

# Report to the The General Assembly on Public Health, Innovation, and Intellectual Property

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On the 19 to 22 of November, Member States and Observing Bodies present at the World Health Assembly discussed the topic of Public Health, Innovation, and Intellectual Property.

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The World Health Assembly discussed three major topics within the main area of consideration, including Past Documents, Intellectual Property, and Development,
Distribution, and Research. One resolution, Resolution I/1, was passed by the body. Draft Resolution I/2 was considered by the body, but failed when brought the floor for a vote.
In addition, the Assembly discussed and recommended the consideration of Draft Resolution I/3.

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14 The first chapter of this report addresses the resolutions mentioned above. Draft 15 Resolution I/1 called for a high level discussion of human resource development programs to facilitate monitoring the distribution of medicine. Draft Resolution I/2 16 addresses development, research, and distribution incentives that would bring together 17 public and private sectors as well as developed and developing nations to solve the public 18 goods problem of research and development, the uncertainty of the process, and avoid 19 market exclusivity. The Draft Resolution I/3 attempts to strengthen the health 20 administrative capacity of the United Nations, as well as international actions and actions 21 22 taken within individual countries.

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The second chapter deliberates the three subtopics. Past documents discussed the previous actions and publications concerning the topic of Public Health, Innovation, and Intellectual Property. The section on Intellectual Property addressed international law, extended patent licensing, compulsory licensing, and patent pools. The final subtopic of Development, Distribution, and Research focuses on initiatives to promote new research and methods of creating and distributing health care services to developing and developed countries.

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The third chapter explains the decisions adopted by the Assembly at the 2011 session, including Draft resolution I/1.

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35 The final chapter details the acceptance of this report, which was adopted by consensus

36 37	Chapter I
38 39	Matters calling for action by the General Assembly or brought to its attention
40 41	Section A: Draft resolutions for adoption by the General Assembly
42 43 44	The World Health Assembly recommends to the General Assembly the adoption of the following draft resolutions:
45	Draft Resolution I/1
46 47 48	SUBJECT OF RESOLUTION: Public health, innovation and intellectual property: global strategy and plan for action
50	SUBMITTED TO: The General Assembly
52	The General Assembly,
54 55 56	<i>Recalling</i> previous resolution WHA 62.16 on adoption in the final plan of action on specific actions, stakeholders and time frames,
57 58 59	<i>Reaffirming</i> the eight elements of global strategy in resolution WHA 61.21 on global strategy and plan of action on public health, innovation and intellectual property,
60 61 62	<i>Recognizing</i> the implementation of The African Network for Drugs and Diagnostics Innovation,
63 64 65	Welcoming development of the Quick Start Programme for instantaneous execution of action items in the global strategy,
66 67 68	1. <i>Notes</i> that effective usage of advanced drugs is highly dependent on distribution and education by local medical staffs;
69 70 71 72	2. <i>Recommends</i> the implementation of factsheets into the global action plan in order to create guidelines for effective use of drugs to medical staffs in developing nations;
73 74 75 76	3. <i>Draws the attention</i> to the importance of having fully-informed and well-educated medical staffs such as physicians, nurses, and midwives in the rural areas of developing countries;
77 78 79 80	4. <i>Expresses its hope</i> for the inclusion of promoting human resource development plans of action as an element of the global strategy and plan of action in order to maintain domestic knowledge and talent to provide care to under-served regional populations;
81 82	5. <i>Calls</i> for high-level discussions on the subject of generating human resource development programs in health workforces and medical staffs in rural areas;

83 84	6. <i>Encourages</i> all developed nations to share technologies and medical
85 86 87	intelligence which enhances human resources development programs of developing nations;
88 89 90	7. <i>Urges</i> all developing nations to support developed nations assistance in terms of providing resources and cooperation such a way as to make developed nations' efforts effective;
92 93 94 95 96	8. <i>Encourages</i> Member States to develop exchange programs for health professional students and practitioners as well as those working for multinational healthcare corporations between developing and developed nations in order to improve knowledge and skill distribution;
97 98 99 100 101	9. <i>Affirms</i> the importance of access to technological advances in the improvement of medical practice and treatment by the efficient and timely sharing and transfer of medical advances to nation-states without regular access to such developments in treatments, procedures, and products.
102 103	Passed, Yes: 63 / No: 1 / Abstain: 14
104 105	Draft Resolution I/2
106 107	SUBJECT OF RESOLUTION: Public health, innovation and intellectual property: global strategy and plan for action
109	SUBMITTED TO: The General Assembly
111	The General Assembly,
113 114 115	<i>Recalling</i> the report of the Commission on Intellectual Property Rights, Innovation, and Public Health, its ideas, and the wide range of issues and policy options,
116 117 118 119	<i>Recognizing</i> known market failures such as the public goods of pharmaceutical research and development, uncertainty of the research and development process and asymmetrical information from buyers and sellers of drugs,
120 121 122 123 124	<i>Realizing</i> that if left alone, markets will not provide knowledge in the necessary quantities, in that a company incurring the initial cost of generating knowledge is unable to recoup this cost, as competitors may utilize the open source creator's efforts once the knowledge is made public,
125 126 127 128	<i>Realizing further</i> that at the time of discovery of a promising compound, it is uncertain whether that promise will turn into a marketable product and that no insurance markets exist that would protect firms against the risk that promising products will not

Acknowledging that pharmaceutical products fall into a class of goods economists call experience goods, meaning that by observation alone, patients cannot tell whether different products will cure their ailments,

Recognizing three types of diseases of the following categories which are Type I diseases - those diseases in which a large number of vulnerable populations are in both wealthy and poor countries (i.e. measles, hepatitis B, diabetes, cardiovascular disease and tobacco related illnesses), Type II diseases - those diseases in which poor countries account for the majority of cases (i.e. HIV/AIDS and tuberculosis), and Type III diseases - those diseases which are exclusive to poor countries (i.e. African trypanosomiasis and onchocerciasis),

Acknowledging further that discriminatory prices in countries with the highest demand elasticity may still be far above marginal costs and the poorest sectors of society may still not have access to patented medicines, additionally, there are no guarantees that demand elasticities correlate negatively with per capita income,

*Acknowledging further* that prices for patented pharmaceuticals do not appear to correlate with per capita incomes,

Realizing that the apparent lack of per capita income-oriented discriminatory pricing in private markets may reflect that demand conditions are such that the companies' profit-maximizing strategy is to always focus on most with a higher socio-economic status as well as measurement problems, government price controls and imperfect market segmentation,

*Recognizing* the numerous benefits of patent extensions in both developed and developing nations,

- 1) *Promotes* the development of medicines while continuing to promote research and development, innovation and broaden access to medicines through:
  - (a) Publicly funded research institutions may enter into collaborative agreements with private pharmaceutical companies for the development of treatments against a certain disease;
    - (b) Public-private partnerships (PPPs) may still involve the patenting of research outputs, but up-front contractual arrangements can provide for the distribution of medicines at preferential or cost-based prices to low income countries;
    - (c) Governments and aid agencies may make advance commitments on minimum purchases for new vaccines or drug treatments that meet certain predefined standards in order to reduce the uncertainty about future demand and thereby lowering the risk of research and favor drug access in developing countries;
    - (d) Governments may create incentives which reward private companies for inventing drug treatments that are of benefit to society, releasing their inventions to the free public in return in order to broaden access to drugs and reduce distribution inefficiencies;

177 178 179	(e) Respond to additional public health challenges with highly trained personnel, sophisticated information and up-to-date systems;
180 181 182	2) <i>Encourages</i> Member States to consider offering patent extensions to companies in exchange for the development of specific beneficial technology for developing nations.
183 184	Failed, Yes:12 / No: 42 / Abstain: 30
185	Draft Resolution I/3
186	Dian Resolution 1/5
187 188	SUBJECT OF RESOLUTION: Public health, innovation and intellectual property: global strategy and plan for action
190	SUBMITTED TO: The General Assembly
192	The General Assembly,
194 195 196	Fully aware that comprehensive public data can greatly benefit the quality of healthcare and administration,
197	Recognizing the need for qualified individuals in the successful running of
198 199	healthcare systems within Member States,
200 201	Reaffirming the contributions of Non-Governmental Organizations (NGOs) towards ameliorating deficiencies in healthcare systems,
<ul><li>202</li><li>203</li><li>204</li><li>205</li></ul>	<i>Taking note</i> that the condition of healthcare systems is a matter of international concern that spans multiple United Nations bodies and Intergovernmental Organizations,
206 207	1. <i>Promotes</i> the use of data banks in order to compile successful strategies regarding health infrastructure and policy;
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209	2. <i>Urges</i> the World Health Organization (WHO) to run various professional
210	development workshops for health industry and policy officials from several nations
211	including:
212 213	<ul> <li>a. Individuals in health related fields such as doctors, lawyers, and government officials;</li> </ul>
213 214	b. Workshops designed to educate its participants in various healthcare
214	systems, policies, and solutions that could be tailored to meet an individual
216	country's needs;
217	country 5 needs,
218	3. <i>Recommends</i> that the WHO act as a body to further communication between
219	member states for the purpose of increasing capacity on a governing and administrative
220	level, while not ignoring primary care;
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222	4. Further requests that the WHO act as a coordinator for various healthcare
223	NGOs in order to reduce the overlap of complimentary functions:

224	a. This is a voluntary arrangement, as NGOs may opt in or out at any
225	point;
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227	5. <i>Expresses</i> its hope that the Annual Ministerial Review of the Economic and
228	Social Council consider the discussion of strengthening healthcare and administrative
229	capacity, specifically within the context of:
230	a. Innovation and Intellectual Property Rights of Public Health;
231	b. Prevention and Control of NCDs, as it pertains to a global strategy.
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# **Chapter II**

# Consideration of Public Health, Innovation, and Intellectual Property

In its 2011 session, the World Health Assembly considered the issues of public health, innovation, and intellectual property. Many issues were considered, including but not limited to: international patent law, property rights, and the development and distribution of pharmaceuticals.

### A: Deliberations

Issues discussed in this assembly were related to International Patent Law and Development, Distribution, and Research of technology concerning drugs. Specifically, the subcommittee of International Patent Law discussed the role of patents and their relationship with providing access to affordable drugs. Member States and Observing Bodies discussed the possibility of implementing an international patent law, extending patent licensing, compulsory licensing, and patent pools. Various proposals offered by developing and developed nations were also examined and the potential for solutions based on compromise was heavily considered. The subcommittee of Research and Development discussed transferring technology and possible incentives for doing so. Options for training medical personnel were offered in developing nations, while providing both centralized and decentralized approaches to the issue.

This topic is especially important to the World Health Assembly (WHA) because of the recognized difficulties regarding intellectual property rights. The WHA is also aware of the need to better facilitate the distribution of drugs throughout the world and the importance of making drugs available and affordable to meet the needs of the developing nations. Current patent laws, however, can lead to innovation being concentrated in the developed world where the markets are more profitable, thus the WHA sought to address this issue in the developing world. Simultaneously, however, the WHA also notes the significance of encouraging innovation and recognizes that intellectual property rights encourage companies to create new medicine and treatments by confirming that they will be able to profit as a result of their research. Several Member states recommended that developers lose incentive to work in areas that do not have appropriate patent laws.

The body found that situations around the globe mandate the need for greater access to a variety of medicines; 90% of the mortality from communicable diseases occurs in the developing world. Nearly 4.8 billion people live in developing countries, making up about 70% of the world's population. The World Health Assembly is working toward solutions that recognize patent laws as an important tool to encourage innovation, and also to balance these solutions with the need to make medicine available in the developing world.

Representatives found that new rules were needed to ensure that all people had access to the health care they need, despite the potential difficulties in adopting new legislation. One chief concern was that there are many prerequisites for developing countries to apply for a compulsory licensing that would only apply under certain conditions.

 Another important topic examined within this committee was whether a decentralized or centralized approach would be most appropriate for the Global Strategy and Plan of Action. A decentralized approach is the process of giving more decision-making power to the individual states rather than governing body. This relies on more lateral relationships and a wider span of control. This approach is often favored by those who have concerns over access to resources and funding. On the other hand, the centralized approach is defined as the process by which the planning and decision-making power is concentrated within a particular group. This implies more of a chain of command system and is most likely favored by countries who are concerned with keeping innovation potentially prosperous and maintaining central control.

#### I. Past Documents

For consideration of Public Health, Innovation, and Intellectual Property, the Assembly had before it the following documents:

(a) The 1948 Universal Declaration of Human Rights states that everyone deserves the right to health;

(b) The 1995 agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) addresses standards, enforcement, and dispute resolution for the protection of intellectual property rights for all member states and the importance that all states have in assisting with combating disease;

(c) The 2001 Doha Ministerial Declaration ensures compulsory licensing and aid for medical emergency;

(d) The 2011 World Intellectual Property Organization (WIPO) development agenda which discusses issues of technology transfer and norm-setting flexibilities in public policy;

(e) The report of the Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH) establishes the current Strategy and Plan of Action (WHA 61.21). This defines what governments and companies should do to help protect intellectual property rights, but at the same time help people in developing countries who need the information contained within patents;

(f) The 2008 World Trade Organization (WTO) report on Compulsory Licensing examines whether these licenses actually assisted with health problems within developing countries.

# II. Intellectual Property

It is clear that patents must play some role in protecting intellectual property and providing proper incentives for corporations to operate within the borders of developing nations. This discussion concerns international patent law, extended patent licensing, compulsory licensing, and patent pools, all of which must be considered in order to clearly define to what extent patents affect the deliberations. When discussing these issues, many Member States and Observing Bodies who identified themselves as developing nations stressed access to medicine over specific regulations. Several other Member States who identified themselves as developed nations, understood the imbalance of healthcare between developed and undeveloped nations, and attempted to account for considerations of both groups.

### 1. International Law

 Representatives from present Member States and Observing Bodies agreed that the World Health Organization and other UN organs should be responsible for developing a set of international standards regarding patent law. All delegations believed that the integrity of patent law should be respected through these recommendations. However, multiple approaches were taken in terms of enforcing these ideals. Most developed nations supported enforcement of patent laws on a global level. However, fearing loss of national sovereignty, most developing nations were in favor of national enforcement, so each country could choose to adapt the developed standards as they see appropriate.

# 2. Extended Patent Licensing

It was agreed that some form of incentive is necessary for corporations, especially those from developed nations, to be encouraged to develop and market drugs within developing states. One idea proposed was that of extending patent licensing. Should a corporation develop and sell a specific drug within the borders of a developing nation, it would receive control of a patent for a longer period of time. Disagreement regarding the merits of this system arose mostly between developed and developing nations. Developed nations, barring Spain and the US, were generally inclined to support the extension of patent licenses, as the corporations that would receive these extensions would generally be from these nations. Some of these delegations argued that the increased revenue gained by these corporations would be used to further fund research.

Most developing nations, with the support of Spain, the United States, and the Arab bloc, were in opposition to the extension of patent licenses as incentives. These delegations felt that extended patents would encourage increased prices and monopolization of certain drugs and also believed that competition and development of generic drugs would be negatively restricted. Spain in particular presented that should a Member State decide top use the extension of patent licensing as an incentive to encourage research and development, that those Member States do so as a conditional and temporary measure. In cases of emergency, Spain would also recommend the suspension of patents in order to allow the production of the necessary pharmaceuticals.

## 3. Compulsory Licensing

Compulsory licensing was the most contentious issue of debate. As defined by the World

Trade Organization, "compulsory licensing is when a government allows someone else to produce the patented product or license without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property - the TRIPS (Trade-Related Aspects of Intellectual Property Rights)." Nations producing patented products would be restricted to marketing these within their own borders, and not internationally. This would encourage corporations to sell their goods at lower, more affordable rates, and would allow developing nations to purchase drugs at economically feasible levels. The supporting opinion was echoed by most Latin American and Asian countries, who believed that this would lead to affordable sources of medication for their peoples. Nations from the European Union (EU) and North American nations were also in support of compulsory licensing, and suggested that corporations be allowed to decide whether to permit such actions or not. These nations believed that compulsory licensing would allow for financially unstable or developing nations to access the medical drugs they need at an affordable rate. Additionally, the present EU nations supported compulsory licensing, especially in situations of epidemics or other such emergencies. Nations such as Chile and China, however, voiced strong opposition to compulsory licensing, on the basis that they valued the intellectual property of their corporations. A third intermediary stance was taken by nations of the Arab and African blocs, who would want the ability not only to produce generic pharmaceuticals on their own, but also market them internationally in the future.

4. Patent Pool

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The creation of an international patent pool or database was advocated almost unequivocally by all delegations present. This patent pool would serve as a source of information regarding various patents. Should oversight of this be required, it was recommended by the African bloc that a committee made up of WHA members, corporate representatives, and NGO representatives do so. The purpose of the patent pool would be to allow various corporations in both the developed and developing world to share vital information contained within patents. The committee stressed that this would not violate patent law; corporations would be able to access the content of patents but not use this information without the appropriate approval. If a company desired to use technology represented within a patent, it would be able to develop a new patent in conjunction with the original patent-holder, thus providing incentive for collaboration between both parties. This would allow increased research, so various companies may work together towards a common goal. Representatives agreed that this patent pool would provide a forum for cooperation between various corporations, with the intent of developing new innovations to benefit all countries involved. This idea was especially advocated by signatories of the TRIPS agreement<sup>1</sup>.

Some nations voiced their concerns regarding the security of the information included within this pool. Nations within the African bloc see a lack of adequate incentive as a possible limitation to the patent pool. These delegations strongly stress public ownership of intellectual property.

III. Development, Distribution, and Research

Members of the WHA expressed their concern for the current inefficiency of technological advances, medical practices, and treatments. Representatives discussed ideas for international communications to expand and greater facilitate transfers of technology. It was recommended that developed nations should offer medical equipment, support, and training to developing nations in order to increase standards. Transfers of technology authorized through the TRIPS agreement and the Doha Declaration<sup>2</sup> promote access to medicines for all, encouraging the provisions on assistance to developing nations. More specifically, representatives mentioned the utilization of the PLOS (Public Library of Science) as a database for collaboration of medical literature and research that makes information publicly accessible and available on a regional level. Discussing further, representatives recommended strengthening existing programs for medical staff and pharmaceutical practitioners. To do so, representatives encourage all developed nations to share technologies, medical intelligence and advancements with all nations independent and otherwise. Representatives note that inexpensive, efficient, and culturally sensitive programs should be implemented to assist education regarding public health. Programs considered included the dissemination of voluntary medical and pharmaceutical engineers, the education of midwives in rural areas, strengthening student exchange plans, and the promotion of basic medical information through community directors and religious and civil organizations.

Member States and Observing Bodies agreed that the education and training of medical personnel is essential to further sustain public health of developing nations and regions. This will strengthen the social and academic community in nations throughout the world. Representatives suggested the training of midwives in medicinal applications and maternal consulting. This agenda supports efficient and inexpensive means to aid citizens of all nations. Representatives note that effective usage of advanced drugs is highly dependent on distribution and education by local medical staffs. The development of exchange programs for health professionals, corporate workers, students, and practitioners was advocated in order to improve knowledge and skill distribution.

Nations stressed that pharmaceutical companies should be driven by research-oriented goals rather than market-driven ideas. Many developing nations suggested further research regarding their most pressing issues, including exploration of the specific costs of research, development, and technology transfer, so that corporations would have an accurate estimate of necessary costs.

Representatives shared concerns regarding cooperation among developed and developing nations, and urged all nations to implement an efficient global strategy. Furthermore, representatives recommend implementing incentive programs to elevate research and development. Possible initiatives included a tax levy on airline tickets, where this excess money is used to finance research for the developing world. This initiative is already supported by many countries in the EU and African Union (AU). Nations also stressed that the high demand for drugs in developing countries should entice corporations to market their pharmaceuticals within these borders. Representatives also discussed the role of mass media in the distribution of knowledge and basic medical information. It was recommended that Member States participate in a tailored and culturally sensitive mass

<sup>2</sup> World Health Organization, 2001.

media campaign that is managed through a separate entity, not correlated with government or religious organizations. Representatives suggested using civil methods to promote public health including but not limited to community directors and civil and religious organizations.

However, the Arab bloc expressed its concerns about the incentives proposed to keep drug manufacturing corporations in developing nations. These nations were concerned about possible violations of labor rights by these corporations. Many of the citizens in developing nations are impoverished, and there is concern that these corporations may be able to exploit them for cheap labor, as part of the production process would be expected to take part in the host state. The Arab bloc and numerous Middle-Eastern and Central-Asian States believe that any incentives given to drug manufacturing corporations to produce in developing nations should be in the form of tax breaks and other incentives. The drug manufacturing corporations should also be held to the highest standards of conduct regarding the labor regulations in the host countries. Further dissent regarding distribution, development, and research was voiced by the African bloc, who sought to increase utilization of medical services by decreasing consultation fees and drug prices, possibly through exemption programs.

In order to foster a more robust pharmaceutical industry in developing countries, it was recommended by the body that developed countries should work in partnerships to improve current standards. This recommendation would sustain nations' independence, stimulate their economy, and extinguish dependence on aid from developed countries in the long term. Member States and Observing bodies of the World Health Assembly strongly encourage high-level discussions on this subject and research, development, and affirm that distribution can be enhanced on a global scale.

#### Chapter III.

## Decisions adopted by the Assembly at its 2011 session

The World Health Assembly adopted Resolution I/1 on Public health, innovation and intellectual property: global strategy and plan for action by a vote of: Yes: 63 / No: 1 / Abstain: 14, and therefore recomends its adoption by the General Assembly.

- 531 The World Health Assembly also adopted this report on Public health, innovation and
- 532 intellectual property: global strategy and plan for action by consensus with 0 abstentions,
- and therefore recomends its consideration by the General Assembly.