

# Making International Intellectual Property and Trade Regimes Work to Address the Health Response to COVID-19

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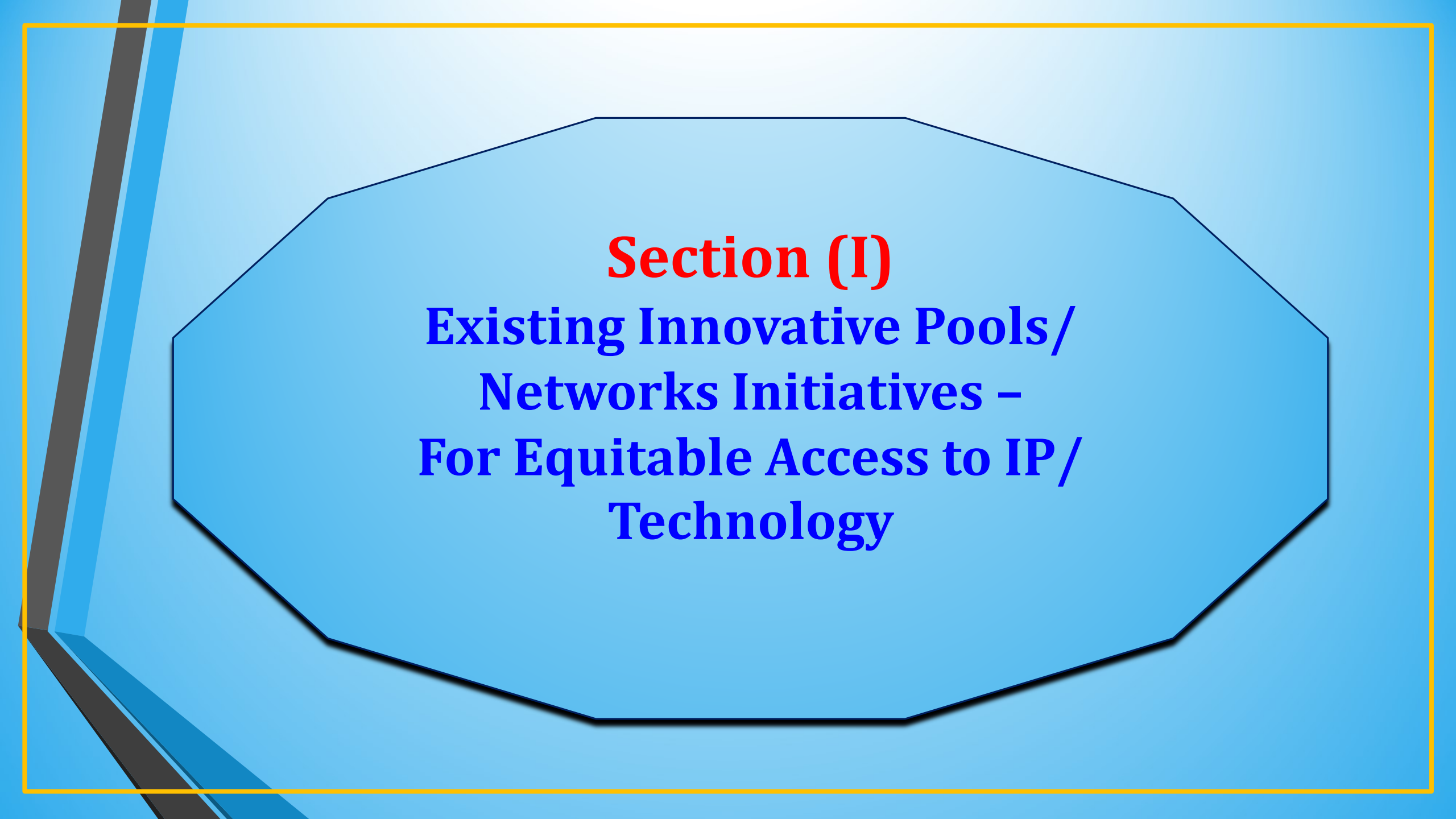
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**Section (I)**  
**Existing Innovative Pools/  
Networks Initiatives -  
For Equitable Access to IP/  
Technology**

## ❖ **COVID-19 Technology Access Framework** **(University level)**

- ❑ Harvard University, Massachusetts Institute of Technology, and Stanford University (10+ Universities) Correll, Ohio, Oregon, Maryland, Yale etc.
- ❑ Involves rapidly executable non-exclusive royalty-free licenses to intellectual property rights that they have the right to license, for the purpose of making/ distributing products related to COVID-19 infection during the pandemic and for a short period thereafter.
- ❑ In return Assurance- Commitment to distribute the resulting products as widely as possible and at a low cost that allows broad accessibility during the term of the license.

## ❖ **Covid-19 Therapeutics Accelerator** **(Manufacturers and Funding Agencies)**

- ❑ At least 15 large companies (Novartis, Eli Lilly, Gilead, GlaxoSmith, Pfizer, Sanofi and Merck KGaA) agreed to share proprietary information.
- ❑ Initiated by the Gates Foundation, Well-come Trust and Mastercard, to tackle the pandemic.
- ❑ Sharing proprietary information (drugs, and vaccines). To tackle the pandemic

## ❖ **Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) (Government Research Institutions /Regulatory Agency/Manufacturers)**

- ❑ The National Institutes of Health (NIH) has created a partnership with the U.S. Food and Drug Agency (FDA), the European Medicines Agency (EMA)
- ❑ 16 leading pharmaceutical companies (Merck, AbbVie, Johnson & Johnson and Pfizer) have joined them.
- ❑ It does not specifically discuss intellectual property rights, but establishes among other cooperative efforts “a centralized process and repository for harmonizing and sharing methods and evaluating models.”

## ❖ Disease-directed Patent Pools :

### ❑ **Pool for Open Innovation against Neglected Tropical Diseases**

Initiated by GlaxoSmithKline (GSK), which is referred to as the BIO Ventures for Global Health (BVGH) pool.

## ❖ Disease-directed Patent Pools (contd...) :

### ❑ Medicines Patent Pool (MPP)

Initiated by UNITAID. According to MPP, they negotiate with patent holders for licenses on life-saving medicines and the licenses permit multiple manufacturers to produce and distribute generic versions of patented medicines in developing countries. The MPP licenses also provide the freedom to develop new treatments such as fixed-dose combinations – single pills composed of several medicines – and special formulations for children.

## ❖ Disease-directed Patent Pools (contd....) :

□ **In mid-May 2020, the World Health Organization embraced a proposal to create a voluntary pool**

To collect patent rights, regulatory test data, and other information that could be shared for developing drugs, vaccines, and diagnostics for COVID-19. However, recent comments from at least some pharma industry players suggest resistance to the idea of a COVID-19 patent pool.



## **Section (II)**

**Realistic Innovative Propositions/  
Suggestions for ensuring  
implementation of International  
IPR framework/Policy for rapid  
health response to COVID 19 public  
health crisis :**

## 1) Patent Pooling would be feasible / realistic and beneficial in following Scenarios :

✓ **Scenario-1** : If it is pertaining to an IP barrier (common IP issue) related to aspect utilized for any type of COVID-19 vaccine, irrespective of type of platform technology.

■ For instance, Green Fluorescent Protein (mNeonGreen) infringement suit filed by Allele Biotechnology against Pfizer alleging that Pfizer's COVID 19 vaccine uses said GFP & has not taken any license from Allele.

■ Same could be applicable to formulation stabilizers providing thermal stability , adjuvants , delivery devices etc.

■ If such common supplementary/allied technology(s) are identified across globe, same can be made available under patent pool.

## 1. Patent Pooling would be feasible / realistic and beneficial in following Scenarios (*contd...*) :

- ✓ **Scenario-2** : If the innovation necessitates use of multiple complementary inventions owned by different parties it will be even more difficult, time consuming, and very expensive to negotiate with possibly tens of patent owners for separate licenses. These pools can be tied with simplified terms that are considered “fair, reasonable and nondiscriminatory (F/RAND)”

**1) Patent Pooling would be feasible / realistic and beneficial in following Scenarios (contd....) :**

***Pools should be for technology/know how (in addition to patents) -***

*Since even if technology developers don't file patents, Still know-how transfer would be charged by developer! Thus unless actual technology /process is shared, manufacturing efficacious vaccines will still remain uphill task.*

## 2) Delaying the IP/Patent Enforcement :

A recent initiative of scientists and lawyers has launched the Open COVID Pledge ([www.opencovidpledge.org](http://www.opencovidpledge.org)) *calling IP owners to not assert relevant IP during the crisis until one year after the WHO declares the pandemic to be over.*

- Later also, a voluntary, amicable low cost license fee can be sought by both party(s).
- This will also ensure that patents covering vaccines will not have to face validity challenges, acquisitions and Compulsory License decisions.
- Perhaps the only workable “blanket pledge” could be a field-specific free license to a COVID-19 vaccine without time limitations.

### **3) Framework for Resolving IP Conflicts /Infringements (if any) that may emerge near/post launch of COVID Vaccines**

**A) Create a “Global Single Special Patent Court for Pandemic purposes”** (mediated by WIPO) that will be responsible for hearing all patent infringement matters pertaining to such types of emergency vaccines (COVID), the board of such court shall comprise of panel of 4 Judges (from USA, European, Indian, African patent courts/patent offices). Even if infringement is found, damages would be nominal, along with some basic license fee.

### 3) Framework for Resolving IP Conflicts/ Infringements (if any) that may emerge near/post launch of COVID Vaccines (contd....)

B) **Collaboration/Cross Licensing** Future (or pending) IP infringement suits can be addressed amicably upfront such that Patent holder agrees not to file any infringement suit, provided prospective infringing party gives a royalty free license to *non-COVID* potential next generation vaccine product technology of patent holder's interest (Cross Licensing). Secondly prospective infringing party can engage in a suitable collaboration for non-COVID potential next generation vaccine product technology of patent holder's interest.

**4) How do we compensate the technology developers/IP holders for their COVID related patent/technology pooling, IP non-enforcement & other good gestures :**

WIPO(#) can issue recommendations to all 152 plus countries (that come under WIPO umbrella) to grant patents related to *non-COVID* potential next generation vaccine products of their choice that too with a waiver of global filing/examination/ maintenance fees.



## 5) What Individual Country Level /Governments can do ?

### **Indemnity against infringement-**

- ✓ Governments of respective countries offering indemnity against IP infringement proceedings.
- ✓ For instance, recent notice of declaration published by the US Department of Health and Human Services under the Public Readiness & Emergency Preparedness (PREP) Act, conferring immunity from tort litigation for those engaging in acts related to COVID-19 countermeasures, also grants indemnity against patent infringement liability for third parties that use health technologies in relation to COVID-19.
- ✓ Though this interpretation has not been tested out in a court of law, this suggests that countries can adopt specific legislation suspending the enforcement of IP rights.

## **6) Voluntary Licensing Still remains a win-win situation :**

- Voluntary licenses (VLs) are a mechanism for patent holders to *voluntarily* allow other parties to exploit their patents. VLs have been applied to several discoveries in biotechnology, genetics and, lately, to patented products repurposed for COVID-19.
- For instance for Efficacious COVID-19 vaccines provided by mRNA, VL should be preferred for Viral Vector (Adeno, Measles), Live Attenuated, Inactivated platforms.

## **6) Voluntary Licensing Still remains a win-win situation (*contd....*) :**

➤ We suggest especially for COVID-19 /pandemic, the most preferred approach would be WHO/WTO foremost seeking voluntary licensing for aforementioned technology(s) *from* Patent/ Technology/Know How owners *to* interested vaccine manufacturers. Secondly, if Patent/ Technology/Know How owners disagree or deny such voluntary licensing, then utilize emergency provisions in all countries to immediately issue compulsory licensing for such patents.

**(#Note- As the agency within the United Nations system responsible for IP services, policy, information and cooperation, WIPO is well equipped to address the issues arising for IP and innovation, with expertise and experience in the policy, economic and legal aspects of IP dating from its foundation in the 19th Century)**

