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Abstract

We investigate the global spread of pharmaceutical patent protections as acquired by firms, based on a novel global patent database for all significant medical drugs introduced in Japan. It gives us the propensity of filing and grant rate for each country for the granted patents in Japan. Major findings are the following. Both the filing propensity to and the grant rate of major Asian countries approached those of the OECD economies by the early 2000s for chemical substance inventions. However, there still exists substantial heterogeneity with respect to the other drug inventions: crystal, use, formulation or combination, suggesting a significant future room for international harmonization of patent granting standard. We found clear evidence for policy impact on the spread of protections for the two largest non-OECD economies. The Patent Law reform in China in 1993 had an immediate and significant impact on patent filing propensity to China (25 percentage points increase) well before it becoming a WTO member in late 2001. Furthermore, the mailbox application system in India had a substantial effect: the filing propensity reached 80 percent of the number of corresponding EP patent applications around year 2000, well before the year of TRIPS implementation for drug patents.

JEL classifications: O34, O38, K29

Keywords: pharmaceutical patent, chemical substance patent; TRIPS Agreement; India, China, propensity of patent filing, grant rate

1. Introduction

Patent system plays a major role in pharmaceutical innovations. Appropriability that patents confer to its owner differs significantly among technologies and medical drug is known as the field where the highest appropriability is conferred by patents (Cohen et al. (2000); Mansfield (1986)). It is well known that value of patent is highly skewed following a log normal distribution (Scherer and Harhoff (2000)) and a large majority of most valuable patens come from chemical substance patens that protect medical drug products. Medical drug and chemistry is one of the few areas where patent systems effectively work as a property system and gives net incentives to the innovators and innovators seek global patent protection, according to Bessen and Meurer (2008). Furthermore, patent protection also plays a significant role in diffusing the newly developed drugs globally, as the resent study by Cockburn et.al. (2016) convincingly suggests.

Not only because the economic value of medical drug patents is very large, but also because the medical drugs directly affect the welfare of public at large, the protection of drugs by patent system is also of highly political concern. In the negotiation of TRIPS Agreement, one of the most confrontational matters between developed countries and developing countries was the protection of pharmaceutical patents (Cockburn et al. (2016) Kyle and McGahan (2012)).

In the late 1970s, the Government of the United States initiated trade policy to recover the US industrial competitiveness by strengthening intellectual property rights such as patents, which is well known in Japan as ‘Pro-patent policy’. One of the main strategy is to realize the strong protection of intellectual property rights in foreign countries through bilateral negotiations with foreign countries and multilateral trade

negotiations such as the GATT Uruguay Round. Partly pushed by such pressure, countries such as China, South Korea, Taiwan and Indonesia revised or enacted their patent law in order to strengthen patent protection. The GATT Uruguay Round reached the Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) that is a part of a single undertaking of the WTO agreements and entered into force as of January 1, 1995. TRIPS Agreement, among others, obliged a signatory to protect substance patent which is a corner stone in drug patent protection. As a result, worldwide protection of intellectual property has been significantly and substantially reinforced, as far as the patent law provisions are concerned. At the same time, however, given that the effectiveness of patent protection heavily depends on the details of institutional setting of each country such as the patent examination and the court system, it is quite another matter whether they actually affect the R&D and innovations.

This paper investigates this issue by examining how pharmaceutical firms actually began to choose applying patents globally and actually acquired them, based on a novel global patent database for those patents that protect or once protected the medical drugs introduced to the Japanese market. Our main focus is to understand how extensively the patent protection in major Asian countries have converged to those of Major OECD economies in terms of filing propensity and grant rates by types of patents such as chemical substance patent, medical use patents and manufacturing process patents as well as to assess the impact of policy reforms, focusing on China and India: the domestic patent reform in China in 1993 and the introduction of mail box system in India, in response to the TRIPS Agreement.

The rest of this paper is organized as follows: the next section presents a short description of institutional background and prior literature; section 3 describes the data construction and the composition of our sample patents; section 4 discusses global

patent filing and their grant rates of drug inventions launched in Japan and section 5 discusses the impact of policy reforms and changes, focusing the effect of policy reform in China and the effect of mailbox system in India; and section 6 concludes the study.

2. Background of this study and prior literature

2.1. TRIPS Agreement

The TRIPS Agreement stipulates the minimum standard of the protection of Intellectual Property Rights. As to the scope and term of patents, TRIPS Agreement stipulates the following contents(see Article 27): i) patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Nevertheless, the member states may also exclude from patentability the diagnostic, therapeutic and surgical methods for the treatment of humans or animals; ii)patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. iii) The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date. It also stipulates the clauses concerning the enforcement of patent right in order to ensure that the enforcement procedures are available so as to permit an effective action against infringement of intellectual property rights, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.

The TRIPS Agreement entered into force in January 1, 1995. The deadline that a member country has to apply the provisions of TRIPS Agreement differs by the

categories of member country, such as developed country, developing country and least-developed country: a developed country, by January 1, 1996; a developing country member, by January 1, 2000; least-developed country Members, January 1, 2006[i]. However, there is transition provisions as to the protection of pharmaceutical chemical product patents. Application of the pharmaceutical chemical substance patent provisions to developing countries can be deferred to January 1, 2005[ii].

Together with the exception of the deadline of the introduction of chemical substance patents, the TRIPS Agreement introduced a special patent application system, so-called 'mailbox application system,' which is stipulated in the Article 70(8): "A member country has to provide a means by which applications for patents for pharmaceutical chemical products can be filed as from January 1, 1995,the date of the entry into force of the WTO Agreement, if the member apply for the transition provision as to the protection of pharmaceutical chemical product patents. This study investigate the impact of this provision in India as a part of the assessment of the policy impact (section 5).

2.2. Introduction of chemical substance patent and TRIPS Agreement

One of the biggest confrontation points between the north and south in the TRIPS Agreement negotiations was the introduction of chemical substance patent system[iii]. The United States put pressures on strategically important countries such as China, South Korea, Taiwan, and Indonesia through bilateral negotiations for the protection of chemical substance patent system. In light of the protection of chemical substance patent and TRIPS Agreement, the Asian countries are divided into four categories: i) countries that introduced chemical substance patent system before the

TRIPS Agreement; ii) those where the protection of chemical substance was substantially obtained through registering exclusive rights based on the United Kingdom patents although three is no chemical substance patent system in their own patent law; iii) those that adopted chemical substance patent system in order to implement TRIPS obligation; iv) those that adopted chemical substance patent system and entered WTO. Table 1 shows the WTO membership date in calendar year and month, the deadline of pharmaceutical chemical patent, the date of introduction of chemical substance patent for 11 Asian countries with Japan, Europe (the members of the European Patent) and United States as references.

(Table 1 around here.)

2.3. Prior literature

Cockburn et.al. (2016) empirically investigated how quickly new medical drugs with an active ingredient become commercially available in a country by being protected by patents. Analysis is made for the timing of the launches of 642 new ingredient drugs in 76 countries during 1983-2002. In order to measure the effect of protection by patents, they made the database of drug patents which identifies the presence of chemical substance patent, the presence of manufacturing process patent and their terms of protections by each active ingredient and country. They also collected data of price regulation regime and the strength of patent protection in general for each country. Their econometric analysis shows that longer and more extensive patent rights for chemical substance significantly shortened the period of time to the market for a new drug. They also showed that estimated effects were generally robust to controlling for the endogeneity of policy regimes with country fixed effects and to the estimations by instrumental variables. This study clearly showed that medical drugs are required to

pass clinical tests of each country for marketing in the country and a patent protection is important for a pharmaceutical company to have a good prospect of recovering heavy investments necessary to implement such clinical tests. If the patent is critical to develop as well as to diffuse medical drugs to developing countries, patent protection is beneficial for both developing and developed countries.

Kyle and McGahan (2012) investigated on what disease area pharmaceutical companies increased their R&D activities after the TRIPS Agreement. They captured their R&D activities by the number of phase I clinical trials, the first stage of human clinical testing, that are implemented globally. As is expected, their study shows that there is a complementarity between the introduction of patent protection and the income level as to their effect on the activation of research and development activities. Patent protection in wealthy countries is associated with increases in R&D effort. However, the introduction of patents in developing countries has not been followed by greater R&D investment in the diseases that are most prevalent there.

Duggan et.al. (2016) analysed the India's implementation of a patent reform for pharmaceuticals in 2005 that was intended to comply with the TRIPS Agreement. Because price sharply plummets down after the entrance of generic companies into the market, there were significant fears across a variety of constituencies that this new system would cause dramatic prices increases by several times and further limit access to pharmaceuticals in India. However, the fact is that price increase is relatively small, just 3–6 percent. This might have been caused by the competition with the existing drugs without patents, pricing to the market practice as well as by the threat of price controls by government.

Branstetter et.al. (2006) examined the activities of U.S.-based multinational

enterprises and royalty payment to parent companies in 16 countries that strengthened their intellectual property right systems in the 1980s and 1990s, including Japan and Korea and obtained positive effects although this study is not dedicated to the pharmaceutical industry.

Aoki and Saiki (2005) investigated effect of the material product patents introduced to Japan in 1976. They examined data prior to 1976 and years immediately following to determine the law's effect on domestic pharmaceutical market, innovation by pharmaceutical firms, and relationship of the Japanese market to the rest of the world. There is evidence that the domestic market became more concentrated and quality of pharmaceutical innovation changed after the introduction. This is because introduction of product patents is different from simple strengthening of existing technology protection such as increasing breadth.

Although these existing studies are highly relevant to the analysis of the role of patent protection for pharmaceutical innovations, they did not give us a direct assessment of the global spread of pharmaceutical patent protections as acquired by pharmaceutical companies, in response to the policy or institutional change.

3. Data

3.1. Data construction

Since the value of patens is highly skewed, if we investigate the average propensity to obtaining pharmaceutical patents as a whole in a foreign country, it will provide a highly inaccurate picture (a downward biased picture) on the patent protection in such country. In order to address this problem, we focus on the patents that are useful for protecting the drugs actually commercialized. The novel database we constructed

consists of all patents that protect or once protected all significant medical drug products that were actually introduced to the Japanese market. It also contains patent family information: the publication numbers assigned by foreign patent office for the corresponding patents of patent applications, which enables us to investigate the propensity for filing to each foreign county and grant rate of the country, all relative to the granted Japanese drug patents. There are three steps for preparing this novel database.

First, we list up all patents that appear in 'San-ei Report (2015 October edition),' which lists up all the major medical drug products that were introduced to the Japanese market with the information of patents that protect or once protected it. It also gives the information of the category of claims of patents that effectively protect or once protected the medical drug product. The category symbols and the categories are as follows: Symbol 'S,' chemical substance (including biologics) ; symbol 's', crystal; symbol 'U,' medical use, symbol 'P,' pharmaceutical formulation; symbol 'C,' combination of drugs; symbol 'M,' manufacturing process. A patent may contain more than two claims that protect the drug product and in this case more than one category symbols are assigned to one patent. We list up all the patents that appear in the 'San-ei Report' with claim category symbols

Second, we connected with above prepared data with patent database of 'Pat-R' database which is provided by Artificial Life Laboratory, Inc. This database are composed of bibliographic and examination process data that were originally provided by the Japan Patent Office (JPO). Utilizing the 'Pat-R' database, we gathered such corresponding number for each patens as application number, 18 month pre-grant publication number (*Kokai-Koho*), examined publication number which were published

under the old version of the Patent Law (*Kokoku-koho*), PCT national publication number that were made for Patent Cooperation Treaty (PCT) route applications entering Japanese national phase (*Kohyo-koho* and *Saikohyo-tokkyo*), international application number and publication number for PCT route applications. Because some data are missing in the 'Pat-R' database because of truncations, we supplemented the corresponding data by utilizing J-PlatPat (Japan Platform for Patent Information) that is an internet patent information service provided by the National Center for Industrial Property Information and Training, which is an affiliated organization of the JPO.

Finally we obtained patent family publication list, i.e. the list of publications that were made by foreign governments for corresponding foreign patents or patent applications by retrieving corresponding patent families in the 'Derwent World Patents Index' (DWPI) database of 'Thomson Innovation' patent retrieval system provided by Thomson Reuters, using all the corresponding numbers such as application number, publication numbers and patent number.

3.2. Composition of the drug patents in Japan

According to the information of the category of patent claim of 'San-ei Report' that substantially protect the drug product, we introduced the following dummy variables:

S_dummy: set to one if the patent includes chemical substance claim that protect the medical drug product and set to zero otherwise.

s_dummy: set to one if the patent includes crystal claim that protect the medical drug product and set to zero otherwise.

U_dummy: set to one if the patent includes medical use claim that protect the medical drug product and set to zero otherwise.

PC_dummy: set to one if the patent includes pharmaceutical formulation claim or combination of drugs claim that protect the medical drug product and set to zero otherwise.

M_dummy: set to one if the patent includes manufacturing process claim that protect the medical drug product and set to zero otherwise.

A patent may contain more than two claims that protect the medical drug products and in this case more than one categories are assigned to one patent. If the patent contains not only the chemical substance claim, but also crystal claim and manufacturing process claim, the effect of crystal claim and manufacturing process claim is substantially negligible because the medical drug product is protected by chemical substance claim and the existence of crystal claim and manufacturing process claim does not matter in most settings. In Japan the invention of medical use of chemical product is protected as a product claim, which is believed to be relatively important than manufacturing process claim or even than pharmaceutical formulation claim or combination of the drugs claim, considering the possibility of circumventing the patents. Based on the hierarchy of 'S,' 's,' 'U,' 'PC,' 'M' (more left sided, the stronger), we introduce the first set of categories of patents that one patent belong to only one category (we refer as 'first mutually exclusive category.':

essentially_s_dummy: set to 1 if s_dummy = 1 & S_dummy = 0, and set to zero otherwise.

essentially_U_dummy1: set to 1 if U_dummy = 1 & S_dummy = s_dummy =0, and set to zero otherwise.

essentially_PC_dummy1: set to 1 if PC_dummy = 1 & S_dummy = s_dummy = U_dummy = 0, and set to zero otherwise.

essentially_M_dummy1: set to one if M_dummy = 1 & S_dummy = s_dummy = U_dummy = PC_dummy = 0, and set to zero otherwise.

In counties such as China[iv], India[v] and the old European Patent system, inventions of the new medical use of known product is not protected as product claims but for what is called 'Swiss-type claims,'[vi] which is in the form of 'Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z.' Swiss type claim can be said a kind of claim directed to the combination of manufacturing process and medical use and it can be placed the last level of the hierarchy. Based on the second hierarchy of 'S,' 's,' 'PC,' 'M,' 'U' (more left sided, the

stronger), we introduced the second set of the categories of patents that one patent belong to only one category (we refer as 'second mutually exclusive category.'):

essentially_PC_dummy2: set to 1 if PC_dummy = 1 & S_dummy = s_dummy = 0, and set to zero otherwise.

essentially_M_dummy2: set to one if M_dummy = 1 & S_dummy = s_dummy = PC_dummy = 0, and set to zero otherwise.

essentially_U_dummy2: set to 1 if U_dummy = 1 & S_dummy = s_dummy = M_dummy = 0, and set to zero otherwise.

Table 2. shows the composition of the drug patents in Japan by all firms including non-Japanese firms, of which the priority year is in or after 1976 when the revised Japanese Patent Law became effective and chemical substance inventions and pharmaceutical product inventions became patentable[vii]. The share of chemical substance patents, that is, category 'S' is 34 percent and that of broadly-defined chemical substance patents, that is, category 'S' or 's' is 40 percent. Pharmaceutical product patent, which is category 'S', 's,' 'U,' 'P', or 'C' is 83 percent. The impact of introducing product patents is quite large, because manufacturing process inventions accounts for only a minor part of the pharmaceutical inventions.

(Table 2 around here.)

4. Global patent filing and their grant rates of drug inventions launched in Japan

4.1 Patent filing propensity to major Asia countries and to the US and Europe

Fig. 1. shows the recent propensity for filing patents to major Asia countries and to the US and Europe by the type of a patent based on the first mutually exclusive category, which is given by the number of pre-grant publications divided by the number of the base drug patents in Japan by Japanese and non-Japanese firms. We wanted to collect information of all major Asian countries as indicated in Table 1, including Indonesia, Thailand, Vietnam, Hong Kong, Malaysia, and Singapore. Unfortunately, DWPI data base lacks data for these countries.[viii] The data for Fig. 1 is limited to patent publications

of which priority year is between 2002 and 2006 to avoid truncations that come from the restriction of DWPI database or the institutional restriction such as lacking 18-month publication system[ix].

The figure shows that more than 80 percent of the most important recent inventions of chemical substance is globally filed to economically large countries, including India, Brazil, Mexico. Inventions for crystal are also widely filed to these countries. It is also noted that the inventions of manufacturing process also have high level of propensity for global filing. Propensity for global filing is relatively small in the inventions of medical use or the inventions of pharmaceutical formulation or the combination of drugs, but it is notable that the propensity of these inventions for filing United Sates and European Patent is high(more than 80 percent).

(Fig. 1 around here.)

4.2 Patenting rates & Grant rates

Fig. 2 shows the grant rate by country by category of inventions for 5 major Asian countries, together with those for the US and EP. The grant rate is calculated by the number of examined patent publications divided by the number of patent filings of which priority year is between 2001 and 2004 to avoid truncations caused by the delay of examination as well as limitations of the coverage of our database. The value for Taiwan is calculated for patent application of which filing year is between 2002 and 2004. The number of samples for calculating grant rate is shown in Table 3 for Fig 2. The figure shows the grant rate for chemical substance is quite high: 90 percent or more for all countries in this figure. However, grant rate for inventions of crystal inventions and medical use in India is low, 50 percent in both, compared to those of other nations which is more than 90 percent and more than 70 percent respectively. On the other hand,

the grant rates for inventions of medical use and pharmaceutical formulation and combination of drugs differ among countries. These facts mean the standard for granting patens still significantly differ among countries for these types of drug inventions. The system for globally filing patent has been established as an outcome of TRIPS Agreement, however, there seems to be much future room for international harmonization or convergence of patent granting standard for these inventions.

(Fig. 2 and Table 3 around here.)

The Fig. 3 shows patenting rate in each country, that is given by the number granted patents in each country divided by those in Japan. This ratio can be interpreted as the product of filing propensity to the country and the grant rate of the country. We have two figures for two groups: i) the patents with priority between 1995 and 1999; and ii) the patents with priority between 2000 and 2004. Patenting rates in China for chemical substance inventions and the crystal inventions in both periods are lower than but close to those of United States and European Patent. Therefore the propensity and the grant rate in China already became close to those in United States and Europe after the legal change in China in 1993. A significantly lower but similar pattern is observed in Taiwan. As to the India, the patenting rate for chemical substance inventions between 2000 and 2004 doubled compared to those between 1995 and 1999.

(Fig. 3 around here.)

A significant amount of patent data that covers both before and after the significant legal change is available only in China in the DWPI patent database. We therefore investigate the impact of legal change in China using our novel patent database in the next section. In addition, we investigate how the filing propensity has evolved in India, as a consequence of pharmaceutical firms utilizing the ‘mailbox filing system’.

5. Impacts of policy reform

5.1 Domestic reform in 1993 and the patent propensity to China

Fig. 4 shows the ratio of the number of Chinese patent families against those of corresponding European Patent families of the drug patents in Japan, which means the propensity for filing to China normalized by propensity for filing European Patent during the period from 1985 to 2004. In China, chemical substance, including drug inventions, became patentable if the filing date is on and after January 1, 1993. The figure clearly show that the propensity to filing to China drastically rose right after the Patent Law change. China became a WTO member on December 11, 2001. It seems there is no significant change after the entrance of WTO membership. We implement regression analysis in order to investigate the effect of these events on the propensity for patent filing to China[x]. The explained variable is a dummy variable '*CN_fam_dummy*,' which is set to one if the patent has a Chinese corresponding patent application, and set to zero if it has no Chinese corresponding application. In order to control for trend or the influence of macro-economic factors extensively, we introduce quasi fiscal_year dummies, which begins July and ends June in the next year, of which the base period is between July 1992 and June 1993. In order to identify the policy impact, we introduce a dummy variable '*CN_reform9301_6m*,' which is set to one if the filing date is between January 1993 and June 1993 and set to zero otherwise, and dummy variable '*CN_TRIPS0201_6m*,' which is set to one if the filing date is between January 2000 and June 2000 and set to zero otherwise. Thus, we essentially assess the policy impact within the 6 months period immediately following the policy changes. The estimation period is between July 1984 and June 2006. The lower limit is set because of the

availability of database. Upper period is set to avoid the truncation. In order to accommodate three types of categorizing inventions, we implement 3 regressions: the first one uses category dummies; the second one uses the first mutually exclusive category dummies; and the last one uses second mutually exclusive category dummies.

Namely, the estimation models are defined by the following formula:

(model 1)

$$CN\_fam\_dummy = \beta_0\, CN\_reform9301\_6m + \beta_1\, CN\_TRIPS0201\_6m$$
$$+ \beta_2\, S\_dummy + \beta_3\, s\_dummy + \beta_4\, U\_dummy + \beta_5\, PC\_dummy$$
$$+ \beta_i\, fiscal\_year\_dummy + \varepsilon \qquad (1)$$

(model 2)

$$CN\_fam\_dummy = \beta_0\, CN\_reform9301\_6m + \beta_1\, CN\_TRIPS0201\_6m$$
$$+ \beta_2\, S\_dummy + \beta_3\, essentially\_s\_dummy$$
$$+ \beta_4\, essentially\_U\_dummy1 + \beta_5\, essentially\_PC\_dummy1$$
$$+ \beta_i\, fiscal\_year\_dummy + \varepsilon \qquad (2)$$

(model 3)

$$CN\_fam\_dummy = \beta_0\, CN\_reform9301\_6m + \beta_1\, CN\_TRIPS0201\_6m$$
$$+ \beta_2\, S\_dummy + \beta_3\, essentially\_s\_dummy$$
$$+ \beta_4\, essentially\_U\_dummy2 + \beta_5\, essentially\_PC\_dummy2$$

$$+\beta_i \, fiscal\_year\_dummy \, + \, \varepsilon \qquad (3)$$

The summary results of regression analysis are shown in Table 4. As to the coefficients for *fiscal_year_dummies*, only those for 1991 fiscal year and 1993 fiscal year are shown. In all estimations, the values of the coefficients for *CN_reform9301_6m are* quite large, similar and positive value around 0.25 to 0.26, which are statistically significant at least 5 percent level in two tailed test across estimations, while the values of the coefficients for *CN_TRIPS0201_6m* are small around -0.5 and statistically insignificant. Thus, the Patent Law revision in 1993 had a significantly positive impact on patent filing propensity to China and brought an immediate increase amounting to 25 percentage points, while the effect of becoming a WTO member in late 2001 is not associated with a further increase. This estimate of the effect of the domestic reform is conservative, given the very short period used for assessing the impact. In fact, the values for dummy variable *1993.CN_F_*year are around 0.39 in all estimations (1992 fiscal year is the base year). It is highly probable that a large source of this value comes significantly from the Patent Law change and not from other factors like economic growth.

As to the effect of category of inventions, the fixed effects of chemical substance inventions or crystal inventions are positive around 0.2 and highly statistically significant 1 percent level, while for those of medical use invention, pharmaceutical formulation and combination of drugs are statistically insignificant, where the base is manufacturing process invention. The inventions of chemical substance inventions or crystal inventions are important for the applicants and their propensity for filing patents to China for these inventions are 20 percent points larger, relative to the manufacturing process inventions, while the propensity of patent filing for inventions of medical use invention, pharmaceutical formulation and combination of

drugs are at the same level as the manufacturing process inventions. These estimation results are consistent with what we observed in Fig. 1.

(Fig. 4 and Table 4 around here.)

5.2 Mailbox application system in India

Fig. 5 shows the ratio of the number of Indian patent families against those of corresponding European Patent families of the drug patents in Japan, which means the propensity for filing to India normalized by propensity for filing European Patent during the period from 1994 to 2005. Since the adoption of pharmaceutical product patent system in India took place only in 2005, the most inventions of chemical substance, crystals, pharmaceutical formulation and combination of drugs are considered to have been filed by what is called 'Mailbox application system.' The ratios are almost monotonically increasing from 1994 to 2005 which is the deadline of complying with the TRIPS Agreement for India. The number for chemical substance patent reached almost 80 percent around 2000. This means that, due to the use of the mailbox application system, the filing propensity reached 80 percent around year 2000 that is well before the year of TRIPS implementation for drug patents. Therefore the mailbox application system, which is a product of a compromise in the tough negotiation between India and United States, has a substantial effect on accelerating the introduction of drug protections in India.

(Fig. 5 around here.)

6. Conclusion

We investigated the global spread of pharmaceutical patent protections as acquired by pharmaceutical companies, based on our newly developed patent database that constitutes the patents that protect or once protected all significant drugs that were actually introduced to the Japanese market. This database gives us the information of propensity for filing to and grant rate of each country with respect to the granted drug patents in Japan by Japanese as well as by non-Japanese firms.

We found that the global spread was indeed very significant. Both the filing propensity to and the grant rate of major Asian countries approached those of the OECD economies by the early 2000s for chemical substance inventions, although those for inventions of medical use or inventions of pharmaceutical formulation or combination of drugs are smaller compared to those for United States and Europe. As to the grant rate, the grant rate for chemical substance is quite high around 90 percent or more for all major Asian countries (China, Taiwan, South Korea, Philippine, and India). However, the grant rate for the inventions of crystal inventions and medical use in India is low, 50 percent in both, compared to those of the other nations which is more than 90 percent and more than 70 percent respectively. The grant rates for the inventions of medical use and pharmaceutical formulation and the combination of drugs differ among countries. Thus, our second finding is that there still exists substantial heterogeneity in patent grant standard with respect to such drug patents as crystal, medical use, pharmaceutical formulation or combination of drugs, suggesting a significant future room for international harmonization or convergence of patent granting standard.

We also found clear evidence for the causal connections between the policy change and the spread of protections for two largest non-OECD economies: China and India. The Patent Law revision in China in 1993 had an immediate and significant

positive impact on patent filing propensity to China (brought 25 percentage points increase) well before it becoming a WTO member in late 2001. The mailbox application system, which is the product of compromise in the tough negotiation between India and United States, had a substantial effect for accelerating the introduction of drug protection in India: the filing propensity reached 80 percent of the number of corresponding EP patent applications around year 2000, well before the year of TRIPS implementation for drug patents.

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Table 1. Summary table of event dates for major Asian countries

	Developed Country			Countries that introduced chemical substance patent system (CSPS) before TRIPS Agreement					Countries where chemical substance was protected based on UK patent			Countries that introduced CSPS to comply TRIPS Agreement		Later WTO member
	JP	US	EP	KR	TW	CN	ID	PH	HK	MY	SG	TH	IN	VN
WTO member	1995 Jan	1995 Jan	1995 Jan	1995 Jan	2002 Jan	2001 Dec	1995 Jan	1995 Jan	1995 Jan	1995 Jan	1995 Jan	1995 Jan	1995 Jan	2007 Jan
Deadline of Pharmaceutical Chemical Product patent	1996 Jan	1996 Jan	1996 Jan	1996 Jan	2002 Jan	2001 Dec	2000 Jan	2000 Jan	2000 Jan	2000 Jan	2000 Jan	2000 Jan	2005 Jan	2007 Jan
Introduction of chemical substance patent	1976 Jan	1790	1977 Oct	1987 Jul	1986 retro-active	1993 Jan	1991 Aug	1947 Jun	1978 Jun	1978 Jun	1978 Jun	1992 Sep	2005 Jan	2006 Jul

JP: Japan, US: United States of America, EP: European Patent, KR: Korea, TW: Taiwan, CN: China, ID: Indonesia, HK: Hong Kong, MY: Malaysia, SG: Singapore, TH: Thailand, PH: Philippine, IN: India, VN: Vietnam

* One can substantially use PCT route via UK patents.

Table 2. Composition of drug patents in Japan

Table 2A. Compositions of category symbol in 'San-ei Report'

Category symbol	count	share
S	520	34.4 percent
s	99	6.5 percent
U	524	34.6 percent
P or C	583	38.5 percent
M	584	38.6 percent
Total	1513	100.0 percent

Note: More than two category symbols may be assigned to one patent.

Patents are restricted for those of which priority year is in or after 1976.

Table 2B. Compositions by the first mutually exclusive category

Category of patent	count	share
S	520	34.4 percent
essentially_s	90	5.9 percent
essentially_U1	213	14.1 percent
essentially_PC1	440	29.1 percent
essentially_M1	250	16.5 percent
Total	1513	100.0 percent

Table 2B. Compositions by the second mutually exclusive category

Category of patent	count	share
S	520	34.4 percent
essentially_s	90	5.9 percent
essentially_PC2	521	34.4 percent
essentially_M2	253	16.7 percent
essentially_U2	129	8.5 percent
Total	1513	100.0 percent

Table 3. The number of samples for calculating grant rate in Fig. 2.

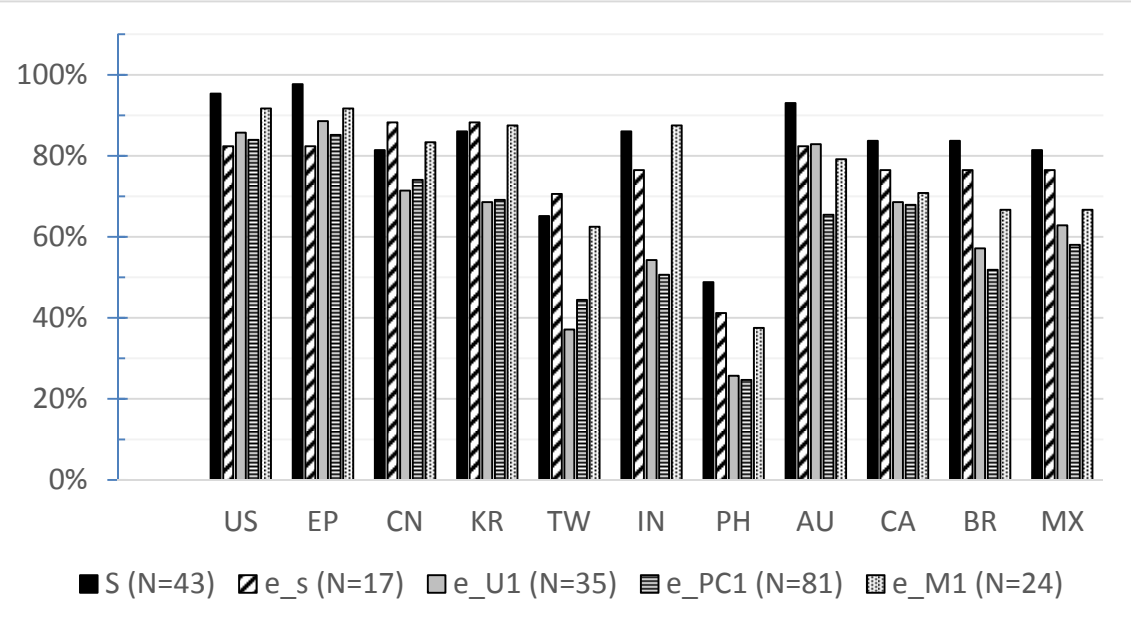
	chemical substance	essentially crystal	essentially medical use	essentially formulation or combination	essentially manufacturing process
US	37	15	30	63	18
EP	38	14	30	64	18
CN	29	16	21	56	13
KR	32	16	20	54	12
IN	31	14	14	34	13
PH	14	7	9	18	7
TW	15	7	7	23	10

Table 4. Summary results of regressions of propensity of patent filing to China

	Explained variable: CN_fam_dummy		
	(1)	(2)	(3)
Explanatory variables			
CN_reform9301_6m	.252**	.260**	.257**
	(.126)	(.126)	(.126)
CN_TRIPS0201_6m	-.0502	-.0511	-.0497
	(.126)	(.126)	(.126)
S_dummy	.209***	.228***	.223***
	(.0335)	(.0405)	(.0403)
s_dummy	.163***		
	(.0503)		
essentially_s_dummy		.195***	.191***
		(.0589)	(.0588)
U_dummy	.00290		
	(.0293)		
essentially_U_dummy1		.0372	
		(.0464)	
essentially_U_dummy2			.0177
			(.0547)
PC_dummy	.0364		
	(.0301)		
essentially_PC_dummy1		.0426	
		(.0399)	
essentially_PC_dummy2			.0385
			(.0387)
1991.CN_F_year	.0714	.0748	.0738
	(.0971)	(.0971)	(.0971)
1993.CN_F_year	.385***	.386***	.386***
	(.0967)	(.0967)	(.0967)
Observations	1,149	1,149	1,149
R-squared	.254	.255	.255
adjusted R-Squared	0.237	0.237	0.237
Log Likelihood	-661.6	-661.3	-661.4

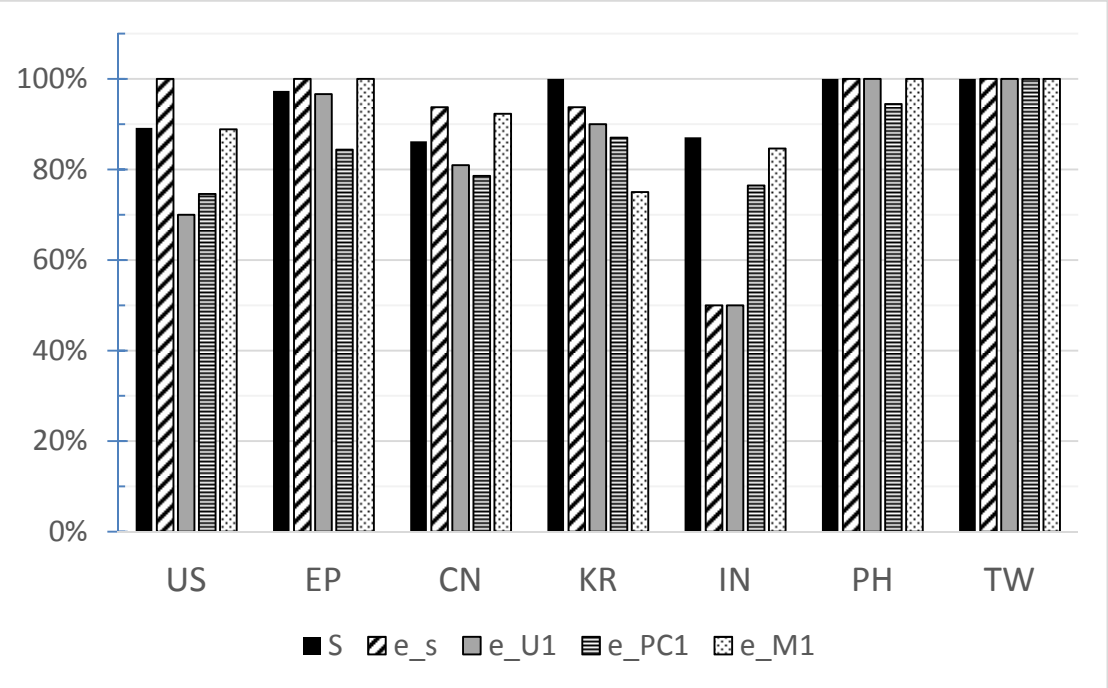
Standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.10

Fig. 1. Propensity to filing patents to foreign countries



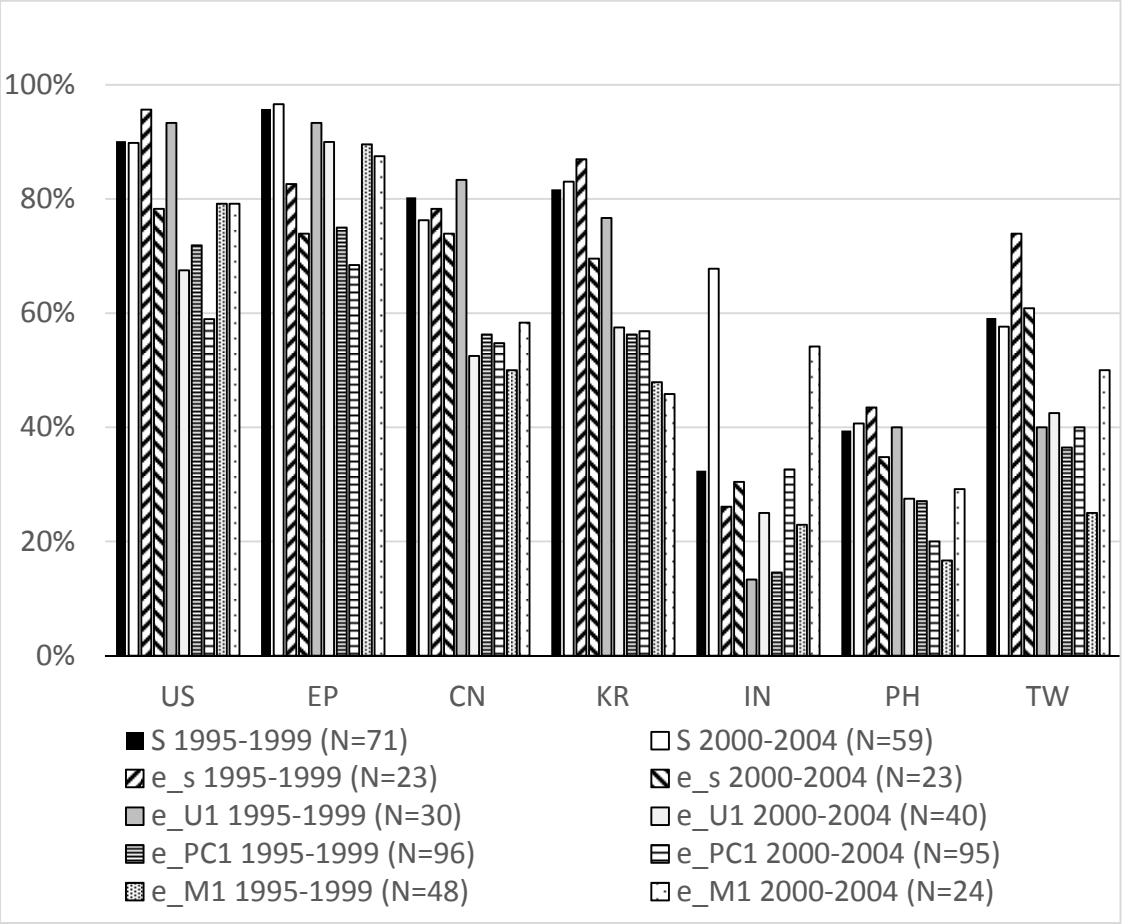
Note: Data is limited to patent publications of which priority year is between 2002 and 2006.US: United States; EP: European Patent; CN: China; KR: Korea; TW: Taiwan; IN: India; PH: Philippines; AU: Australia; CA: Canada; BR: Brazil, MX: Mexico. The indicators of invention kind is based on first mutually exclusive category. Symbols and their meanings are as follows: ‘S,’ chemical substance; ‘e_s,’ essentially crystal; ‘e_U1,’ essentially medical use; ‘e_ PC1,” “essentially formulation or combination”; and ‘e_M1,’ essentially manufacturing process.

Fig. 2. Grant rate in each country by category of patents



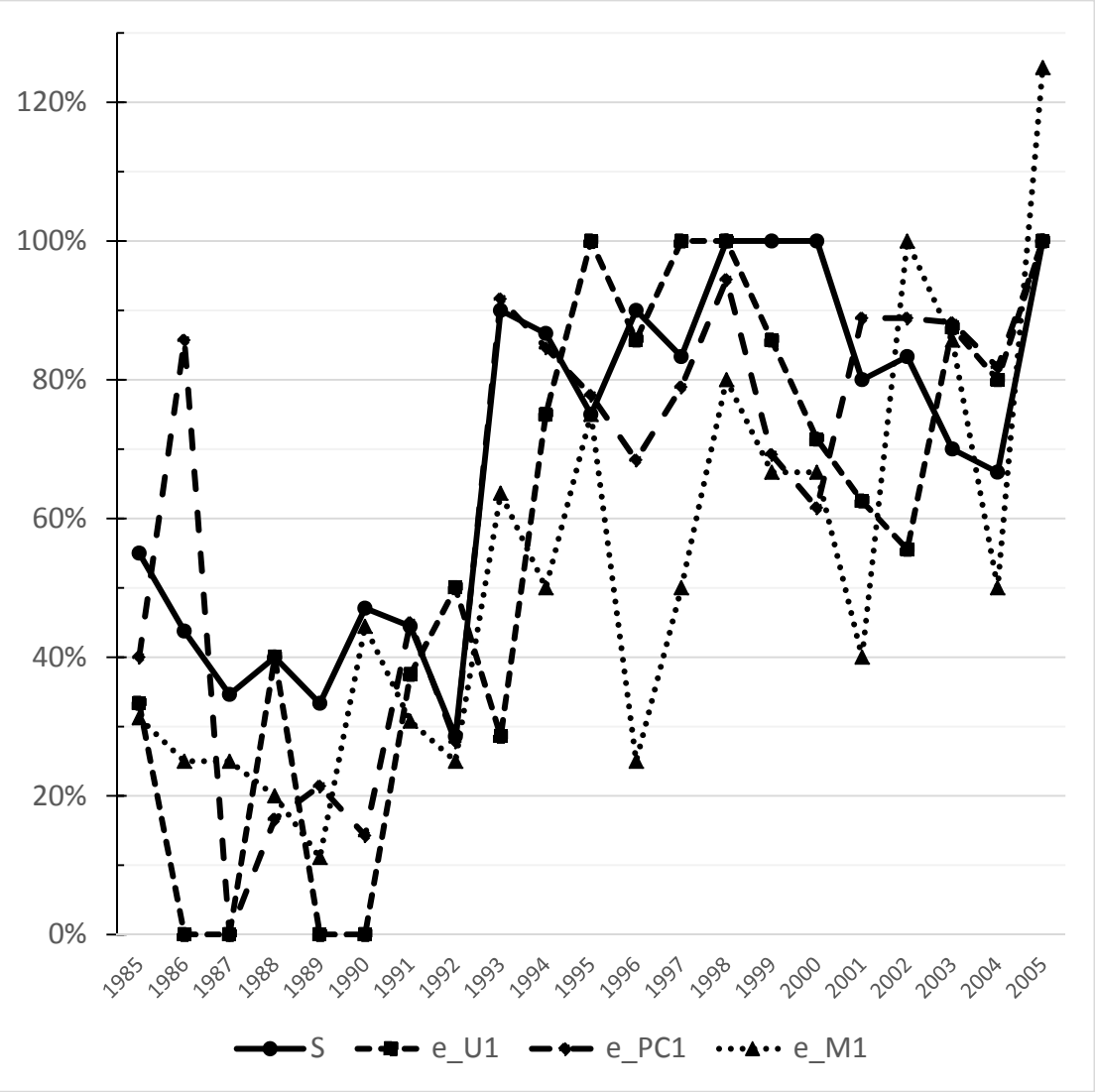
Note: The grant rate is calculated by the number of examined patent publication divided by number of unexamined patent publication of which priority year is between 2001 and 2004 to avoid truncations and restrictions caused by institution and database. The value for Taiwan is calculated for patent application of which filing year is between 2002 and 2004. Symbols and their meanings are as follows: ‘S,’ chemical substance; ‘e_s,’ essentially crystal; ‘e_U1,’ essentially medical use; ‘e_ PC1,” “essentially formulation or combination”; and ‘e_M1,’ essentially manufacturing process.

Fig. 3. Patenting rate for each country



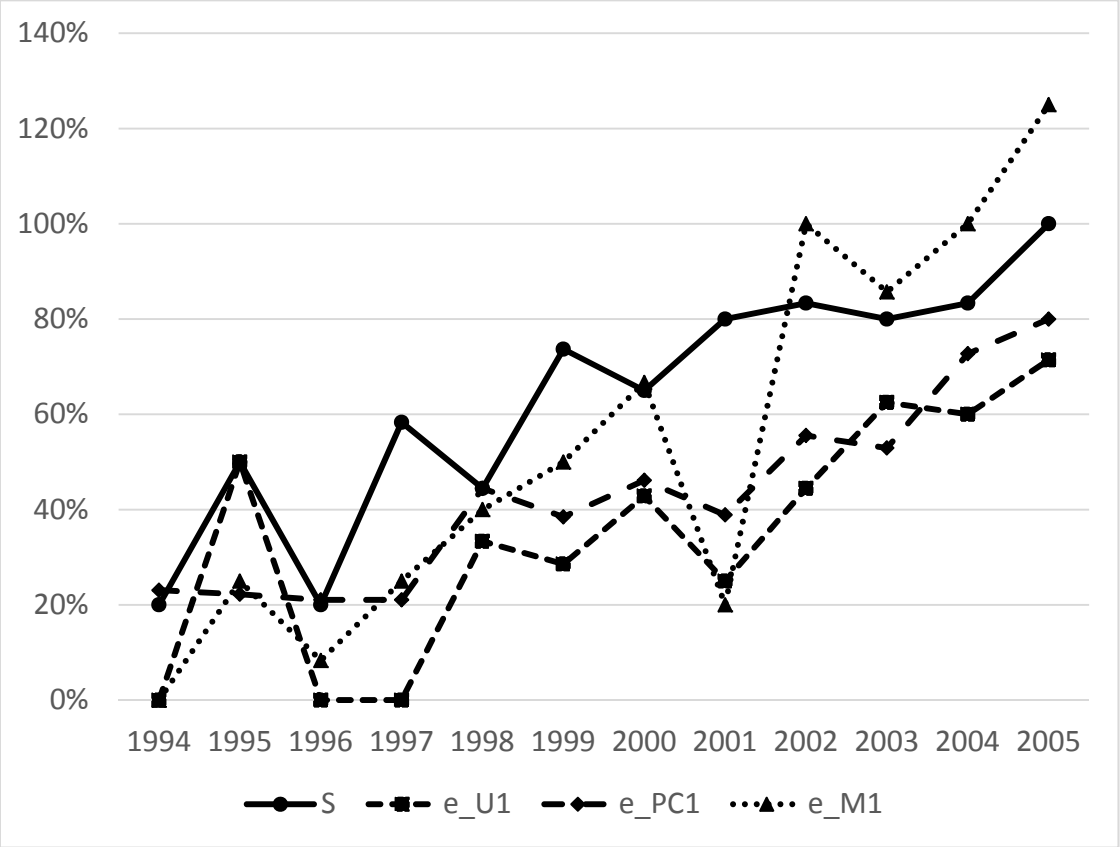
Note: Patenting rate for each country is calculated by the number of granted patents in each country divided by those in Japan. Symbols and their meanings are as follows: ‘S,’ chemical substance; ‘e_s,’ essentially crystal; ‘e_U1,’ essentially medical use; ‘e_ PC1,” “essentially formulation or combination”; and ‘e_M1,’ essentially manufacturing process.

Fig. 4. Propensity for filing to China normalized by propensity for filing to EP



Note: Symbols and their meanings are as follows: 'S,' chemical substance; 'e_U1,' essentially medical use; 'e_ PC1," "essentially formulation or combination"; and 'e_M1,' essentially manufacturing process.

Fig. 5 Propensity for filing to India normalized by propensity for filing to EP



Note: Symbols and their meanings are as follows: 'S,' chemical substance; 'e_U1,' essentially medical use; 'e_ PC1," "essentially formulation or combination"; and 'e_M1,' essentially manufacturing process.

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[i] In the TRIPS Council of November 29, 2005, it was resolved to extend the implementation date of the agreement of the least developed countries until July 1, 2013.

[ii] In the TRIPS Council informal meeting of July 2002, it was resolved to extend the exemption of pharmaceutical patents introduction of the least developed countries until January 1, 2016.

[iii] We use the term chemical substance patent to cover not only the invention on a new chemical drug but also an invention on the new biological drug such as anti-body drug.

[iv] See Shiwen and Lihua (2014) for the patentability of Swiss-type claims in China.

[v] See Mirandah (2005) for the patentability of Swiss-type claims in India.

[vi] See EPO Guidelines for Examination, Part G - Patentability, Chapter VI - Novelty, 7. Examination of novelty, 7.1 Second or further medical use of known pharmaceutical products. Contrastingly, in the United States, inventions of the new medical use of known product is protected as process claims of therapy or treatment and not protected by product claims or Swiss-type claims.

[vii] Share of the country of the first applicant's residence is as follows: Japan, 44.6 percent; Europe, 29.9 percent; United States, 24.0 percent; and Others, 1.5 percent.

[viii] According to a manual of the DWPI database, the first publication date of both pre-grant 18-month patent application publications and patent publications included in the DWPI database for such countries as Indonesia, Thailand and Vietnam is January, 2010. As to Hong Kong, the DWPI includes granted patent and application published as of January 2011 and non-PCT route application published as of August 1995. As to Malaysia, the DWPI includes only granted patent published as of January 2006. As to Singapore, the DWPI includes granted patent and PCT route application published as of January 2006 and non-PCT route application published as of August 1995.

[ix] Taiwan introduced pre-grant 18-month publication on and after October 26, 2002. Most applications claiming priority year of 2002 is filed to Taiwan in 2003. United States introduced pre-grant 18-month publication on and after November, 29, 2000.

[x] We have got essentially the same results for the patent rates, given that grant rates are high for these drug patents in China.