7 An Empirical Study of Pharmaceutical Patent Harmonization (*)

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How harmonized is patent protection today? Despite the long history of the harmonization process and the central role of pharmaceutical patent protection within the debate, we currently face a paucity of empirical studies measuring the degree of convergence or divergence among the actual patents issued by major patent offices and nothing on the subject of pharmaceutical patents. This empirical study begins filling this gap by comparing the patents issued by the United States Patent and Trademark Office (USPTO), the Japanese Patent Office (JPO), and the State Intellectual Property Office of China (SIPO) to the same pharmaceutical invention. Thus this is the first study that examines the de facto level of harmonization among the three countries that boast the three largest pharmaceutical markets as well as the three largest patent offices. Surprisingly, considerable differences exist between the USPTO and JPO despite ongoing harmonization efforts. In contrast, the JPO grants slightly more patents and claim than SIPO but the results are generally comparable in the absence of extensive harmonization effort. This suggests that the current harmonization effort may have overestimated the extent of difference in some instances while overlooking conditions that contribute to significant divergence in other instances.

Ⅰ Introduction

Technology knows no borders, but patent protection does. The latest iPhone is available in 115 countries, the asthma medicine Symbicort in 70. But the patents protecting them remain territorial, issued by national patent offices thousands of miles apart pursuant to the patent laws of each state. This patchwork of legal protections has been criticized for being archaic and inconsistent with modern business practices.

How harmonized is patent protection today? Despite the long history of the harmonization process and the central role of pharmaceutical patent protection within the debate, we currently face a paucity of empirical studies measuring the degree of convergence or divergence among the actual pharmaceutical patents issued by major patent offices and nothing on the subject of pharmaceutical patents. This empirical study begins filling this gap by comparing the patents issued by the United States Patent and Trademark Office (USPTO), the Japanese Patent Office (JPO), and the State Intellectual Property Office of China (SIPO) to the same pharmaceutical invention. Thus this is the first study that examines the *de facto* level of harmonization among the three countries that boast the three largest pharmaceutical markets as well as the three largest patent offices.

Ⅱ The Harmonization of Patent Examination

Although further harmonization is stalled in WTO and WIPO, countries may still harmonize substantive patent law outside the context of international treaties. This section summarizes the current harmonization at the national and administrative level as well as highlighting significant harmonization developments within the pharmaceutical area.

1 National Patent Law Amendments

The US, Japan and China have all amended their national patent law in recent years. On March 16, 2013, the United States moved away from its first-to-invent system of determining patent priority when the American Invents Act (AIA) came into effect, resolving one of the sticking points that doomed the Patent Law Treaty 20 years earlier. China and Japan have both amended their respective patent laws to bring their law closer to each other.

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2 Patent Office Collaborations

While changes to national law are highly visible, the less noticed administration harmonization at the patent office level is more far-reaching. The harmonization of administrative procedures ostensibly promotes the time-honored virtue of consistency, and patent administrators are motivated to pursue harmonization to cut expense, reduce backlog and improve applicant service. Administrative harmonization is less visible to critics and sidesteps legislative politics. It is also easier to initiate, so long as two likeminded patent offices decide to converge their practices. For these reasons, coalitions of the top patent offices now spearhead sundry initiatives to bring their operations closer together.

For example, two patent offices can coordinate the examination of related applications. Under the Patent Prosecution Highway (PPH) program, an applicant with applications pending in two or more offices may use the patent grant in one country to expedite the examination process in another.

Multiple patent offices may also establish regular collaborations. The oldest of these arrangements is the Trilateral Co-operation project between the USPTO, JPO and EPO in 1983. Similarly, patent administrators of China, Japan and South Korea began the Trilateral Policy Dialogue Meeting in 2000. This Asia-based trilateral arrangement also conducts comparative studies of different practices between these three patent offices. By 2007, the top five patent offices came together in the IP5 working group. The IP5 office currently operates three Working Groups to standardize technology classification, develop a global dossier portal for users, and to enhance work-sharing through the Patent Corporation Treaty and the Patent Prosecution Highway. Other broad initiatives include the B+ working group and the Tegernsee Expert group in response to the stalled WIPO substantive patent law treaty negotiation. These concerted efforts create a positive feedback loop, whereby the more patent offices standardize their processes and standards, the easier it is to standardize further.

Lastly, the harmonization of patent protection can take place through the integration of unwritten customs and interpretive communities. To this end, the Trilateral and IP5 projects include eLearning and examiner exchange programs. JPO examiners and administrators often attend U.S. law schools as visiting scholars. Similarly, many examiners from the State Intellectual Property Office of China have attended U.S. law schools for patent law training. These training and exchange programs have the effect of reducing the differences between states.

3 Pharmaceutical Patent Harmonization

Pharmaceutical inventions provide a particularly rich context for examining global patent harmonization. On the one hand, drug companies are keen on promoting standards of heightened patent and quasi-patent protections to safeguard the worldwide market their products command. Professor Susan Sall expanded this theme in the seminal book “Private Power, Public Law: The Globalization of Intellectual Property Rights.” On the other hand, the adoption of the 2001 Doha Declaration on the TRIPS Agreement and Public Health marked a watershed event highlighting the flexibilities in the patent system that pushes back harmonization. Throughout all these maneuvers, pharmaceutical patents protection remains the lightning rod subject of harmonization.

Ⅲ Data Selection and Gathering

1 Technology Selection

This study focuses on patented technologies enumerated in the list of Approved Drug Products with Therapeutic Equivalence Evaluations, a.k.a. the “Orange Book”, for pharmaceuticals approved by the U.S. Food and Drug Administration (FDA) in 2010. More specifically, the list includes only pharmaceuticals based on a new molecular entity, and therefore excludes generic drugs, over-the-counter products, diagnostics, medical devices, new dosages or administration form of previously approved compounds.[1] For this study, a single invention is defined as a single disclosure, and all claims based on the identical disclosure are considered the same invention regardless of whether they belong to a single or multiple patents.

2 Country Selection

The patents issued by three patent offices are chosen for analysis: the United States Patent and Trademark Office (USPTO), the Japanese Patent Office (JPO), and the State Intellectual Property Office of China (SIPO).

3 Patent Selection

A Derwent World Patent Index search is conducted for each Orange Book patent using

Westlaw. This search generates the prior art history, family, and title of the patent searched. The "Patent Family" heading generates the patent family for the US patent searched. To ensure the correct family was selected, the US Patent that was originally entered into the search should be one of the US patents listed within the family. After selecting the family, all the US, Chinese and Japanese patent publications listed in this family were recorded. A subsequent search is conducted at the patent database at each of the three patent offices. The actual patent documents are downloaded during this step. Only patents granted as of January 1, 2014 are included in the analysis.

4 Claim Analysis

The claims of the patents within the corresponding disclosure families are extracted for quantitative and qualitative analysis. A human coder manually reviewed the independent claims of all the patents belonging to the same invention (same disclosure) and identify corresponding independent claims between national applications. It should be noted that corresponding independent claims need not be identical—they may contain meaningful but limited differences that are not so encompassing as to elude comparison. It is expected that some independent claims will be unique to a jurisdiction (where one claim embodies a fundamental change from the claims of another jurisdiction), while others are shared among a subset of the three jurisdictions. The degree of overlap provides a rough overview of the equivalence between corresponding national patents.

5 Patent Scope Coding

To assess the degree of difference between the scope of patents in the U.S. and elsewhere, the claims of the U.S. patent are compared to the corresponding claims of the Japanese and Chinese patents. For each pair of the US-others comparison, the exact differences are recorded as a "difference event."

Ⅳ Results and Analysis

1 Patent Counts

Overall, most countries offer some patent protection to these products but the protection offered in the United States outstrips the protection offered in Japan or China. While China offers the least extensive protection of the three, the differences between China and Japan are muted. Of the drugs approved by the US Food and Drug Administration in 2010, 33 new drugs contained patents listed in the Orange Book. Some of these patents are divisional or continuation applications of each other and share the same specification. These patents fall into 83 sets of distinct specifications. These 83 disclosures issued into 177 US patents. The number of patents issued from a specification is greater than the number of patents listed in the Orange Book. This is because that a specification can generate multiple patents and only some of those patents are listed in the Orange Book. On average two patents are issued for every invention disclosure.

In the case of Japan, JPO granted 47 patents based on 41 distinct disclosures. This is about half of the distinct disclosures and a quarter of the patents issued in the United States. However, these patents still cover about two-third of the drug targets, or 24 out of 33 drugs. In the case of China, SIPO granted 38 patents based on 31 disclosures and provided coverage for 20 drugs. That China offers the fewest number of patent rights may not be surprising. China offered patent protection to 1 drug that was not protected in Japan, while Japan offered patent protection to 5 drugs that were not protected in China. Overall, 25 drugs are protected in either Japan or China, which corresponds to a distinct 47 disclosures. In the United States, these 47 matched disclosures resulted in 131 US patents. Table 1 summarizes these results.

Table 1

	Drugs	Disclosure	Patents
US (Total)	33	83	177
US (Matched Disclosure)	27	47	131
JP (Matched Disclosure)	24	41	47
CN (Matched Disclosure)	20	31	38

While most drugs studied have at least one patent issued by each of the trilateral patent offices, the United States stands out for the number of patents it grants for a given set of pharmaceutical products and the innovative ideas embodied in these product—twice as many distinct disclosures received patent protection in the United States.

A disclosure that leads to patents outside of the U.S. generates more patents within the United States. The protection of disclosure in the United States is deeper as it is broader. For the 47 disclosures that were patented in both the United States and either Japan or China, they receive on average three US patents each and one patent in Japan or China. In contrast, the 36 disclosures that did not result in a Japanese or Chinese patent generated only 46 US patents altogether. Silenor again illustrates this trend: Five disclosures led to a single US patent each and no Japanese or Chinese patents. A sixth disclosure generated seven US patents but only one Japanese patent. The patent protection of pharmaceutical knowledge in the United States is thick as it is broad.

2 Claim Counts

The 177 US patents correspond to 3623 claims, of which 522 are independent claims. However, only 47 of the 83 disclosure families have a counterpart patent in Japan or China and these matched invention disclosures offer a better comparison. These 47 matching disclosures correspond to 131 US patents and accounts for 2726 claims and 402 independents clams. In contrast, Japan grants 47 patents that accounts for 727 total claims and 126 independent claims—far fewer claims and independent claims for the corresponding patent disclosures. Similarly, China grants 571 total claims and 117 independent claims. Table 2 summarizes this result.

Table 2

Claim Count	Disclosure	Patents	Total C.	Ind. C.
US (Total)	83	177	3623	522
US (Matched Disclosure)	47	131	2726	402
JP (Matched Disclosure)	41	47	727	126
CN (Matched Disclosure)	31	38	571	117

With respect to the comparison between US, Japan and China, both Japan and China grant fewer claims per disclosure and per patent. However, the numbers of independent claims remain similar between the jurisdictions. The claim ratios between Japan and China are very similar, especially when viewed in light of the US ratios, while Chinese patents contain slightly more independent claims than in Japan. Table 3 summarizes these results.

Table 3

Claim Ratios	All Claim/ Disclosure	All Claim/ Patents	Ind. Claim/ Disclosure	Ind. Claim/ Patent
US (Total)	43.65	20.47	6.28	2.95
US (Matched Disclosure)	58.00	20.81	8.55	3.07
JP (Matched Disclosure)	17.73	15.47	3.07	2.68
CN (Matched Disclosure)	18.42	15.03	3.77	3.08

The 126 matched Japanese independent claims and 117 matched Chinese independent claims are translated for further comparison. Of these 402 independent claims in the US, 127 match either a Japanese or Chinese independent claim (or both). A great majority (95) of the Japanese independent claims (126) can be matched to a US independent claim. In contrast, only about half (65) of the Chinese independent claims (117) has a match in the US. 25 Japanese claims and 22 Chinese claims are practically identical to US independent claims (41). On average there are 2.32 matched independent claims per disclosure between Japan and the US, and 2.10 matched independent claims per disclosure between China and the US. Less than one independent claim per disclosure is practically identical among the jurisdictions. Table 4 summarizes the finding.

Table 4

Matched Claims	Disclosure	Ind. C.	Matched	Practically Identical	Matched/ Disclosure	Identical/ Disclosure
US (Matched Disclosure)	47	402	127	41	2.70	0.87
JP (Matched Disclosure)	41	126	95	25	2.32	0.61
CN (Matched Disclosure)	31	117	65	22	2.10	0.71

3 Claim Difference

The 95 matching Japanese independent claims and 65 matching Chinese independent claims are compared to their US counterpart to determine the exact claim level difference between US-Japan and US-China. A comparison of US and Japanese matching independent claims show a good number of changes relating to formulations and compounds, with slightly more narrowing events than broadening events. In the case of US and China, the number of narrowing events out number broadening events two to one.

Ⅴ Implication for Harmonization

The varying breadth of protection and the different coverage among the three jurisdictions reveals important clues to the level of harmonization among these patent offices. The data shows considerable differences between the scope of patents granted in the United States, Japan and China for the same pharmaceutical invention. The United States protects more distinct disclosures, more patents, and more dependent and independent claims per drug. The number in each category is multiples of the protection in Japan or China. With respect to individual claim elements, the US-Japan comparison shows the notable a number of differences with the Chinese claim elements, where claim elements are narrowed slightly more often than expanded. The narrowing tendency is much more pronounced for Chinese patents. In summary, considerable differences exist between what the United States offer versus what Japan and China offers to the same pharmaceutical inventions.

As between the two Asian patent offices, Japan grants slightly more patents and claims than its China but the difference is muted. In fact, by most of the measures used in the analysis the figures for China are close to Japan. This finding is consistent with recent research noting that China's patent system is now close to parity with developed countries. On the other hand, it calls into question the perceived alliance of Japan and the US on the issue of patent harmonization. Although Japan and the US often take similar positions in international negotiations and their patent offices have been in collaboration for the last 30 years, this study shows that considerable differences persist, which in turn highlights the difficulty of genuine harmonization even among countries that occupies similar runes of the development ladder. On the other hand, it also showcases a degree of convergence between Japanese and Chinese patent regimes that suggests a patent norm in the region different from that espoused by the United States. The remainder of this section considers the implication of these similarities and differences for the stakeholders of the pharmaceutical patent harmonization process—the trade negotiators, the pharmaceutical companies, and public health advocates.

1 Trade Negotiators

This empirical study questions the goal of harmonizing the level of patent protection upward through the harmonization project. This study shows that China is already offering the number of patents and claims near the level of Japan. To the extent differences exist, the study suggests that it is of a type not easily remedied through international treaties or free trade agreements. Instead of the all-or-nothing choices of pharmaceutical product or secondary use patent eligibility that were the subject of the debate during TRIPs negotiation, it is the subtle judgment calls to narrow a claim that separates a Chinese claim from its counterpart in US or Japan. These decisions flow from internal policies nestled deep within customary practices there are difficult to reach through international lawmaking. Moreover, it is through the exercise of these judgments that patent administrations of individual countries maintain their relevance during the era of harmonization. Therefore it is unlikely that patent offices will relinquish its discretion.

2 Pharmaceutical Companies

Companies are primarily concerned with the extent of protection for the drugs they sell.

Although this study focused on disclosures, the term "invention" can refer to innovative products and services. This is also consistent with the conventional wisdom that the patent system incentivizes the development of tangible inventions that are welfare enhancing.

The analysis here indicates considerable differences among patent protection between China, Japan and the US. We see that the majority of "invention as a drug product" received patent protection outside the US while only half of the "invention as disclosed information" received patent protection outside the US. Generic drug manufacturers in Japan and China can begin producing a third of the pharmaceutical products studied (unless there are patents granted in Japan or China that do not have a US counterpart in the Orange Book).

As for the majority of drugs where at least one patents exist in Japan or China, the overall patenting pattern there fosters greater direct competition than in the United States for two reasons. First, a drug in the US is likely covered by a portfolio of patents directed to multiple disclosures while the same drug is likely protected under a single patent family in Japan or China. This means that the US patents are likely to expire on different dates and protect the drug over a longer period of time—a phenomenon labeled "evergreening." In contrast, the practice of evergreening does not appear prevalent in China or Japan.

Lastly, substitute competition is likely greater in China and Japan. Again, it is much easier to design a competing product around a single patent than a portfolio of patents. Second, in the instances where the patent claims scope appears narrower than that in the US, competitors may design a substitute product around the patent protection. Overall, narrower patents permit the development of more me-too and me-better drugs.

3 Health Advocates

The number of pharmaceutical patents differs greatly and patent offices are granting patents of varying scopes that permit the emergence of substitute products. This means that countries with some R&D capacity and patent examination expertise may adopt the strategy of developing "me-too" solutions to meet local healthcare demand. Moreover this strategy has the added benefit of incentivizing a local pharmaceutical industry based on derivations and improvement instead of slavish copying. This strategy is a departure from the Indian paradigm of issuing compulsory license or denying patent protection all together. This flexibility within the patent system may provide new levers for balancing public health concern and innovation in a more precise, surgical manner in contrast with India's all-or-nothing approach to pharmaceutical patenting.

Ⅳ Conclusion

This study delivers the first empirical look at the level of harmonization among the top three patent offices and shows that similarities and differences between patent systems may not be what we may have expected. But more importantly the methodology here offers a path to broader and richer studies that will ultimately connect legal doctrines with actual results. We now have more tools to develop evidence- and outcome-based patent harmonization policy.

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[1] The definitions are established by the Tufts Center for the Study of Drug Development and the FDA's definitions of a new drug approval or a new molecular entity.