

特許法調和の展望

Overview of Patent Law Harmonization Developments

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- I. Age of BIRPI (19th Century—1960)
- II. Age of United Nations (UNCTAD) – WIPO (1960—1985)
- III. Age of GATT/WTO – WIPO (1986—2000)
- IV. Age of Multiple Fora (After 2000)
 - ◆ 1. *Development*
 - ◆ 2. *Sustainable environment / genetic resources (GR) / traditional knowledge (TK)*
 - ◆ 3. *Public Health*
 - ◆ 4. *Substantive Patent Law Treaty (SPLT)*

I. Age of BIRPI (19th Century—1960)

● Establishment of Basic International IP Framework: Paris Convention

1873: The first international conference on industrial property right protection was held during the Vienna Expo; protection of the inventions exhibited at the Expo, restrictions on sanctions against non-working ;

1883: Adopted

1884: Came into effect with 11 member countries

BIRPI (United international Bureau for the Protection of Intellectual Property):
Established in 1893 and moved from Berne to Geneva in 1960

(Reference) Overview of Paris Convention Revisions

Diplomatic Conference	Venue	Main Subjects
1st in 1886	Rome	No substantial revision (No ratifications)
2nd in 1890-1891	Madrid	Madrid Agreement (International Registration of Marks, False Indications of Source)
3rd in 1897 & 1900	Brussels	Independence of Patent, Unfair Competition, Right of Priority, Mitigation of Sanctions against Failure to Work etc.)
4th in 1911	Washington D.C.	Utility Model, Right of Priority, Collective Marks
5th in 1925	the Hague	Indications of Source, Appellations of origin, Definition of Industrial Property, Right of Priority, Mitigation of Sanctions against Failure to Work etc. (The Hague Agreement)
6th in 1934	London	Right of Priority, Mitigation of Sanctions against Failure to Work etc.
7th in 1958	Lisbon	Service marks , Mitigation of Sanctions against Failure to Work etc. (Lisbon Agreement)
8th in 1967	Stockholm	Right of Priority based on Inventor's Certificate, Administrative Provisions (WIPO Convention)
9th in 1980-1984	Geneva and Nairobi	No revision (Appellations of Origin, Non-voluntary License , Developmental Provisions) (Nairobi Treaty)

Article 5

A. Patents: *Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses*

- A.
- (1) **Importation by the patentee** into the country where the patent has been granted of articles manufactured in any of the countries of the Union **shall not entail forfeiture of the patent.**
- (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the **abuses** which might result from the exercise of the exclusive rights conferred by the patent, **for example, failure to work.**
- (3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
- (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be **non-exclusive** and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

II. Age of United Nations (UNCTAD) – WIPO (1960—1985)

● The United Nations (UN)

General Assembly (1961): Cosponsored by Brazil and Colombia (Resolution based on “the role of patents in **technology transfer** to developing countries”)

UN Secretary General Report (1964): The role of patents in **technology transfer** to developing countries

Establishment of UNCTAD (1964): Resolution “**technology transfer**” (1972)

Joint report by the UN, WIPO and UNCTAD (1974): The role of patents in technology transfer to developing countries

The UN/UNCTAD

1. UNCTAD “Principles and Rules for the Control of Restrictive Business Practices” (1980)
2. UN draft of international code of conduct on **technology transfer** (1985, not adopted)

● WIPO

WIPO Convention (1967): Establishment of WIPO (1970): Objectives introduced (promoting protection)

PCT: Decided to discuss PCT (1966), adopted (1970); System of international application/search /preliminary examination; economic development of developing countries was advocated in its preamble and a provision of technical assistance to developing countries was introduced.

Made into specialized agencies related to the United Nations (1974) (Support of **technology transfer** was stipulated as a mission of WIPO.)

Coordination Committee/Paris Union Executive Committee (1974): Intergovernmental Experts Meeting was set to discuss revision of the Paris Convention.

Diplomatic conference on revision of the Paris Convention (Four sessions from 1980 to 1984) :Non-voluntary license clause, protection of geographical indications, etc. were negotiated without conclusion .

Negotiation of Patent Law Treaty: Started in 1984 with discussion of the grace period issue; Intergovernmental Experts Meeting was set in 1985.

Reference: WIPO's Missions

WIPO Convention (1967) Article 3

“The objectives of the Organization are:

- (i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization,
- (ii) to ensure administrative cooperation among the Unions.”

UN-WIPO Agreement (1974)

“The United Nations recognizes the World Intellectual Property Organization— as being responsible for taking appropriate action, *inter alia*, for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development ”

III. Age of GATT/WTO – WIPO (1986—2000)

- **GATT/WTO**

Punta Del Este Declaration (1986): Trade-related aspects of intellectual property rights; TRIPS Mid-term review (1989)

- **WIPO**

Negotiation of Patent Law Treaty: Diplomatic conference was held (1991) without leading to adoption.

- **WTO was established and TRIPS came into effect (1995):** Minimum protection level higher than that of Paris/Berne, most-favored-nation (MFN) clause, enforcement clause, dispute resolution clause; Also public interest exception (Article 27), development clause (Article 7, Objectives [promotion of technological innovation, contribution to transfer of technology], Article 8, Principles [protection of public interest, promotion of technology transfer], etc.)

- **WIPO**

The Patent Law Treaty (PLT, 2000): For harmonization of formality /procedure aspects of patent law, came into effect in April 2005.

IV. Age of GATT/WTO – WIPO (1986—2000)

< UN agency 国連機関 >

総会

- HRC(人権理事会)
- UNHCHR(OHCHR)(国連人権高等弁務官(事務所))
- UNDP(国連開発計画)
- UNEP(国連環境計画)/SCBD(生物多様性条約事務局)
- UNCITRAL(国連国際商取引法委員会)
- ECOSOC(経済社会理事会)
- UNPFII(国連先住民族問題常設会議)
- UNCSD(国連持続可能な開発委員会)

< UN specialized agencies 国連専門機関 >

- WIPO(世界知的所有権機関)
- UNESCO(国連教育科学文化機関)
- FAO(国連食料農業機関)
- IFAD(国際農業開発基金)
- WHO(世界保健機関)
- ITU(国際電気通信連合)
- UNIDO(国連工業開発機関)
- ILO(国際労働機関)
- WB(世界銀行)

< Non-UN agencies 非国連機関 >

- WTO(世界貿易機関; 前GATT)
- WCO(世界関税機構)
- UPOV(植物新品種保護国際同盟)
- INTERPOL/ICPO(国際刑事警察機構)
- HCCH(ヘーグ国際私法会議)
- OECD(経済協力開発機構)

< NGO 非政府機関 >

- ICANN(Internet Corporation For Assigned Names And Numbers)
- ISO(国際標準化機構)
- IEC(国際電気標準会議)
- IEEE(電気電子学会)

< Regional Fora 地域フォーラム >

- APEC(アジア太平洋経済協力)
- ASEM(アジア欧州会合)
- ASEAN(東南アジア諸国連合)
- SAARC(南アジア地域協力連合)等

< Other Fora その他域フォーラム、NGO >

- G8, Trilateral(三極)、Quinquelateral(五極)、FTA/EPA; AIPPI、ALAI、FICPI、INTA、ICC、MSF

1. Development

- UNITED NATIONS

Millennium Development Goals (MDGs)

The MDGs are eight goals to be achieved by 2015 that respond to the world's main development challenges. The MDGs are drawn from the actions and targets contained in the Millennium Declaration that was adopted by 189 nations-and signed by 147 heads of state and governments during the UN Millennium Summit in September 2000.

The 8 MDGs break down into 18 quantifiable targets that are measured by 48 indicators.

Goal 1. Eradicate extreme poverty and hunger

Goal 6. Combat HIV/AIDS, malaria and other diseases

Goal 7. Ensure environmental sustainability

Goal 8. Develop a global partnership for development

Target 12. Develop further an open, rule-based, predictable, non-discriminatory trading and financial system Includes a commitment to good governance, development, and poverty reduction — both nationally and internationally

1. Development (continued)

- **UNCTAD Sao Paulo Consensus** (2004): Right balance between **policy space** and international rule, research/study on development aspects of multilateral trade rules (intellectual property rights, trade and the environment, etc.)
- **ILO World Commission on the Social Dimension of Globalization** (2002): Suggested the importance of balancing the interest of technology producers and technology users in low-income countries, in the context of fair trade rule in global governance.
- **Report by the UN Secretary General** proposed "In Larger Freedom": development, security, and human rights for all" (Mar. 2005): Freedom from want (development) (fulfillment of the development-related commitment of the Doha round of the negotiations, etc.), Freedom from fear (peace and security), Freedom to live in dignity (rule of law and protection of the weak), strengthening the United Nations (reform of the UN organization)
- **UN Summit on the Millennium Declaration** (Sept. 2005): Expression of strong determination to realize the development goals including MDGs: Confirmation of the need for more effective ECOSOC as a major organization for coordination of economic/social development issues, policy review, policy dialogues, recommendations, and international development goals.
- **WTO Doha Ministerial Declaration** (2001): also called **"Doha Development Agenda"**; Recognized the urgent need for addressing the negative side of globalization (expanding gap, etc.), as symbolized by synchronized terrorist attacks, strengthening the WTO system for stable development of the world economy and integrating developing countries into the world trade system; Public health and CBD (mentioned above)-related issues in terms of intellectual property rights

TRIPS: AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Flexibilities
in the Agreement

- **Article 6**
Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 **nothing in this Agreement shall be used to address the issue of the exhaustion** of intellectual property rights.

- **Article 7**
Objectives

The protection and enforcement of intellectual property rights should **contribute to the promotion of technological innovation and to the transfer and dissemination of technology**, to the mutual advantage of producers and users of technological knowledge and in a manner **conducive to social and economic welfare**, and to a balance of rights and obligations.

- **Article 8**
Principles

1. **Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development**, provided that such measures are consistent with the provisions of this Agreement.
2. **Appropriate measures**, provided that they are consistent with the provisions of this Agreement, **may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.**

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, 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. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, 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.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is **necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment**, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

● *Article 30*

Exceptions to Rights Conferred

- Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use (7) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if, prior to such use, the proposed user has made **efforts to obtain authorization** from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. **This requirement may be waived** by a Member in the case of a **national emergency or other circumstances of extreme urgency or in cases of public non-commercial use**. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES [Back to top](#)

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example **exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing**, in the light of the relevant laws and regulations of that Member.

WIPO-- “WIPO Development Agenda”--

- Sept. -Oct., 2004: **WIPO General assembly**
Proposal by Argentina and Brazil to review the mission/governance of WIPO from the perspective of development promotion, create rules for development promotion, explore technology transfer/competition policy, etc
WIPO General Assembly decided:
 - (1) Inter-Sessional Intergovernmental Meeting (IIM) is held to discuss “WIPO development agenda proposal” by Argentina, Brazil, etc. as well as proposals from other member countries and a report was developed for consideration at the next General Assembly.
 - (2) WIPO Secretariat will start, together with UNCTAD, WHO, UNIDO, WTO, and others, to prepare for holding international seminars on intellectual property and development.
 - (3) The issue shall be included in the agenda of the next General Assembly.
- Apr. 11—13, 2005: The first session of **IIM**
- June 20—22, 2005: The second session of **IIM**: Proposal by Bahrain and other 10 countries
- July 20—22, 2005: The third session of **IIM** Proposal by African Group
- Sept.-Oct., 2005: **WIPO General Assembly** : Establishment of the Provisional Committee for follow-up of IIM discussions, conclusion and recommendation to the next General Assembly, during which PCIPD (Permanent Committee on Cooperation for Development related to Intellectual Property) ceases to exist.
- Feb. 20—24, 2006: First session of the Provisional Committee (Provisional Committee on Proposals Related to a WIPO Development Agenda, **PCDA**):
- June 26-30, 2006: The second session of **PCDA**
- Sept. -Oct., 2006 **WIPO General assembly**: Decided to hold two sessions of **PCDA**
- February 19-23, 2007: The third session of **PCDA**
- June 11-16, 2007: The Fourth session of **PCDA**
- Sept. -Oct., 2008: **WIPO General assembly**

Committee on Development and Intellectual Property

The mandate of the CDIP, as established by the General Assembly (document [A/43/16](#), page 135), is to:

- ✓ develop a work-program for implementation of the 45 agreed recommendations;
- ✓ monitor, assess, discuss and report on the implementation of all recommendations; and
- ✓ discuss IP and development related issues as agreed by the Committee, as well as those decided by the General Assembly.

The Committee reports and makes recommendations annually to the General Assembly.

WIPO Development agenda(excerpt)1 / 5

CLUSTERS

- A. Technical Assistance and Capacity Building
- B. Norm-Setting, Flexibilities, Public Policy and Public Domain
- C. Technology Transfer, Information and Communication Technology (ICT) and Access to Knowledge
- D. Assessments, Evaluation and Impact Studies
- E. Institutional Matters including Mandate and Governance
- F. Other Issues

WIPO Development agenda(excerpt)2/5

15. **Norm-setting activities** shall:

- be inclusive and member driven;
- take into account **different levels of development**;
- take into consideration a **balance between costs and benefits**;
- be a **participatory process**, which takes into consideration the interests and priorities of all WIPO Member States and the viewpoints of other stakeholders, including accredited inter-governmental organizations and non-governmental organizations; and
- be in line with the principle of neutrality of the WIPO Secretariat.

16. Consider the **preservation of the public domain** within WIPO's normative processes and deepen the analysis of the implications and benefits of a rich and accessible public domain.

- 17. In its activities, including norm setting, WIPO should take into account the **flexibilities in international IP agreements**, especially those which are of interest to developing countries and LDCs.
- 18. To **urge the IGC to accelerate the process** on the protection of genetic resources, traditional knowledge and folklore, without prejudice to any outcome, including the possible development of an international instrument or instruments.
- 19. To initiate discussions on how, within WIPO's mandate, **to further facilitate access to knowledge and technology** for developing countries and LDCs to foster creativity and innovation and to strengthen such existing activities within WIPO.

WIPO Development agenda(excerpt)4/5

- 20. To promote norm-setting activities related to IP that support a robust public domain in WIPO's Member States, including the possibility of preparing guidelines which could assist interested Member States in identifying subject matters that have fallen into the public domain within their respective jurisdictions.
- 21. WIPO shall conduct informal, open and balanced consultations, as appropriate, prior to any new norm setting activities, through a member-driven process, promoting the participation of experts from Member States, particularly developing countries and LDCs.
- 22. WIPO's norm setting activities should be supportive of the development goals agreed within the UN system, including those contained in the Millennium Declaration.²³

WIPO Development agenda(excerpt)5/5

- 23. The WIPO Secretariat, without prejudice to the outcome of Member States considerations, should **address** in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as: a) **safeguarding national implementation of intellectual property rules** b) **links between IP and competition** c) **IP-related transfer of technology** d) **potential flexibilities, exceptions and limitations for Member States** and e) **the possibility of additional special provisions for developing countries and LDCs.**
- 23. To **consider how to better promote pro-competitive IP licensing practices**, particularly with a view to fostering creativity, innovation and the transfer and dissemination of technology to interested countries, in particular developing countries and LDCs.
- 40. To request WIPO to intensify its **cooperation on IP related issues with UN agencies**, according to Member States' orientation, in particular UNCTAD, UNEP, **WHO**, UNIDO, UNESCO and other relevant international organizations, especially **WTO** in order to strengthen the coordination for maximum efficiency in undertaking development programs

2. Sustainable environment / genetic resources (GR) / traditional knowledge (TK)

- **WIPO:** Intergovernmental Committee (IGC, 2000), Standing Committee on the Law of Patents (SCP)/SPLT negotiation; International Dimension of GRTKF protection, GR(country of origin or source) disclosure requirements, etc.
- **WTO:** TRIPS Council examined relations between TRIPS and the Convention on Biological Diversity (CBD), TK as well as EoF; Examination of relations between the trade regimes and the environmental regimes (Doha Ministerial Declaration, 2001)
- **UNEP/SCBD** Establishment of a working group on Access and Benefit-sharing (ABS: exploration of an international certification system of country of origin and an international regime for benefit-sharing) and TK working group (2004); Bonn Guideline; COP8 (Mar. 2006, Agreement to complete work at the ABS working group by 2010 [COP10 in Nagoya]).
- **FAO:** ITPGRFA (International Treaty on Plant Genetic Resources for Food and Agriculture [tentative name]) was adopted in 2001 and entered into effect on June 29, 2004. It stipulates access method and benefit-sharing for major agricultural products assuming a multilateral system. IP clause and Farmers' rights clause were included.

3. Public Health

- **WTO:** Doha Ministerial Meeting “Declaration on TRIPS Agreement and Public Health (2001): Agreement on the interpretation of the Article 31(b) “National emergency”; Mandated TRIPs Council to consider easing the requirement of Article 31(f) “Producing exclusively for the domestic market,” General Council Agreement (Aug. 30, 2003; Dec. 6, 2005)
- **WHO:** Commission on Intellectual Property Rights, Innovation and Public Health (**CIPRH**) (established in 2003): Exploration of incentives for new drug development for developing countries /poor people(Report in Apr. 2006;
WHO General Assembly in May 2006: Establishment of "an intergovernmental working group open to all Member States to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission");
WHO General Assembly in May 2008: Adopted **WHA61.21** (24 May 2008) "Global strategy and plan of action on public health, innovation and IP"
- **WIPO:** Technical/law-development assistance for developing countries;
Start of Discussion at SCP

(Reference) WHO CIPIH REPORT (Examples of Issues of relevance to Intellectual Property) 1/2

1. The Deep Well of Discovery; Early Stage Research 初期段階の研究(探索)
 - Promotion of Research Tool Utilization リサーチツールの利用促進
 - Resort to Patent Pools パテントプールの利用
 - Experimental Use Exemption 試験研究の例外
 - Resort to Compulsory License (TRIPs) 強制実施権 (TRIPs) の利用
 - Licensing Policy of Developed Countries' Research Institutions (先進国) 研究機関のライセンシング・ポリシー
2. The Long Road from Discovery to Development 探索から開発へ
 - Transferable intellectual property rights 交換条件型知的財産権
 - Transferable fast-track review scheme 交換型優先医薬製造承認
 - Open source type Research オープンソース型研究手法
3. Delivery: Getting Products to Patents デリバリー
 - Resort to Compulsory License 強制実施権の活用
 - Promotion of Use of 2003.8 Agreement 2003. 8合意の利用促進策
 - Corporates' Policy on Patent and its Enforcement 企業の特許、権利行使政策
 - Transparency of Patent Information, Construction of Data Base 特許情報の透明性、データベース
 - Technology Transfer (Action in accordance with TRIPS Section 66.2 and Doha Declaration Para.7) 技術移転 (TRIPS 66. 2条、ドーハ宣言パラ7の行動)

(Reference) WHO CIPIH REPORT (Examples of Issues of relevance to Intellectual Property) 2/2

Parallel Import 並行輸入

Data Protection データ保護

FTA

Competition Laws 競争法

Promotion of Generics ジェネリック参入の推進

Pro-Competitive Examination Standard (to avoid barriers to legitimate competition, e.g. evergreening)

競争促進のための特許性審査基準 (Evergreening の防止)

4. Fostering Innovation in Developing Countries 革新強化

Fortification of Education (Access to Knowledge) 教育(知識へのアクセス)強化

Implementation of TRIPS Section 66.2 and Doha Declaration Para.2, including on Transfer Technology 技術移転(含む、TRIPS66. 2条、ドーハ宣言パラ7の遵守)

Improvement of Patent Examination (Collection of TK Information) 特許審査の質の向上 (TK情報の整備)

Objective of CBD CBDの目的

5. Towards A Sustainable Plan To Promote Innovation and Access 持続化計画

Global Plan to be launched by WHO, including for Fund Raising WHOによるグローバルプランの策定(資金確保)

Monitoring by WHO of IPR's Effects on Public Health WHOにより知財権の公衆衛生への影響を監視

Global strategy and plan of action on public health, innovation and IP(excerpt)

The Sixty-first World Health Assembly,

1. ADOPTS the global strategy and the agreed parts of the plan of action on public health, innovation and IP, attached to this resolution;

3. CALLS UPON relevant international organizations and other relevant stakeholders to give priority within their respective mandates and programmes to implementing the global strategy and plan of action on public health, innovation and IP;

4. REQUESTS the Director-General in implementing the global strategy and agreed parts of the plan of action without prejudice to the existing mandates:

(4) to finalize urgently the outstanding components of the plan of action, concerning timeframes, progress indicators and estimated funding needs, and to submit the final plan of action including the open paragraphs on stakeholders for consideration by the Sixty-second World Health Assembly through the Executive Board;

(5) to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action;

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(7) to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development, -----

(9) to include adequate resources in the forthcoming proposed programme budgets for effective implementation of the global strategy and plan of action on public health, innovation and IP;

(10) to monitor performance and progress in implementing the global strategy and plan of action on public health, innovation and IP, and to report progress to the Sixtythird World Health Assembly through the Executive Board, and subsequently every two years,
until the fulfilment of the time frame, to the Health Assembly, through the Executive Board.

5. Substantive Patent Law Treaty (SPLT) [WIPO] 1/2

- **Nov. 2000:** It was decided that SCP start deliberation of SPLT
- **May 2001—May 2004: SCP met in 5 to 10 sessions.** Focus was placed on easing the examination work load. Developing countries demanded the disclosure of genetic resources, etc. Japan, the US, and Europe proposed limitation to prior art, grace period, novelty, and inventive step only to lead to a deadlock.
- **Sep.—Oct. 2004 WIPO General Assembly:** US-Japan joint proposal could not gain agreement. Schedule of the next SCP was to be decided based on the DG informal consultations.
- **Feb. 16—17, 2005 SCP informal session (Casablanca Statement)**
 - (1) Prior art, grace period, inventive step and novelty to be discussed at SCP while sufficient disclosure and genetic resources at IGC simultaneously
 - (2) IIM to discuss the international development agenda to be held in Apr. 2005;
 - (3) Next SCP and IGC to discuss this session's agreement to be held in May and June 2005, respectively;
 - (4) Resolutions of the meetings including their timeframe to be sent to and discussed at the General Assembly in Sept. 2005;
 - (5) Brazil did not join the statement.
- **June 1—2, 2005 The 11th SCP**
 - (1) Developed countries supported the Casablanca Statement (joined by Morocco, Korea, and Sudan). Friends of Development (FoD), including Argentina, Brazil, and other 12 countries, opposed arguing that SPLT should include all of the clauses including public interest, technology transfer, and anticompetitive practice. China proposed that the disclosure of genetic resources should also be handled at SCP. No consensus was reached.
 - (2) Pakistan proposed that the impact of SPLT draft be evaluated jointly with UNCTAD.
 - (3) The Chair's Summary refer only to the facts of (1) and (2)
- **Sept.—Oct. 2005 WIPO General Assembly:** A three-day informal open session to be held during the first quarter of 2006; a proposal on the subject of discussion and speakers to be submitted by Nov.15. Consultation by the chair of WIPO General Assembly; WIPO Director General to announce the final program in Jan. 2006; Agreement on the SCP work program to be aimed at the three-day informal open session; Discussion based on the agreed work program to be made during the regular five-day session; Next year's work program to be decided at the 2006 WIPO General Assembly.
- **Mar. 1—3, 2006 Open forum on the SPLT draft**

Speech by 38 speakers and discussion on the purpose of SPLT, patent requirements, license, advanced technology (bio, software), public health, etc.

5. Substantive Patent Law Treaty (SPLT) [WIPO] (2/2)

- **Apr. 10—12, 2006** SPLT informal open session (opinions divided between developed countries and developing countries regarding the work program for the July session of SCP, leaving the issue to discussion at the September WIPO General Assembly). Some proposals discussed were:
 - ✓ Four items (1) Definition of prior art 2) Grace period 3) Novelty and 4) Inventive step) should be made the priority issues of SPLT (US, JP);
 - ✓ Total of 13 items should be discussed adding all nine issues proposed at the open forum : 1) Policy space for development and flexibility, 2) Exception to patentable subject matter, 3) Exception to patent rights, 4) Anticompetitive practice, 5) Genetic resource disclosure, PIC and benefit-sharing, 6) Effective means for opposition to the validity of a patent, 7) Sufficient disclosure, 8) Technology transfer, and 9) Other models to promote technological innovation (FD=Friends of Development).

- 特許制度の経済的影響 Economic impact of the patent system
- 技術移転 Transfer of technology
- 競争政策と反競争的慣行 Competition policy and anti-competitive practices
- 特許情報の普及流通 (含ライセンス登録) Dissemination of patent information (including the registration of licenses)
- 標準と特許 Standards and patent
- イノベーションの為の別のモデル Alternative models for innovation
- 実体的特許要件の基本的考え方の調和 (例えば従来技術、新規性、進歩性、産業上利用可能性、開示) Harmonization of basic notions of substantive patentability requirements (e.g. prior art, novelty, inventive step, industrial applicability, disclosure)
- 発明の開示 Disclosure of inventions
- 調査・審査報告書のデータベース Database on search and examination reports
- 異議制度 Opposition system
- 特許対象の例外 Exceptions from patentable subject matter
- 権利制限 Limitations to the rights
- リサーチの適用除外 Research exemption
- 強制実施件 Compulsory licenses
- クライアント・代理人間秘匿特権 Client-attorney privilege
- 特許と公衆衛生(含消尽、ドーハ宣言及びその他のWTO文書、パテントランドスケーピング) Patents and health (including exhaustion, the Doha Declaration and other WTO instruments, patent landscaping)
- 特許制度とCBDの関係(遺伝子源・伝統的知識・出所開示) Relationship between the patent system and the CBD (Geneticresources/Traditional knowledge/disclosure of origin)
- 特許と他の公共政策課題との関係 Relation of patents with other public policy issues

Group B's
priority

Thank You!