system for publicizing the trading and conveyance of the rights would appear to be essential. The intellectual property right is authorized by patent and trademark office, the maintenance status can be searched online, but there is no compulsory enforcement. In the United States, the future creditor's right is allowable for conveyance in the Uniform Commercial Code (U.C.C.), Article 9.<sup>40</sup> However, registration of the security interest with an appropriate authority is a must to claim the security right in the event that any dispute arises.

In Taiwan, the Supreme Court case, 90 Tai-Sun-Zi, no. 1438, confirmed that the conditional creditor's right can be conveyed.<sup>41</sup> The registration system was originally established for recording security interests in real estate and financial assets. However, such a registration system can be extended to provide a further protection for investors and help to prevent risk and disputes relating to the security interest and the rights

of the various parties in the secured assets. The future creditor's right may be conveyed in Taiwan based on that Supreme Court judgment. Therefore, the future creditor's rights, such as the right to receive royalty based on future or existing licensing contracts should be available to be securitized.

In particular, special attention on reviewing the licensing contracts of the targeted intellectual property is required, in case they have a clause prohibiting their conveyance. Since the beginning of the securitization is a true-sale between the originator and the special purpose vehicle, sometimes a third party, such as a trust, will need to be included in the securitization as a second special purpose vehicle for additional protection for the securitized patents, in case their conveyance is prohibited by the licensing contract of the securitized patent. This can lead to the failure of the whole securitization.

Flaws in the assets or unsatisfactory outcomes may happen or only become apparent after securitization, especially where biomedical or drug patents are involved, in that, there are many unexpected circumstances, both scientific/medical as well as legal, which are beyond control of the parties. Such scientific/medical problems include unexpected side effects on minority of human being, low market acceptance, government policy changes (for example, compulsory licensing) and amendments to FDA regulations to name but a few. Such legal problems include patent validity, true inventorship (in the USA) and prior user rights that only first arise during litigation and can provide challenges to the underlying patent rights causing them to fail.

In the event of legal failures, securitization provides investors with a measure of security in that, if the patent rights are sustained and existed during the securitization period,<sup>42</sup> the licensor is not liable for the loss or damages on the future developments or outcomes.<sup>43</sup>

In the event of scientific/medical failures, investor protection is provided by credit enhancement and risk management mechanisms included in the securitization infrastructure (such as the special purpose vehicle and vehicles to shield the assets from bankruptcy). This is understandable in that there are

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38. See Tsuei K-W, Chen Y-S, "The Prior Study on Intellectual Property Securitization," *Security Market Development*, 147, 2005.

39. See Chen Y-T, "Advantage and Crisis for the Future of Intellectual Property Securitization," *Technology Law Analysis*, Vol 17, no. 9, 3, 2005.

40. See Wang W-Y, "Basic Studies on Legislation of Assets Securitization," *Yue-Dan Law Journal*, no. 88, 118-119, 2002.

41. See Supreme Court case, Tai-Sun-Zi no. 1438, [http://jirs.judicial.gov.tw/FJUD/FJUDQRY01\\_1.aspx](http://jirs.judicial.gov.tw/FJUD/FJUDQRY01_1.aspx).

42. See Supreme Court case, Tai-Sun-Zi no. 4297, [http://jirs.judicial.gov.tw/FJUD/FJUDQRY01\\_1.aspx](http://jirs.judicial.gov.tw/FJUD/FJUDQRY01_1.aspx), 8 Aug 2012 visited.

43. See Taiwan Patent Act, article 73, paragraph 2, [http://www.tipo.gov.tw/ch/Download\\_DownloadPage.aspx?path=1616&Language=1&UID=13&ClsID=14&ClsTwoID=15&ClsThreeID=28](http://www.tipo.gov.tw/ch/Download_DownloadPage.aspx?path=1616&Language=1&UID=13&ClsID=14&ClsTwoID=15&ClsThreeID=28), 8 Aug 2012 visited.

various factors that impact on the success of patent implementation, such the qualities of the product (*i.e.* made in developed countries vs. made in developing countries), commercialization design, manufacturing standards and marketing investments, macroeconomics, etc., and against which risk needs to be hedged.

All of the foregoing point out the need and advantages of providing “special-built” legislation to provide

for the opportunities and to minimize, to the greatest extent possible, the risks that patent securitization provides instead of merely trying to adapt existing legislation to do the task; so that government monitoring for a higher level of protection to investors and to the economy as a whole while providing innovators and companies with the benefits of access to funds for further innovation and development. ■