

# Is there a case to be made for a global patent system? The example of plant biotechnology

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## Abstract

The assessment of patterns of patentability in plant biotechnology on the basis of existing statistics shows a considerable concentration of patents to a few countries, in particular the United States, Australia, Japan, China, Mexico, Brazil, Germany, Canada, New Zealand, South Korea, India, Spain and Hungary. These patterns suggest that there is a clear relationship between the choice of patent jurisdictions and the biotechnology regulatory framework. This observation of the geographic distribution of biotechnology patents lends credence to maintaining a system of territorial rights that allow for regulatory competition, but continuing the process of substantive patent law harmonization which potentially minimize trade barriers,

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*Premier en date en nos jardins potagers, après la fève d'abord et plus tard le pois, le chou était tenu en haute estime par l'Antiquité classique ; mais il remonte bien plus haut, à tel point que tout souvenir s'est perdu concernant son acquisition. L'histoire ne s'occupe guère de ces détails ; elle célèbre les champs de bataille qui nous tuent, elle garde le silence sur les champs de culture qui nous font vivre ; elle sait les bâtards des rois, elle ne sait pas l'origine du froment. Ainsi le veut la sottise humaine.*

Jean Henri Fabre 'Souvenirs Entomologiques' (1823 -1915)

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## I. Introduction

Intellectual property protection and the patent system are based upon the principle of territoriality and independence. Despite an extensive amount of harmonization in treaty law, in particular the Paris Convention and the TRIPs Agreement, as well prominently the European Patent System, titles of protection essentially pertain to domestic law and thus may vary from country to country. In a globalizing economy, the quest for uniform and single patent titles, harmonization and cooperation in registration has been advanced for good reasons: legal security, reducing costs and efficiency.<sup>1</sup> The last century saw the entry into force, inter alia, of the Patent Cooperation Treaty (PCT), the European Patent Convention (EPC), the Euroasian Patent Convention (EAPO), the African Regional Intellectual Property Organization (ARIPO), the African Intellectual Property Organization (OAPI), and several attempts at the World Intellectual Property Organization (WIPO) sponsored Patent Law Treaty (PLT) without a concluded agreement. A recent increment in these efforts was in 2010 when the Cooperative Patent Classification project (CPC) was launched between the USPTO and the EPO. This event was preceded by the IP5 initiative between the USPTO, EPO, JPO, SIPO, and KIPO which aims at avoiding work duplication in database management, patent classification and examiner training in 2008.<sup>2</sup> In addition, under the umbrella of PCT-Patent Prosecution Highway (PCT-PPH) a number of bilateral agreements between patent offices have been signed that enable patent applicants to request a fast-track examination procedure where examiners can make use of the work products from the other offices.<sup>3</sup>

Efforts in substantive harmonization within the European Union have led the path in a regional context. They witnessed, for many years, great difficulties in bringing about a single patent with comprehensive geographical coverage of all the 27 Member States: issues of languages and translation, and issues of judicial review suitable not only for EU members, but also other contracting parties of the EPO. The current developments in the unification of European patent law also do not seem to add to the reduction of cost, simplification or streamlining of the system.<sup>4</sup> Difficulties abound. The more so, this is true on a global scale. A global patent may streamline the system of rules and procedures and eliminate parallel duplicate or redundant searches and procedures, but that too awaits proof. It may support innovation more than a decentralised system, however that is also contested.<sup>5</sup> Yet, it is unclear

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<sup>1</sup> MN Meller, 'Planning For a Global Patent System', *Journal of the Patent and Trademark Office Society* vol. 80, 1998, pp. 379-391.

<sup>2</sup> See the web brochure at : <http://www.epo.org/papers/classification-ip5/index.html> and <http://www.fiveipoffices.org/> (accessed 11.6.2012)

<sup>3</sup> See the list of such agreements maintained by the WIPO : [http://www.wipo.int/pct/en/filing/pct\\_pph.html](http://www.wipo.int/pct/en/filing/pct_pph.html) (accessed 22.6.2012); note that there are also a number of PPH agreements which do not include PCT work products. The first pilot PCT-PPH started on January 29, 2010 and involved the Trilateral Offices : EPO, JPO and USPTO.

<sup>4</sup> See Jaeger, T, *All Back to Square One? - An Assessment of the Latest Proposals for a Patent and Court for the Internal Market and Possible Alternatives*, 2012, <<http://papers.ssrn.com/abstract=1973518>>; Ullrich, H, *Harmonizing Patent Law: The Untamable Union Patent*, 2012, <<http://papers.ssrn.com/abstract=2027920>>.

<sup>5</sup> For arguments that distinguish unjustifiable and unjustified in the context of intellectual property rights, and the proposal that « intellectual property law, in general,

at this point in time whether differences in legal culture, levels of social and economic development and thus diverging interests encourage or discourage the advent of a global patent law, or if its advantages in terms of efficiency will be able to cope with the challenges of equity involved.<sup>6</sup> In assessing pros and cons, much depends upon assessing past and current patterns of patenting around the globe. The broader coverage can be observed, the stronger a case for a global patent system and indeed global law beyond the TRIPs Agreement can be made. Vice-versa, the stronger we observe diversity and uneven distributions of patents sought, the less a case for global patents can be made. Observations and answers may vary from sector to sector. At this stage, it would seem that a comprehensive view is not yet established and in sight.

In this paper we look at the patent application patterns for plant biotechnology patents, We are interested in clarifying whether the need for a uniform global patent<sup>7</sup> or patent system<sup>8</sup> is born out by patenting patterns in this particular field of technology. We chose to address this sector because this is one area of technology where markets, consumer perceptions and preferences, as well as regulatory environments have been well studied. Plant and animal biotechnology offer technological solutions for many of the health<sup>9</sup> and resource-based<sup>10</sup> problems facing the world, thus these remain of central importance in a globalized economy.<sup>11</sup> Plant biotechnology patents<sup>12</sup> find their implementation in two main sectors: industrial agriculture

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should be sunsetted » see Johnson, EE, *Intellectual Property and the Incentive Fallacy*, <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1746343](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1746343)>. Florida State University Law Review, forthcoming, at 52.

<sup>6</sup> JH Barton, 'Issues Posed by a World Patent System', *Journal of International Economic Law* vol. 7, no. 2, 2004, pp. 341-357.

<sup>7</sup>For the purpose of this paper a 'global patent' is a single title specification with universal effect (legal).

<sup>8</sup> A 'global patent system' includes the global patent and the organizations that issue, administer and adjudicate matters pertaining to it.

<sup>9</sup> For example: AM Pohlit, NP Lopes, RA Gama, WP Tadei, & VF Neto, 'Patent literature on mosquito repellent inventions which contain plant essential oils--a review.', *Planta Medica* vol. 77, no. 6, 2011, pp. 598-617; SA Wilson, & SC Roberts, 'Recent advances towards development and commercialization of plant cell culture processes for the synthesis of biomolecules.', *Plant Biotechnol J* vol. 10, no. 3, 2012, pp. 249-268.

<sup>10</sup> For example: UT Bornscheuer, GW Huisman, RJ Kazlauskas, S Lutz, JC Moore, & K Robins, 'Engineering the third wave of biocatalysis.', *Nature* vol. 485, no. 7397, 2012, pp. 185-194.

<sup>11</sup> 'The bioeconomy to 2030: Designing a Policy Agenda', 2009, OECD, pp. 322. at 15 (Executive Summary).

<sup>12</sup> An example of such a patent application is WO 2007/127206 *Biological Systems Input-Output : Response Systems and Plant Sentinels*, that includes synthetic eukaryotic signal transduction pathways, synthetic signal sensitive promoter which would cause plants to turn white in colour (de-greening) thus turning the plant into a detector for some specified chemical agent. Other examples would be those that deal with genetically modified crops and could include biopharming applications, herbicide tolerance, pest resistance, agronomic traits, product quality or characteristics, and technical traits such as chemical markers which are essential for breeding programmes, but have no commercial value for growers.

and pharmaceuticals.<sup>13</sup> This paper seeks to assess patterns of patenting of biotechnology in section II and to square results found with the different regulatory environments encountered in different countries in section III. We do not address issues raised by the use of plant genetic resources<sup>14</sup> or any biodiversity concerns. We also do not address issues relating to the production of new plant varieties using biotechnology methods that may be eligible for protection under the International Union for the Protection of New Varieties of Plants (UPOV) regime. In section IV we conclude that our data suggests that the world of plant biotechnology lends support to the thesis that patent law exhibits strong reasons for maintaining diversity between states, and that the case for a global patent or the unification of patent laws remains unsupported by our considerations of plant biotechnology.<sup>15</sup>

## II. Patent Priority Statistics for Plant Biotechnology

The current global patent system has been labelled as one of ‘labyrinths and catacombs’ because it is riddled by rules and procedures that are in principle harmonized, but that are by far not streamlined.<sup>16</sup> In addition, the mix (plant variety, patent, utility patent, plant patent) and scope of intellectual property protection for plant biotechnology subject matter varies across jurisdictions.<sup>17</sup> An applicant seeking patent protection has five options depending on which procedural option is chosen. Often the most frequent option is to file nationally first (resident filing), and then within the twelve months of priority pursue additional routes towards non-resident patent application. There are four possibilities within the Paris Convention members and non-members, Patent Cooperation Treaty and European patent Convention member states, all with harmonized, but not identical procedures and deadlines.

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<sup>13</sup> For a practitioner’s perspective on biotechnology inventions see: Grubb, PW, & PR Thomsen, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy*, 5 edn., Oxford University Press, USA, 2010. at 274-300.

<sup>14</sup> Within the context of the International Treaty for Plant Genetic Resources for Food and Agriculture adopted by the Conference of the Food and Agriculture Organization of the United Nations (FAO) on 3 November 2001 in Rome, ‘plant genetic resources’ means genetic material of plant origin where ‘genetic material’ means any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity. In broad terms, plant genetic resources issues have to do with whole genetic functional units of hereditary, plant varieties, biodiversity and conservation of genomes.

<sup>15</sup> Stack, A, *International Patent Law: Cooperation, Harmonization and an Institutional Analysis of WIPO and the WTO*, Edward Elgar Pub, 2011. at 157.

<sup>16</sup> Drahos, P, *The Global Governance of Knowledge: Patent Offices and their Clients*, Cambridge University Press, 2010. at 55-90.

<sup>17</sup> KA Sechley, & H Schroeder, ‘Intellectual property protection of plant biotechnology inventions’, *Trends in Biotechnology* vol. 20, no. 11, pp. 456-461; M Llewelyn, ‘From ‘outmoded impediment’ to global player: the evolution of plant variety rights’ in D Vaver, & L Bently (eds.), *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish*, Cambridge University Press, 2004, pp. 137-156.

## **A. Patent Statistics: Methods Used**

### *1. Data Structure and Search Strategy*

For purposes of this investigation the EPODOC<sup>18</sup> database has been used to generate an initial data set using the IPC<sup>19</sup> patent classes identified in Annex A.<sup>20</sup> In the EPODOC database 113'638 patents were identified. This initial data set was further restricted to a subset of 45'783 patents containing (in bibliographic data) the keywords in Annex B. This subset of selected patents in EPODOC corresponds to 20'337 patent families in the Derwent World Patent Index database (DWPI)<sup>21</sup>. Using patent families affords the advantage of dealing with single inventions instead of individual patents in various jurisdictions. DWPI uses priority data to group patents into families; a subsequent patent application may have more than one priority but this is not very frequent. Simple statistics on this data subset were generated using patent families in DWPI and displayed in the figures below where the number of documents in each of the jurisdictions or origins is visualized. No time restrictions have been applied to the searches.<sup>22</sup>

In order to check the accuracy rate of the selected IPC classes (as refined through the selected keywords), the contents of a sample of 991 EPODOC patent documents was inspected. This has shown that a total of 870 patent documents were dealing with plants where 803 of them belonged to the field of plant genetics (81%). Patent applications are published after 18 months following the first filing date (priority date). Subsequent applications in other countries are not published after 18 months, but in most cases only after being granted, thus several years may elapse before these show up in any database. This depends on the specific rules in a country and on the local examination procedure in general. Thus a cut-off date allowing for the 18 months delay in publication is not sufficient to assure that all members of a patent family are included in the subset.<sup>23</sup>

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<sup>18</sup> EPODOC is the EPO's worldwide bibliographic database used for prior art searches. The country coverage of the database is in Annex D ; it includes the two letter country codes.

<sup>19</sup> The International Patent Classification (IPC) established in 1971 (Strasbourg Agreement) provides for a hierarchical system of language independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain; see <http://www.wipo.int/classifications/ipc/en/>.

<sup>20</sup> This has been made available by the Swiss Federal Institute of Intellectual Property, Berne, Switzerland (June 2011; November 2011) and accessed by Heinz Müller; the data discussed was generated 15.11.2011.

<sup>21</sup> DWPI coverage: <<http://scientific.thomson.com/support/patents/coverage/>> .

<sup>22</sup> Search executed 15.11.2011 at the Swiss Federal Institute for Intellectual Property by Heinz Müller.

<sup>23</sup> This difficulty is also acknowledged in the OECD Patent Statistics Manual which states that, at all offices, there is a processing and examination time, which can be very lengthy in some cases. As a consequence, statistics based on granted patents only are not strictly comparable across patent offices owing to the variability in the time needed to grant a patent in each patent office. In addition, as patent offices have faced a surge of their workload since the mid-1990s, the grant delays have increased, so that "the number of grants would reflect the underlying dynamics only in a smoothed and delayed manner ('calendar effect')" oecd.org, 'OECD Patent Statistics Manual', 2009, at 64.

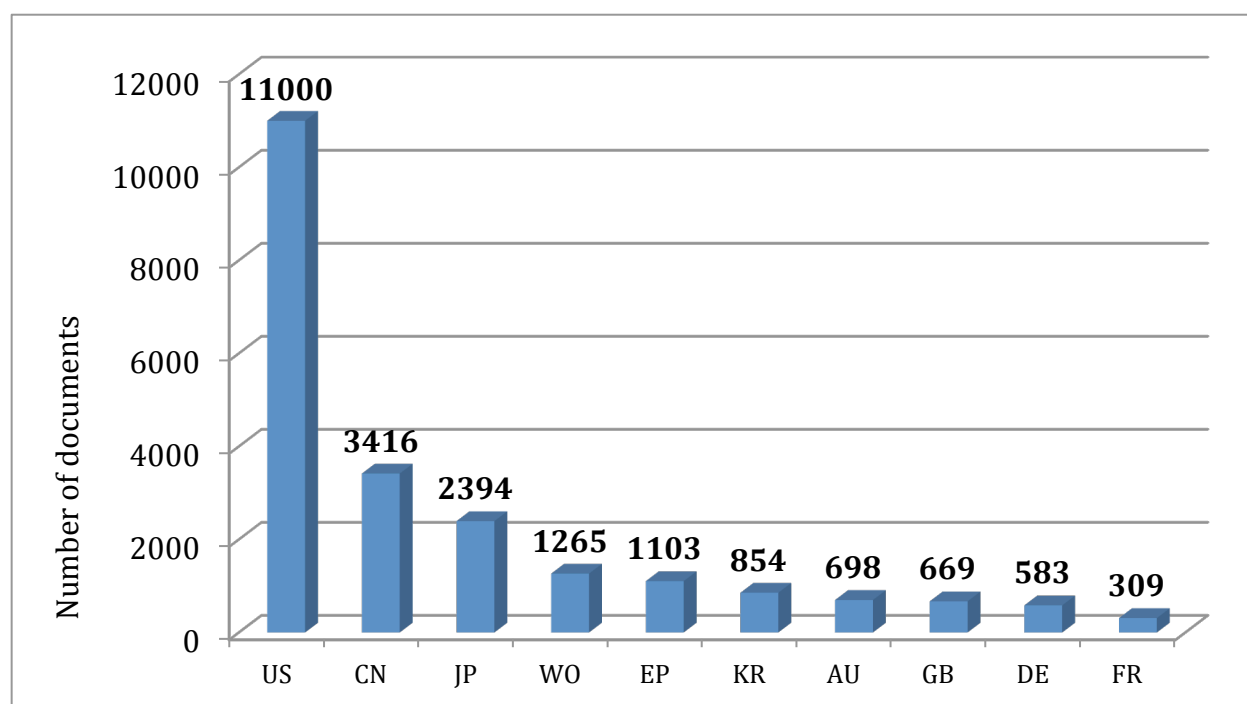


## 2. Results

A total of 21'208 patent families were retrieved from DWPI following the search criteria in Annexes A and B in EPODOC.<sup>24</sup> From this total, 11'000 families have US priority. This amounts to almost 50% of all inventions in plant genetic resources in this database which originate in the US. The terms of art to distinguish between national applications and foreign one are resident and non-resident applications (or granted patents) based on the priority. Residency of a patent is determined relative to the county or entity code assigned to its priority (CH for Switzerland, CN for China, WO for PCT routed applications, etc.).<sup>25</sup>

### a) **Relative Number of Filings for USA (US), China (CN), Japan (JP), South Korea (KR), Australia (AU), Great Britain (GB), Germany (DE), and France (FR)**

In Figure 1 a selection from the total data set of 21'208 families representing priorities according to initial registration entity is displayed. Of note is that the US priorities

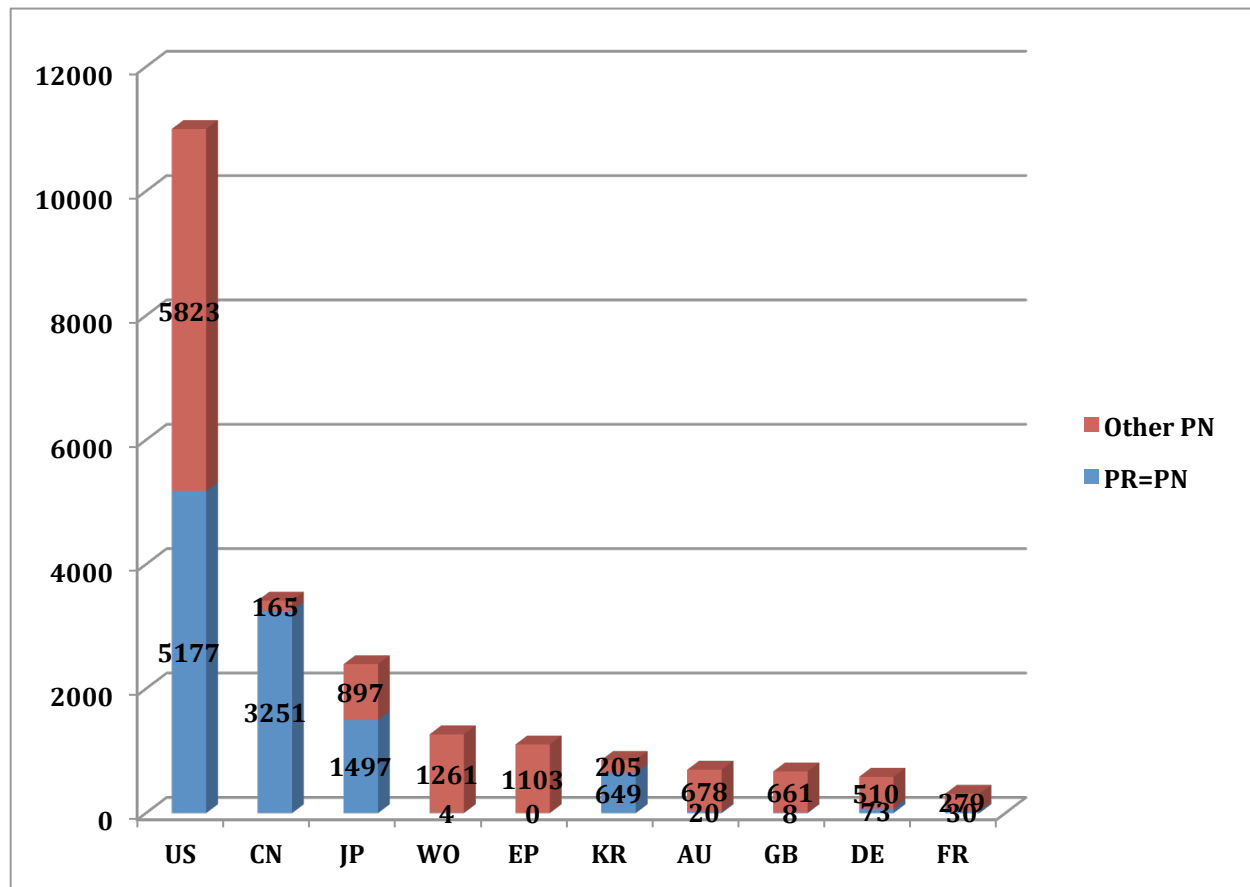


account for almost 50 per cent of the total, followed by China and Japan. The PCT (WO) and the EPC (EP) routes are taken by ca. 5 per cent of the applicants and account only for a total 10 per cent of the total. The y-axis in this and all subsequent figures corresponds to the number of documents in the subset. Note that Figure 1 does not display a complete list of all jurisdictions on the x-axis, just a selection of the more frequent ones.

<sup>24</sup> A sample of 991 documents from the initial EPODOC set was verified for accuracy and 81% of these were found to correctly correspond to inventions in plant genetics. This is significant when considering absolute numbers, but irrelevant when examining trends.

<sup>25</sup> Country codes are standardized ; the various standards, recommendations and guidelines in use can be downloaded at:  
[http://www.wipo.int/standards/en/part\\_03\\_standards.html#group-b](http://www.wipo.int/standards/en/part_03_standards.html#group-b) (16.11.2011).

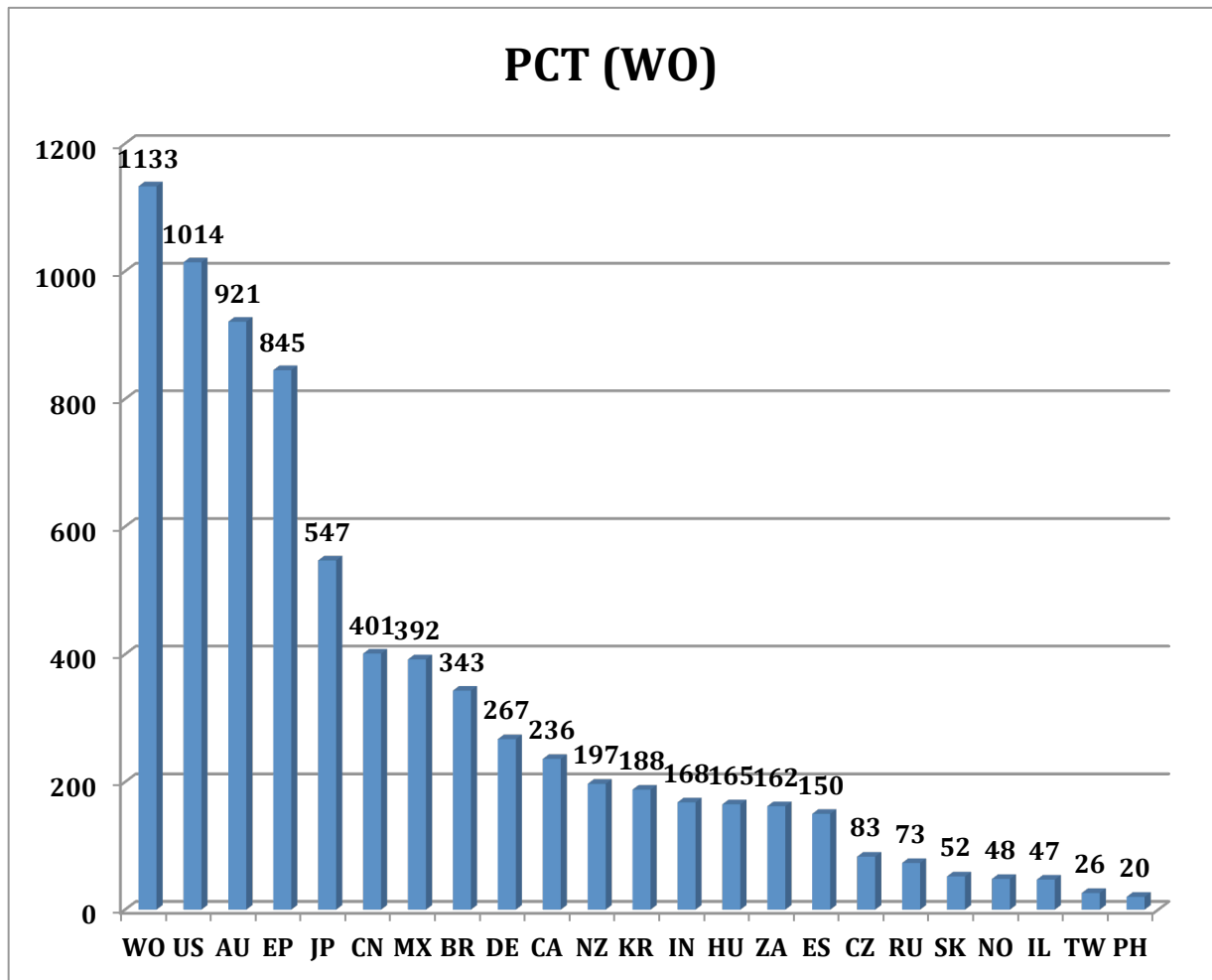
b) **National and International Applications**



In Figure 2 the proportion of national versus international filings is displayed. Filings where the priority and patent number are identical (PR=PN) are resident filing in the country or origin (national filings). Of significance is that 55 per cent of all US applications are used as priority for subsequent filings in other jurisdictions either through the PCT, EPC or by any of the other available routes. This is marked contrast with SIPO (CN) original filings where less than five per cent are also subsequently filed abroad (non-resident applications). PCT and EPC filings are by definition (multilateral conventions) destined for subsequent filings in the jurisdictions of its member states and are thus automatically international.

We recognize two kinds of behaviours that depend on the origin of the initial (priority) filing. One is represented by the US, GB, DE, FR all of which see a majority of their national filings follow some international route(s) towards building a patent family for the invention. The second kind of behaviour represented by CN, JP, and KR exhibits a domination of the national patent, and only a small fraction of the domestic filings are chosen to cover other markets. One can say that what is invented in China, stays in China, and what is invented in the US, goes out into the world. There are many plausible explanations for these patterns that could be used to understand the behaviours. One possible explanation is that Chinese firms and inventors are mostly concerned with their original market and place of production, and are not keen on strong patent protection in the rest of the world, while is the US looks to protect both its knowledge and commercial markets.

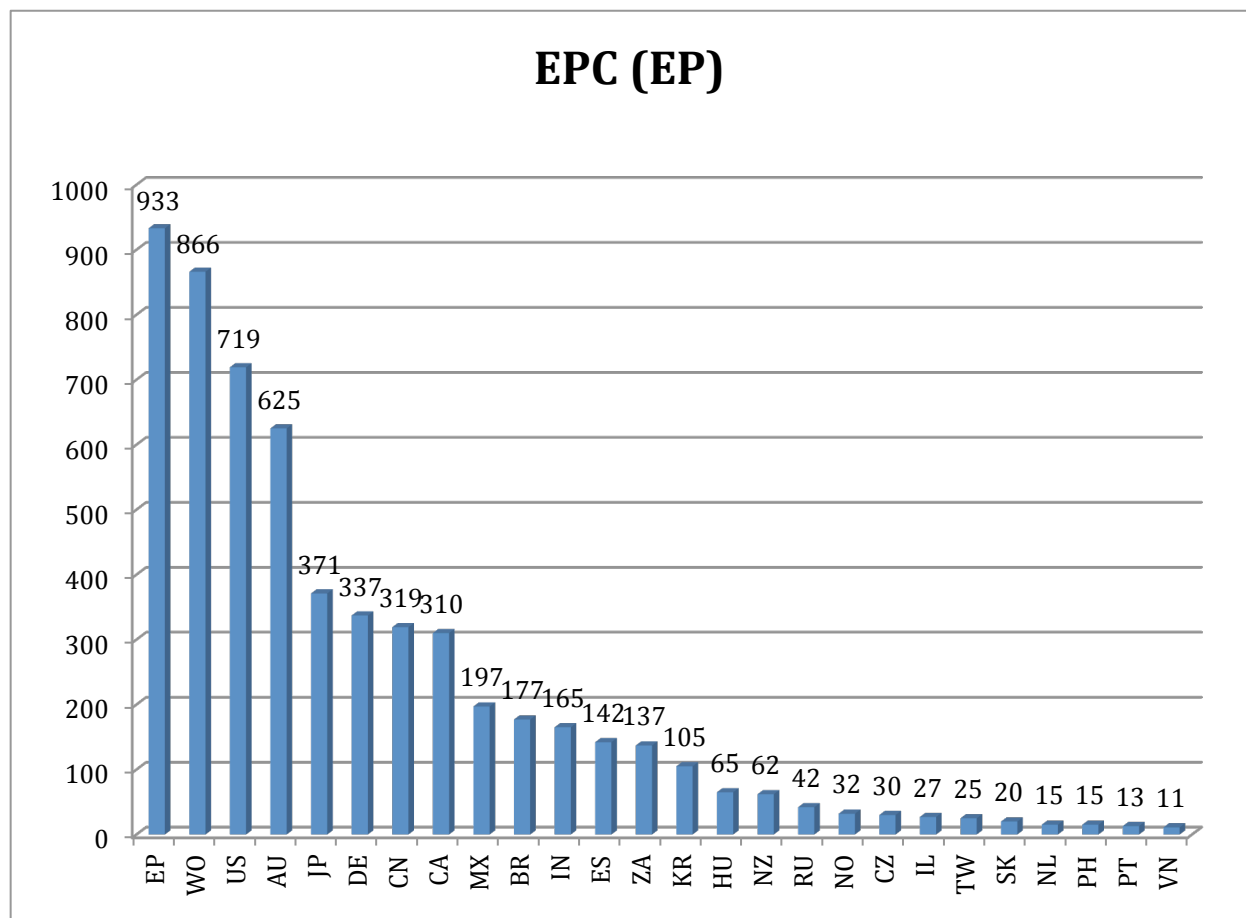
c) **PCT Filings**



Of the 1261 documents in the data set, 1133 were published as WO documents (application, search report, etc.). That not all documents with WO priorities are published as WO documents is not surprising as some of these may have gone through the EPC-PCT route claiming the priority, but before publication the PCT process was dropped once the priority had been claimed.

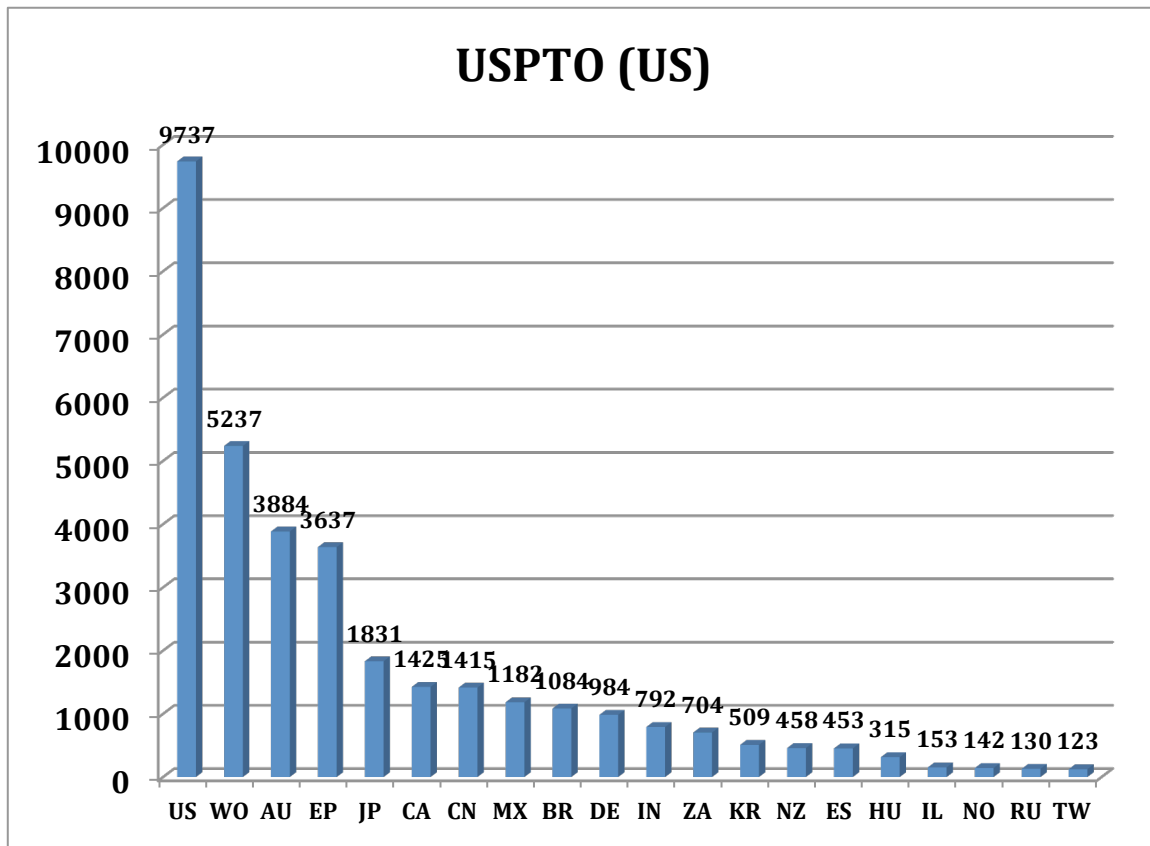
In this figure we also observe that majority of patent filings for the subset representing plant biotechnology seek protection in the USA, Australia, Japan, China, Mexico, Brazil, Germany, Canada, New Zealand, South Korea, India, Hungary, South Africa and Spain. All state designations below Spain (ES) have less than 100 documents (less than 10 per cent of the original 1261 documents represented in this graph).

d) **EPC Fillings**



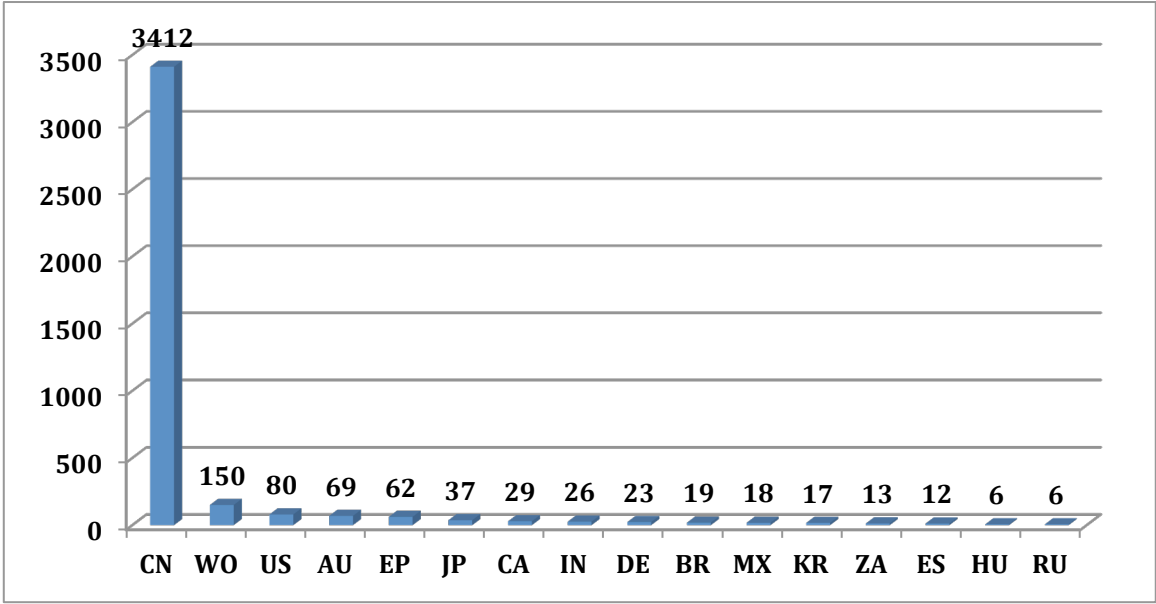
In Figure 4, the destination distribution of the 1103 documents with an EPC priority is shown. It shows that the majority of the applications entering the patent system through this route are destined are routed through the PCT system. A majority of these applicants then seek patent protection in the US, Australia, Japan, Germany, China, Canada, Mexico, Brazil, India, Spain, South Africa, South Korea, Hungary, and New Zealand (62/1103). One explanation for the DE documents with EP priority could be that these were also filed at the German Patent Office, or that these correspond to DE utility models or publications of the translation of the EP application to German. More than 90 per cent of the EP filings at the EPO or one of its national intake office also have a corresponding PCT (WO) document thus representing the so-called EP-PCT route. This data does not allow the separation of documents according to which route was used. That is a AU document could have been obtained directly through a national filing using a foreign priority or through a PCT filing.

e) **USPTO (US) Priority Filings**



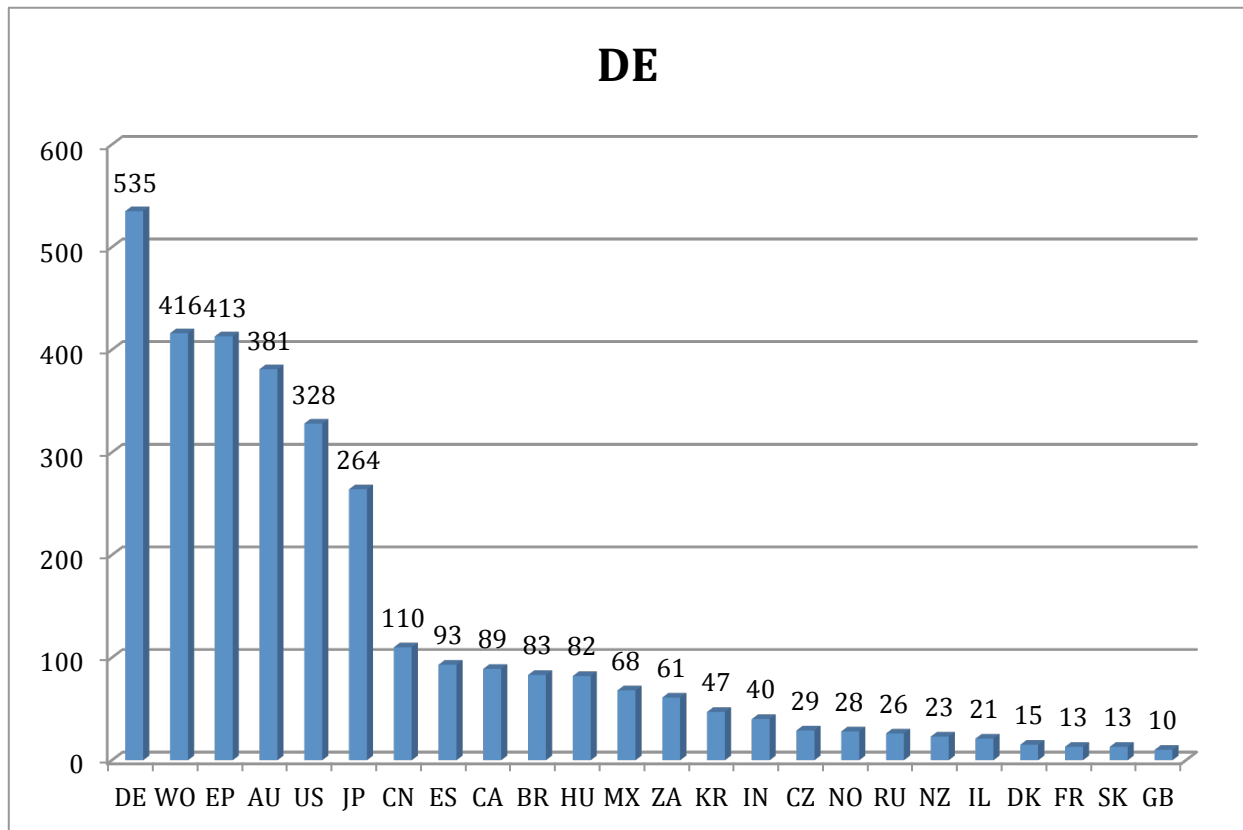
In Figure 5 the filing pattern of the US priority filings is displayed. About 50 per cent of these filings are followed with a PCT application. The preferred jurisdictions for patent protection for those US priority filings are Australia, Japan, Canada, China, Mexico, Brazil, Germany, India, South Africa, South Korea, New Zealand, Spain, Hungary, and to a lesser degree, Israel, Norway, Russian and Taiwan.

f) **China (CN) Priority Documents**



The distribution in Figure 5 shows that the vast majority of CN applications never go beyond the original resident application to seek international protection as seen in Figure 2. Of these the major markets sought for protection are the US, Australia, Japan, Canada, India, Germany, Brazil, Mexico, Korea, New Zealand, and Spain. All other jurisdictions have a number of applications below 10

g) **Germany (DE) Priority Filings**



In Figure 7 the fate of the DE priority applications displays a preference for markets in Australia, United States, Japan, China, Spain, Canada, Brazil, Hungary, Mexico, South Africa, South Korea, India, Czech Republic, Norway, Russia, New Zealand, and Israel.

### 3. *Patenting Patterns for Plant Biotechnology*

In summary the data above reveals the following patterns for plant biotechnology:

- i.) More than 50 per cent of all patent families in the data set originate in the US. Second ranked are China and Japan with roughly 10 per cent each. In the EU the UK, Germany and France only contribute a small fraction of the originating patents in this data set.
- ii.) US and European patent applicants have a majority of international applications while China, Japan and South Korea only take a small fraction of their inventions abroad.
- iii.) The majority of international patent filings (EPC and PCT) seek protection in the US, Australia, Japan, China, Mexico, Brazil, Germany, Canada, New Zealand, South Korea, India, Spain and Hungary.

The limitations of the data set are given by the coverage in the databases. In particular least developed countries and developing countries are underrepresented in DWPI; from the African continent only South Africa is represented (Annex E.1).

The WIPO offers a breakdown of the 2008 PCT national phase entry data by patent office and country of origin reveals the ‘flow of patents’ between countries. Here one learns that the

EPO received the largest number of national phase entries (83,576), most of which originated from the US (33.1%), followed by Japan (14.5%) and Germany (14.4%). Applicants from Japan and US filed approximately 55% of all national phase entries at the SIPO (Chinese patent office).<sup>26</sup> That is, China sees a large influx of non-resident patent applications, and a very small outflow of resident inventions, a trend that our results mirror.

In addition, the WIPO database also offers a breakdown of the statistical analysis by field of technology which can be used to further cement or refute arguments relevant to the issue of a global patent system. Of note is that patent applications in the life sciences (analysis of biological materials and biotechnology) experienced a decline from 2003 to 2007.<sup>27</sup>

The trends in the ratios of resident to non-resident patent applications for plant genetic resources deserves mentioning. In summary, one can say that industrialized nations have a propensity towards applying for non-resident patent protection in territories which may be of significance either for production or market reasons. Thus the US resident applicants engage to a large extent in non-resident patent application activities through the various routes while developing economies such as China find it important to secure protection of their own inventions primarily within their own resident territory. This is to be contrasted with the observation that high and middle income countries tend to have a higher proportion of resident patent applications, while low income countries show a propensity towards having a large proportion of non-resident patent applications.<sup>28</sup> Again, our data set reflects the same pattern. What appears like China's attitude of 'what gets invented in China, stays in China' reflects the overall pattern of CIPO patent applications. In 2011, China with 293,066 resident applications displaced Japan (with 290,081) to become the top country for resident applications.<sup>29</sup>

### **III. Usage and the Regulatory Environment of Biotechnology and Genetically Modified Crops**

#### ***A. Global Commercialization***

According to Clive James' report<sup>30</sup> countries that grew more than 50,000 hectares of biotech crops in 2010 are USA, Brazil, Argentina, India, Canada, China, Paraguay, Pakistan, South Africa, Uruguay, Bolivia, Australia, Philippines, Myanmar, Burkina Faso, Mexico, and Spain.<sup>31</sup> That this list of jurisdictions is not fully reflected by our data set has two possible explanations that may apply simultaneously. Firstly, it has to do with of the limitations of the database used for extracting the patent families. Secondly, this could be a reflection that some

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<sup>26</sup> WIPO, *World Intellectual Property Indicators*, 2010 at 58; Available at: <http://www.wipo.int/ipstats/en/statistics/patents/>

<sup>27</sup> *Ibid.* at 59.

<sup>28</sup> *Ibid.* at 41.

<sup>29</sup> WIPO, *World Intellectual Property Indicators - 2011 Edition*, <<http://www.wipo.int/ipstats/en/wipi/index.html>>. at 6, and 192ff. In contrast, Canada, Israel, the Netherlands and Switzerland filed more than 80% of their total applications abroad (2011).

<sup>30</sup> <http://isaaa.org/> (15.6.2012)

<sup>31</sup> Report available at : <http://isaaa.org/resources/publications/pocketk/16/default.asp> (15.6.2012); unfortunately this report does not include the source of the data reported.



of these countries do not have patent systems that are perceived as strong, however this is a speculative statement since we are not looking into this aspect.

While 23 countries planted commercialized biotech crops in 2007, an additional 29 countries, totalling 52, have granted regulatory approvals for biotech crops for import for food and feed use and for release into the environment since 1996. A total of 615 approvals have been granted for 124 events for 23 crops. Thus, biotech crops are accepted for import for food and feed use and for release into the environment in 29 countries, including major food importing countries like Japan, which do not plant biotech crops.<sup>32</sup>

The specific mention of Japan in this context is noteworthy because at the research level Japan has seen considerable success albeit through a path different from that taken by the US.<sup>33</sup> However, Japan has comprehensive regulatory measures in place to guarantee the safe handling of GM crop plants that includes a zero tolerance for imports containing GM products unapproved by Japan.<sup>34</sup>

Of the 52 countries that have granted approvals for biotech crops, Japan tops the list followed by USA, Canada, South Korea, Australia, Mexico, the Philippines, New Zealand, the European Union and China. Maize has the most events approved (40) followed by cotton (18), canola (15), and soybean (8). The event that has received regulatory approval in most countries is herbicide tolerant soybean event GTS-40-3-2 with 24 approvals (EU=27 counted as 1 approval only), followed by insect resistant maize (MON810) and herbicide tolerant maize (NK603) both with 18 approvals, and insect resistant cotton (MON531/757/1076) with 16 approvals worldwide.<sup>35</sup>

According to the same source 75 per cent of 100 million hectares of soybean planted globally in 2011 were biotech (herbicide tolerant) while it accounted for 60% of the world's soybean harvested area in 2005.<sup>36</sup>

The main producer was the US where 87% of the national soybean crop was GM. The other major producers of soybean are, based on FAO data, Brazil, Argentina, China and India. Gómez- Barbero and Rodríguez-Cerezo (2006a) note that 99% of the Argentinean soybean crop was GM in 2005 and that the adoption rate in Brazil was also high (data from GMO-Compass<sup>37</sup> puts the GM share of Brazilian soybeans at 64% in 2007). It should be noted that the US, Brazil and Argentina account for approximately 90% of world trade in soybeans. China was testing the crop in field

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<sup>32</sup> James, Clive. 2007. Global Status of Commercialized Biotech/GM Crops: 2007. ISAAA Brief No. 37. ISAAA: Ithaca, NY.; C James, 'Global Status of Commercialized Biotech/GM Crops: 2007', *ISAAA Brief No 37*, 2008, pp. 1-166. at 106.

<sup>33</sup> T Reiss, 'Success factors for biotechnology: lessons from Japan, Germany and Great Britain', *International Journal of Biotechnology* vol. 3, no. 1, 2001, pp. 134-156.

<sup>34</sup> J-P Nap, PLJ Metz, M Escaler, & AJ Conner, 'The release of genetically modified crops into the environment. Part I. Overview of current status and regulations', *Plant J* vol. 33, no. 1, 2003, pp. 1-18.

<sup>35</sup> Supra note 32.

<sup>36</sup> Food Chain Evaluation Consortium (FCEC), 'Evaluation of the EU legislative framework in the field of GM food and feed', 2010, European Commission: DG SANCO, pp. 1-238. at 19.

<sup>37</sup> <http://www.gmo-compass.org/eng/home/> (30.6.2012)

trials in 2005, but does not appear to have introduced GM varieties commercial as yet.<sup>38</sup>

In agricultural biotechnology a strategy of vertical integration through acquisition and consolidation, rather than licensing or contractual agreements for technology use between biotechnology, seed and agrochemical firms has been used.<sup>39</sup> This suggests there is perception that the patent system does not offer sufficient protection even in jurisdictions with the most developed patent traditions. That is, “outright ownership of the knowledge is the sure way to protect it.”<sup>40</sup> This may be an indication that patent patterns can reflect the perceived markets and the presence of competitors, but that for trade purposes commercial actors will not rely on the patent system alone to protect their interests.

### ***B. Diverging Regulatory Environments***

The public debate in agricultural biotechnology is fraught with popular misconceptions.<sup>41</sup> The world is far from uniform standards, and the Cartagena Protocol, negotiated under the auspices of the Convention on Biodiversity, is not shared among all nations, in particular with the US abstaining. Strongly uneven patterns of use of genetically modified organism focusing on a number of countries, in particular the United States, Brazil, Argentina, China, do not merely reflect the size of countries and the importance of their agricultural sectors, but also the fact of largely diverging regulatory environments. It is not a coincidence that these countries offer regulatory regimes favourable to use and commercialization of plant genetic resources. The European Union, on the other hand, has been operating restrictions and moratoria discouraging recourse to genetically modified organisms.<sup>42</sup>

At time of adoption the Directive and Regulation constituted an attempt at a new and improved legislative framework governing what had proven to be a difficult area of EU policy. Yet, from the time they came into force until March 2010 the EU did not adopt a single decision, positive or negative, on an application to cultivate a GMO. The Amflora potato is the first cultivation approval in Europe since 1998. Applications cycle within the system are stalled, inch forward and then cycle again at the next stage of the process. Dissatisfaction and frustration is widespread in all quarters.”<sup>43</sup>

In contrast, Japan has both a strict regulatory environment for GMOs and a population who

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<sup>38</sup> Supra note 36 at 19 and references therein.

<sup>39</sup> Isaac, G, *Agricultural Biotechnology and Transatlantic Trade: Regulatory Barriers to GM Crops*, CABI Pub., 2002. at 65.

<sup>40</sup> Ibid.

<sup>41</sup> A McHughen, & R Wager, ‘Popular misconceptions: agricultural biotechnology.’, *N Biotechnol* vol. 27, no. 6, 2010, pp. 724-728.

<sup>42</sup> F Daviter, ‘Schattschneider in Brussels: How Policy Conflict Reshaped the Biotechnology Agenda in the European Union’, *West European Politics* vol. 32, no. 6, 2009, pp. 1118-1139; C Burns, ‘How and When Did We Get Here? An Historical Institutional Analysis of EU Biotechnology Policy’, *Journal of European Integration* vol. 34, no. 4, 2012, pp. 341-357.

<sup>43</sup> Conclusion in ‘Evaluation of the EU Legislative Framework in the Field of Cultivation of GMOs Under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the Placing on the Market of GMOs as or in Products Under Directive 2001/18/EC’, 2011, pp. 1-137.

when asked, in general disapproves of biotechnology foods. However the trade figures for GMO's in Japan tell another story:

Japan remains the world's largest per capita importer of foods and feeds that have been produced using modern biotechnology. Annually Japan imports about 16 million metric tons of corn and four million metric tons of soybeans, approximately three quarters of which are produced through biotechnology. Japan also imports billions of dollars worth of processed foods that contain biotech-derived oils, sugars, yeasts, enzymes, and other ingredients.<sup>44</sup>

Two reviews, one of the Association of South East Asian Nations (ASEAN),<sup>45</sup> and another of the Asia Pacific Economic Cooperation (APEC)<sup>46</sup> biotechnology regulations identify a broad spectrum of regulatory measures and recommend some form of regulatory consolidation towards meeting a plethora of goals towards harmonization and to meet the challenges of food price volatilities and other fragilities in global food system. Countries regulating biotechnology take recourse to different standards of liability. They are instrumental in encouraging or discouraging recourse to the technology, and diverging levels of risks assumed. Sufian Jusoh<sup>47</sup> argues in favour of diverging standards able to take into account the needs and preferences of countries. In particular, Jusoh notes that the Kuala Lumpur Supplementary protocol allows for such flexibility in the harmonization of the liability rules for biotechnology products that it may not contribute to harmonization of liability standards.<sup>48</sup> In addition, regulatory competition, "may introduce a race to the top, where countries wish to protect the environment and the biodiversity whilst at the same time trying to gain advantage from the benefits offered by biotechnology."<sup>49</sup>

Similarly, the Committee on Biotechnology of the International Law Association in its interim and final report distinguishes the functions of risk assessment and risk management.<sup>50</sup> While the former should be allocated to international bodies and network of scientific laboratories, the later should be left with national government, commensurate with social and economic needs and preferences relating to biotechnology. These findings were equally confirmed in the doctoral thesis of Michael Burkard.<sup>51</sup>

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<sup>44</sup> S Sato, 'Japan Agricultural Biotechnology Annual: Biotechnology Annual Report 2011', *USDA Foreign Agricultural Service, GAIN Report Number JA1039*, 2011, pp. 1-41. at Executive Summary.

<sup>45</sup> Jusoh, S, *Biotechnology Law and Regulation: The ASEAN Perspective*, Cameron & May, London, 2006.

<sup>46</sup> M Escaler, PPS Teng, & AD Powell, 'Challenges of Harmonization of Agricultural Biotechnology Regulatory Systems across APEC Economies', *Biosafety* vol. 1, no. 3, 2012, pp. 1-7.

<sup>47</sup> Jusoh, S, *Harmonisation of Liability Rules in Transboundary Movement of Biotechnology Crops*, Centre for International Trade and Investment, Kuala Lumpur, 2012.

<sup>48</sup> *Supra* note 47 at 273.

<sup>49</sup> *Ibid.*

<sup>50</sup> T Cottier, & M Footer, 'International Law on Biotechnology: Final Draft Report and Draft Recommendations', *International Law Association*, 2010, pp. 1-27.

<sup>51</sup> M Burkard, 'Risk Assessment and Risk Management in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures: Philosophy, Legal Challenges and

The interaction between international trade regulation and the issues generated by the regulatory environment for biotechnology does not suggest that a ‘one size fits’ all approach is recommended. Some aspects require harmonization and others require regulatory competition.<sup>52</sup> Plant biotechnology skips over the moral and ethical issues associated with animal and human biotech, however in the area of intellectual property, plant biotechnology may defer/default to the norms otherwise established in the sector where it is being applied. In the particular case of plant biotechnology patents, the differentiated pattern of patent activity follows the regulatory environment.

After *Monsanto v. Geertson Seed Farms*, those who fear GM crops degrading natural biodiversity will most likely not prevent deregulation under NEPA. Deregulation considerations under the substantial similarity paradigm, are inherently policy decisions beyond the jurisdiction of the judiciary. However, the Supreme Court has stated that actual contamination would give a farmer standing. Using existing torts, coupled with punitive damages, would adequately pressure GM seed distributors to tightly regulate the practices and geographic distribution of their end-users. It is only fair that GMO intellectual property owners, who have been enforcing their patent rights against infringers, should be liable for the adverse consequences of uncontrolled propagation of their patented products.”<sup>53</sup>

#### IV. Conclusion and Policy Implications

The assessment of patterns of patentability on the basis of existing statistics shows a considerable concentration of patents to a few countries, in particular the United States, Australia, Japan, China, Mexico, Brazil, Germany, Canada, New Zealand, South Korea, India, Spain and Hungary. Many least developed and developing countries, mainly due to the limitations of the patent statistics, are not included, but it would seem that patenting of biotechnology inventions in a majority of countries has not been of interest to industries concerned.<sup>54</sup> There are many reasons why biotechnology may not be used. Restrictive regulatory regimes may be one the most important reasons, but there may be others such as size or lack of information and education in the field. But there is a clear relationship between the patterns of patenting and the regulatory framework. Countries offering open and welcoming regimes attract the bulk of patent applications. Biotechnology industries operating in restrictive environments seek protection abroad to secure market access in potentially lucrative markets. What can be learned from discussing plant biotechnology patents and their geographical distribution is that a global patent automatically encompassing all countries alike would not be appropriate and feasible. It would create protection where none is sought and no need for protection exist. A global system as applied to biotechnology (or any other

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Future Prospects for Regulation’, Ph D, 2010, World Trade Institute, University of Bern, pp. 418..

<sup>52</sup> S Bibber-Klemm, M Burkhard, S Jusoh, & M Temmerman, ‘Challenges of biotechnology in trade regulation’ in T Cottier, & P Delimatsis (eds.), *The Prospects of International Trade Regulation: From Fragmentation to Coherence*, Cambridge University Press, 2011, pp. 284-320.

<sup>53</sup> CB Miller, ‘Honey Get My Gun, the Transgenic Seeds Are in the Field Again’, *The John Marshall Review of Intellectual Property Law* 2011, pp. 439-456.

<sup>54</sup> For instance Switzerland, a country with a significant academic effort in biotechnology, does not have a significant number of patent documents in the data set selected.

technology) therefore could be based upon a bundle patent and could be thus be built upon the model of the current European Patent Convention (EPC) where one single central examination by the EPO serves all the Patent Offices of the member states. Industrial players and stakeholders should be able to select countries for which patent protection is sought in a one-stop shop approach. Failing the availability of such a one-stop shop, several Patent Offices have opted for a bilateral, trilateral or multilateral pragmatic solution with the Patent Prosecution Highway (PPH) which so far is more intensively used by applicants filing first at the JPO.<sup>55</sup> In part, the PPH approach mirrors the EPC approach in that the application is not examined several times, thus it reduces not only duplication of work when the patent application enters the national phase, but also reduces the time between application and subsequent grant of the patent.

The patterns of patenting, on the other hand, do not exclude the possibility of further harmonization in terms of substantive law. To what extent this is feasible depends upon a closer analysis of the relationship of patents and the regulatory environment of the technology and social and economic needs in accord with Stack's argument that patent law cannot be regarded as merely technical in nature, and that it is inherently political.<sup>56</sup> The obvious answer to the question of when is international patent law harmonization well founded, is that when the trade-offs between diversity and harmonization are optimised, then harmonization is justified. In fact, what Stack argues is that "patent law exhibits strong reasons for maintaining diversity between states, and that the case for the unification of patent laws is normatively unsupported."<sup>57</sup>

Importing and exporting countries will not have the same needs, and developing countries may need the benefit of graduation and thus less stringent commitments in order to facilitate technology transfer.<sup>58</sup> For the time being, we conclude that a single title encompassing all countries alike in accordance with single and uniform standards is not matched by the data available on patterns of patents in the field.

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<sup>55</sup> World Intellectual Property Indicators 2011, WIPO Economic Statistics Series, Table A.13.1 Cumulative number of PPH requests (excluding PCT-PPH requests), February 2010 to June 2011, and PCT-PPH requests. For the period reported, 3,799 applications first filed at the JPO were subsequently filed at the USPTO using this fast-track (at 94). For comparison, the JPO received 344,598 (national, resident and non-resident) patent applications, and acted as receiving office for 31'523 PCT applications in 2010 (at 193). For a discussion see D Chun, 'Patent Law Harmonization In The Age of Globalization: The Necessity and Strategy for a Pragmatic Outcome', *Journal of Patent Trademark Office Society* vol. 93, no. 2, 2012, pp. 127-166.

<sup>56</sup> 15 at 158 ; and for a detailed analysis of the recent determination by the Extended Board of Appeal of the European Patent Office that methods for breeding broccoli and tomatoes were not patentable where it concludes that the right to patent agricultural innovations is increasingly located within a political context see : M Blakeney, 'Patenting of plant varieties and plant breeding methods.', *Journal of Experimental Botany* vol. 63, no. 3, 2012, pp. 1069-1074.

<sup>57</sup> Stack, *International Patent Law: Cooperation, Harmonization and an Institutional Analysis of WIPO and the WTO*. at 157.

<sup>58</sup> See also 6

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## VI. Annexes

### C. IPC Classes Selected (Any)

IPC Classes	Description
A01H (2006.01)	SECTION A — HUMAN NECESSITIES AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING NEW PLANTS OR PROCESSES FOR OBTAINING THEM; PLANT REPRODUCTION BY TISSUE CULTURE TECHNIQUES
A61K38/56 (2006.01)	Medicinal preparations containing peptides (peptides containing beta-lactam rings A61K 31/00; cyclic dipeptides not having in their molecule any other peptide link than those which form their ring, e.g. piperazine-2,5-diones, A61K 31/00; ergoline-based peptides A61K 31/48; containing macromolecular compounds having statistically distributed amino acid units A61K 31/74; medicinal preparations containing antigens or antibodies A61K 39/00; medicinal preparations characterised by the non-active ingredients, e.g. peptides as drug carriers, A61K 47/00) Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof .. Protease inhibitors ... from plants
C07K4/10 (2006.01)	Peptides having up to 20 amino acids in an undefined or only partially defined sequence; Derivatives thereof .. from plants
C07K14/415 (2006.01)	Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof .. from plants
C07K16/16 (2006.01)	Immunoglobulins, e.g. monoclonal or polyclonal antibodies .. against material from plants
C12N5/04 (2006.01)	Undifferentiated human, animal or plant cells, e.g. cell lines; Tissues; Cultivation or maintenance thereof; Culture media therefor (plant reproduction by tissue culture techniques A01H 4/00) .. Plant cells or tissues
C12N5/14 (2006.01)	Undifferentiated human, animal or plant cells, e.g. cell lines; Tissues; Cultivation or maintenance thereof; Culture media therefor (plant reproduction by tissue culture techniques A01H 4/00) .. Cells modified by introduction of foreign genetic material, e.g. virus-transformed cells .. Fused cells, e.g. hybridomas ... Plant cells
C12N15/05 (2006.01)	Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered micro-organisms C12N 1/00, C12N 5/00, C12N 7/00; new plants A01H; plant reproduction by tissue culture techniques A01H 4/00; new animals A01K 67/00; use of medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases, gene therapy A61K 48/00; peptides in general C07K) .. Preparation of hybrid cells by fusion of two or more cells, e.g. protoplast fusion .. Plant cells
C12N15/29 (2006.01)	Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered micro-organisms C12N 1/00, C12N 5/00, C12N 7/00; new plants A01H; plant reproduction by tissue culture techniques A01H 4/00; new animals A01K 67/00; use of medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases, gene therapy A61K 48/00; peptides in general C07K) .. Recombinant DNA-technology .. DNA or RNA fragments; Modified forms thereof (DNA or RNA not used in recombinant technology C07H 21/00) ... Genes encoding plant proteins, e.g. thaumatin
C12N15/82 (2006.01)	Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered micro-organisms C12N 1/00, C12N 5/00, C12N 7/00; new plants A01H; plant reproduction by tissue culture techniques A01H 4/00; new animals A01K 67/00; use of medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases, gene therapy A61K 48/00; peptides



IPC Classes	Description
	in general C07K) . Recombinant DNA-technology . Introduction of foreign genetic material using vectors; Vectors; Use of hosts therefor; Regulation of expression ... Vectors or expression systems specially adapted for eukaryotic hosts .... for plant cells

#### *D. Keywords*

Gen+ or proteom+ or transgen+ or cysgen+ or epigen+ or nucleotid+ or (nucleic\_acid) or dna or rdna or cdna or tdna or rna or mran or trna or snrna; exon+ or intron+ or allel+ or oncogene+ or genotype+ or qtls or transcript+ or phenotyp+ or (cloning\_vector+) or (yeast\_artificial\_chromosome) or homozygote+ or heterozygot+; polymorphism+ or recessive or dominant or recombinant or silencing or pcr or shotgun or sequenc+ or microarray or rflp or rapd or aflp or trflp or dgge or fish or facs or blast or **alignement**

## ***E. Derwent World Patent Index Database***

### **1. DWPI Coverage<sup>59</sup>**

Argentina (1975)\*  
Australia (1963-69,1983-pres.)  
Austria (1975-present)  
Belgium (1963-present)  
Brazil (1976-present)  
Canada (1963-present)  
China (1987-present) Czech Republic (1994-present)  
Czechoslovakia (1975-1994)\*  
Denmark (1974-present)  
European Pat. Off. (1978-present)  
Finland (1974-present)  
France (1963-present)  
Germany (1963-present)  
Germany (Utility Models) (1995-present)  
German (Dem. Rep.) (1963-1990)  
Hungary (1975-present)  
India (2004-present)  
Ireland (1963-69,1995-pres.)  
Israel (1975-present)  
Italy (1966-69,1978-present)  
Japan (1963-present)  
Luxembourg (1984-present)  
Mexico (1997-present)  
Netherlands (1963-present)  
New Zealand (1993-present)  
Norway (1974-present)  
PCT (WIPO) (1978-present)  
Philippines (1994-present)  
Portugal (1974-present)  
Rep. of Korea (1986-present)

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<sup>59</sup> <http://www.cas.org/ASSETS/1050EF3EB1AD43698692C0E3E682A34A/wpids.pdf>

Romania (1975-present)

Russian Federation (1994-present)

Singapore (1995-present)

Slovakia (1994-present)

South Africa (1963-present)

Soviet Union (1963-1994)\*

Spain (1983-present)

Sweden (1974-present)

Switzerland (1963-present)

Taiwan (1993-present)

United Kingdom (1963-present)

United States (1963-present)

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International Technology Disclosures (1984-93)\*

\* signifies available within the backfile only

## ***F. Epodoc***

Epodoc is a database produced, administered, and updated daily by the European Patent Office. which compose the systematically classified search documentation of the European Patent Office. The documents consist of published applications, granted patents as well as classified non-patent literature (XP documents). The EPODOC database essentially corresponds to the DOCdb database which is the internal EPO master file used for the management of the search documentation. The bibliographic data (i.e. the publication, application and priority numbers and dates, the IPC classes, the inventors and applicants data and the title) are available for patent documents of most countries or other patent authorities (81 countries in July 2007).

### *1. Epodoc Coverage<sup>60</sup>*

- 1 Albania (AL)
- 2 ARIPO (AP)
- 3 Argentina (AR)
- 4 Austria (AT)
- 5 Australia (AU)
- 6 Bosnia and Herzegovina (BA)
- 7 Belgium (BE)
- 8 Bulgaria (BG)
- 9 Brazil (BR)
- 10 Canada (CA)
- 11 Switzerland (CH)
- 12 Chile (CL)
- 13 China (CN)
- 14 Costa Rica (CR)
- 15 Czechoslovakia (CS)
- 16 Cuba (CU)
- 17 Cyprus (CY)
- 18 Czech republic (CZ)
- 19 German Democratic republic (DD)
- 20 Germany (DE)
- 21 Denmark (DK)
- 22 Algeria (DZ)
- 23 Eurasia (EA)
- 24 Ecuador (EC)

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<sup>60</sup> Status : July 2011 (EPO).

- 25 Estonia (EE)
- 26 Egypt (EG)
- 27 European Patent Office (EP)
- 28 Spain (ES)
- 29 Finland (FI)
- 30 France (FR)
- 31 Great Britain (GB)
- 32 Gulf Cooperation Council (GC)
- 33 Georgia (GE)
- 34 Greece (GR)
- 35 Hong Kong S.A.R (HK)
- 36 Croatia (HR)
- 37 Hungary (HU)
- 38 Indonesia (ID)
- 39 Ireland (IE)
- 40 Israel (IL)
- 41 India (IN)
- 42 Iceland (IS)
- 43 Italy (IT)
- 44 Japan (JP)
- 45 Kenya (KE)
- 46 Korea (South) (KR)
- 47 Liechtenstein (LI)
- 48 Lithuania (LT)
- 49 Luxembourg (LU)
- 50 Latvia (LV)
- 51 Morocco (MA)
- 52 Monaco (MC)
- 53 Moldova (MD)
- 54 Republic of Montenegro (ME)
- 55 Former Yugoslav Republic of Macedonia (MK)
- 56 Mongolia (MN)
- 57 Malta (MT)
- 58 Malawi (MW)
- 59 Mexico (MX)

- 60 Malaysia (MY)
- 61 Nicaragua (NI)
- 62 Netherlands (NL)
- 63 Norway (NO)
- 64 New Zealand (NZ)
- 65 OAPI (OA)
- 66 Panama (PA)
- 67 Peru (PE)
- 68 The Philippines (PH)
- 69 Poland (PL)
- 70 Portugal (PT)
- 71 Romania (RO)
- 72 Republic of Serbia (RS)
- 73 Russia (RU)
- 74 Sweden (SE)
- 75 Singapore (SG)
- 76 Slovenia (SI)
- 77 Slovakia (SK)
- 78 San Marino (SM)
- 79 Soviet Union (SU)
- 80 El Salvador (SV)
- 81 Tajikistan (TJ)
- 82 Turkey (TR)
- 83 Chinese Taipei (TW)
- 84 Ukraine (UA)
- 85 United States of America (US)
- 86 Uruguay (UY)
- 87 Viet Nam (VN)
- 88 World Intellectual Property Organization (WO)
- 89 Former Serbia and Montenegro (YU)
- 90 South Africa (ZA)
- 91 Zambia (ZM)
- 92 Zimbabwe (ZW)