

## ITSSD Response to the Draft Global Strategy and Plan of Action

Submitted: September 30, 2007

### *Focus (par. 1)*

The ‘Focus’ section of the DGSPA inexplicably expands the number of ‘developing country diseases’ that new drugs, treatments and therapies to be created under the Draft Global Strategy and Plan of Action (DGSPA) would target. The CIPIH previously focused primarily on encouraging developing country exercise of the TRIPS ‘flexibilities’ allegedly recognized by WTO members within the Doha Declaration on the TRIPS Agreement and Public Health. As your committee members are well aware, that ministerial document was expressly intended to respond *only* to three diseases - namely “HIV/AIDS, tuberculosis and malaria [-] and other epidemics... afflicting many developing and least-developed countries”.<sup>1</sup> WHA 59.24, which serves as the basis for this DGSPA, subtly adopted an expanded interpretation of this statement as its core mandate and focus – to secure “needs-driven essential health research and development relevant to *diseases that disproportionately affect developing countries*”. This phraseology is now contained within paragraph 1.2 of the DGSPA.<sup>2</sup>

The effort of the IGWG to expand the number of diseases potentially falling within the TRIPS ‘flexibilities’ is immediately recognizable within the first paragraph of the DGSPA, entitled ‘Context’.

Reducing the very high incidence of communicable diseases in those countries is an overriding priority. At the same time, it is important to ensure that the increasing prevalence of *noncommunicable* diseases in those countries is recognized and addressed.<sup>3</sup>

Consequently, it is no surprise that the first footnote within the DGSPA’s ‘Focus’ section adds 12 *additional* diseases beyond the 3 mentioned above, some of which are communicable and others which are not.<sup>4</sup> In particular, given the IGWG’s categorizing of cardiovascular disease as a disease

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<sup>1</sup> “We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” See “Declaration on the TRIPS Agreement and Public Health”, WT/MIN(01)/DEC/2 (Nov. 20, 2001), at par. 1, at: [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>2</sup> “(1.2) facilitating upstream research on new and existing products for diseases that disproportionately affect developing countries”. See “Element 1. Prioritizing research and development needs”, “Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property”, Intergovernmental Working Group on Public Health, Innovation and Intellectual Property A/PHI/IGWG/2/2 (July 31, 2007) (hereinafter referred to as ‘DGSPA’), Annex at p. 4.

<sup>3</sup> *Id.*, Annex at par. 1, p. 3.

<sup>4</sup> “... The Commission highlighted the need to focus on Type II and Type III diseases and the needs of developing countries in relation to Type I diseases. [FN 1] ...*Type I diseases*...increasingly prevalent in developing countries:

affecting developing countries, it is no surprise that the Government of Thailand was emboldened this past year to illegally declare a compulsory license on Sanofi's patented heart disease drug Plavix.<sup>5</sup>

In light of the above, reasonable persons may seriously question whether the IGWG is endeavoring to exploit the term 'epidemic', which appears within the Doha Declaration on the TRIPS Agreement and Public Health. No doubt, IGWG members are well of the public confusion and 'fear' that has arisen as the result of various definitions of the term 'epidemic' being employed by epidemiologists, non-healthcare professionals and the lay community.<sup>6</sup> Furthermore, the WHO's recently released Health Report 2007 evidences an effort to incite public fear<sup>78</sup> and expand the

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diabetes, cardiovascular disease and cancer... *Type II diseases* are...[f]or the purposes of the strategy... **HIV/AIDS and tuberculosis**... *Type III diseases* are those that... disproportionately affect poor and marginalized populations prioritized by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases: Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, **malaria**, onchocerciasis, schistosomiasis and human African trypanosomiasis." *Id.*, at fn 1, p.3.

<sup>5</sup> See Lawrence A. Kogan, "Forced Licensing of Drug Patents Reflects 'IP Counterfeiting' Efforts on World Stage", Washington Legal Foundation Legal Backgrounder Vol. 22 No. 22 (June 22, 2007) at: <http://www.itssd.org/Publications/ForcedLicensingofDrugPatentsReflectsIPCounterfeitingEffortsonWorldStage-WLF06-22-07kogan.pdf>.

<sup>6</sup> "Interpretation of the term 'epidemic' could depend on the context in which it is used. Epidemiologists use it in its most general form and define an epidemic as follows: 'An epidemic is the occurrence in a community or region of cases of an illness, specified health behavior, or other health-related events clearly in excess of normal expectancy; the community or region, and the time period in which cases occur, are specified precisely... The term epidemic is variously defined. The broad definition given by epidemiologists ± namely, more disease than is anticipated by previous experience ± is less meaningful to the general public. In some ways it conflicts with the definitions found in the popular literature, which generally imply danger to the public and a very large number of victims.'". See Manfred S. Green, Tiberio Swartz, Elana Mayshar, Boaz Lev, Alex Leventhal, Paul E. Slater and Joshua Shemer, "When is an Epidemic an Epidemic?", *Perspective Magazine, IMAJ* . Vol. 4, January 2002 at pp. 1, at: <http://www.ima.org.il/imag/ar02jan-1.pdf> . See also Wikipedia (The term 'epidemic' is defined as a classification of a disease that appears as new cases in a given human population, during a given period, *at a rate that substantially exceeds what is "expected," based on recent experience* - the number of new cases in the population during a specified period of time is called the "incidence rate") (emphasis added), at: <http://en.wikipedia.org/wiki/Epidemic> .

<sup>7</sup> The WHO report summary is intended to incite public fear about epidemics, and consequently, public clamor for more international health regulation at the expense of private intellectual property rights. "The world has changed dramatically since then. Now, every day, up to three million people travel by air to another city, another country, or another continent. Every day, millions of tons of cargo are shipped around the world by air, land and sea. Every day, the constant movement of people and products carries with it the potential to spread highly infectious diseases and other hazards more rapidly than at any time in history. *A sudden health crisis in one region of the world is now only a few hours away from becoming a public health emergency in another.* In the last five years, *WHO has verified more than 1100 epidemic events. Among them was a deadly new disease, SARS - Severe Acute Respiratory Syndrome - which sparked an international alert in 2003. Today, there is a real and continuing threat of a human influenza pandemic that could have much more serious human and economic consequences*" (emphasis added). See "Summary - A Safer Future: Global Public Health Security in the 21st Century: The World Health Report 2007, World Health Organization at: <http://who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=24&codcch=2007> .

<sup>8</sup> "The World Health Report 2007 - A safer future: global public health security in the 21st century marks a turning point in the history of public health, and signals what could be one of the biggest advances in health security in half a century. *It shows how the world is at increasing risk of disease outbreaks, epidemics, industrial accidents, natural disasters and other health emergencies which can rapidly become threats to global public health security. The report explains how the revised International Health Regulations (2005), which came into force this year, helps countries to*

definition of the term ‘epidemic’ beyond that expressed currently within the DGSPA, to include 8 *additional* ‘epidemic-prone’ diseases,<sup>9</sup> for a total now of 23 diseases that potentially fall within the ‘scope’ and ‘focus’ of the DGSPA.

*Element 1. Prioritizing Research and Development Needs*

Within Element 1, the DGSPA paragraphs 8 and 9 (1.1) urges WHO member nations to identify “Gaps in research on Type II and Type III diseases and on the needs of developing countries in relation to Type I diseases”. As noted above, this call for action concerns *non-epidemic* type diseases, which is clearly beyond the scope and intent of the Doha Declaration on the TRIPS Agreement and Public Health, which the IGWG must take into account.

Paragraph 9 (1.2), furthermore, recommends that in order to facilitate ‘upstream research on new and existing products for diseases that disproportionately affect developing countries’, it is necessary to “(a) improve accessibility to compound libraries...” However, it does not specify what intellectual property protections would be afforded for purchased or otherwise acquired pharmaceutical compounds needed to develop and ultimately expand such a library.

*Element 2. Promoting Research and Development*

Paragraph 10 within Element 2 of the DGSPA mandates developed countries to ‘invest in’ the financing of measures that “promote, coordinate and finance public and private research in both developed and developing countries into Type II and Type III diseases and into the needs of developing countries in relation to Type I diseases...” As noted above, this call for action concerns *non-epidemic* type diseases, which is clearly beyond the scope and intent of the Doha Declaration on the TRIPS Agreement and Public Health, which the IGWG must take into account.

Within Element 2, the DGSPA paragraph 11 (2.3) suggests that in order to promote “upstream research and product development in developing countries”, it is necessary to “(a) promote discovery science, including *through open-source methods*, in order to develop a sustainable portfolio of new products” and to (b) promote access to drug leads identified through the *screening of compound libraries*”.

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*work together to identify risks and act to contain and control them. The regulations are needed because no single country, regardless of capability or wealth, can protect itself from outbreaks and other hazards without the cooperation of others.* The report says the prospect of a safer future is within reach - and that this is both a collective aspiration and a mutual responsibility” (emphasis added). See “The Current World Health Report”, World Health Organization at: <http://www.who.int/whr/en> .

<sup>9</sup> The WHO report identifies the following epidemic-prone diseases: 1) Cholera; 2) yellow fever; 3) epidemic meningococcal; 4) Severe Acute Respiratory Syndrome (SARS); 5) avian influenza; 6) Ebola; 7) Marburg haemorrhagic fever; 8) Nipah virus. See “The World Health Report 2007 - Global Public Health Security in the 21st Century: A safer future”, World Health Organization (Sept. 2007) at p. x, at: [http://www.who.int/whr/2007/whr07\\_en.pdf](http://www.who.int/whr/2007/whr07_en.pdf) .

Reasonable persons may seriously question whether the use of open-source methods will actually promote discovery science since nothing actually will be owned exclusively at the end of the day by those who make the contributions. Lack of adequate patent and trade secret protection for contributed knowledge and other information and reasonable market-based level compensation are likely to serve as disincentives to key potential participants. No mention is made either of the need for IP protections at the screening level for patented and non-patented compounds qualifying as trade secrets.

DGSPA paragraph 11 (2.4)(c) recommends that national governments “support further discussion of a medical research and development treaty” to improve global coordination and financing of medical research and development”. Reasonable persons may conclude that such a proposal actually reflects an effort to impose a new global ‘*universal access to healthcare*’ tax to be collected directly by national governments and then submitted to and administered ultimately by the WHO, a UN body. Whether or not this is successful will depend on a transparent and open public debate taking place within each WHO member country which entails a thorough review of the proposal by national legislatures and considered taxpayer input.

It should be noted that such a global tax would be conceptually and effectively distinct from a purely nationally-based tax such as the French national solidarity tax. That tax, which is borne by airline passengers boarding flights in France and traveling throughout Europe, is extra-territorial in scope, and perhaps even WTO-inconsistent. It was first imposed by the Government of France during 2006 “on airline tickets to fund a drug purchase facility”. The collected tax revenues are then forwarded by the French Government to the UNITAID. Although it is said that such tax “has not faced heavy criticism from the French public... the airline industry claims that the airline tax will hurt tourism”.<sup>10</sup> The French Government has promoted the tax as a way to use “money...to provide medical access to the poorest citizens of developing countries without compromising the rights of patent holders”.<sup>11</sup> While reasonable persons may conclude that such a tax is a novel idea promoting a worthy cause, the DGSPA would not stop at such a tax. It would also require the international weakening of intellectual property rights which the French tax was intended to prevent.

#### *Element 4. Transfer of technology*

Within paragraph 14 of Element 4, the DGSPA provides that “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

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<sup>10</sup> “Effective on July 1, 2006, passengers boarding aircrafts in France now have to pay a surcharge of 1 euro per economy class ticket and 10 euros per business class ticket if their destination is in the European Union. For flights out of Europe, the surcharge is 4 euros for economy class and 40 euros for business class. France expects its airline tax to generate upward of 200 million euros for UNITAID annually.” See Jacqueline Klosek and Kendrick Nguyen, “French Solidarity Tax: Providing Access to Medicine Without Compromising IP Rights”, Global Intellectual Property Asset Management Report, Vol. 8, No. 9 (Sept. 2006) at p. 1, at: [http://www.goodwinprocter.com/getfile.aspx?filepath=/Files/Publications/klosek\\_nguyen\\_9\\_06.pdf](http://www.goodwinprocter.com/getfile.aspx?filepath=/Files/Publications/klosek_nguyen_9_06.pdf).

<sup>11</sup> *Id.*



technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”

Reasonable persons are likely to agree with the first portion of this statement, namely that intellectual property rights should contribute to technological innovation and the transfer of technology to the public. This is already being facilitated via the maintenance of robust patent examination and enforcement systems within many countries. Unfortunately, reasonable persons may disagree with the second portion of this statement, whose language indirectly reflects social compact theory, and thus, a political compromise within each WHO member country.

What is considered a ‘balance’ of rights and obligations varies from country-to-country. Within the US, for example, intellectual property rights are recognized within US federal and state law as an absolute form of exclusive private property with a limited useful life, and NOT as ‘public goods’ for the ‘taking’ without just compensation, and thereby subject to government’s arbitrary exercise of police power. It is for this reason that the World Bank concluded that the US is the global leader in patent filings and in innovations.<sup>12</sup> Therefore, the proper balance conducive to social and economic welfare within the US is that which provides full and complete compensation for its use or acquisition, in exchange for the public disclosure and sharing of new patented inventions and innovations with society which, in turn, serves as the basis for new inventions and innovations. This quid pro quo ensures not only the reimbursement of all costs and expenses, including time, incurred to discover and develop an invention and to then commercialize it into market-relevant healthcare products from which consumers may later benefit, but also that the inventor and/or innovator can earn a reasonable market-rate profit to boot. This encourages greater public enthusiasm toward inventions and innovations, as well as greater investor enthusiasm in new technologies. In the context of developing countries, to the extent that the IGWG fosters greater governmental and public respect for the role that exclusive private property rights can play in promoting foreign direct investment and technological and managerial spillovers, the more likely developing country citizens will be afforded better healthcare and access to medicines, in fulfillment of national healthcare programs.<sup>13</sup> ‘Universal access to healthcare’ need *not* be synonymous with free public healthcare at the expense of private property interests.

The DGSPA paragraph 15 (4.3) recommends “developing mechanisms to manage intellectual property in order to promote transfer of and access to key technologies”. Intellectual property rights are currently managed/ administered by national laws to promote inventions and innovations that benefit national societies. To the extent that national governments have acceded to the WTO TRIPS Agreement as part of the Uruguay Round of trade negotiations, and to the Paris Convention on Patents at the WIPO, such governments are obligated to provide at least a minimal level of legal

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<sup>12</sup> See Lawrence A. Kogan, *Brazil’s IP Opportunism Threatens U.S. Private Property Rights*, 38 UNIV. OF MIAMI L. REV. 1 (Fall 2006) 24-25, at [http://www.itssd.org/Publications/IAL105-II\(frompublisher\)\[2\].pdf](http://www.itssd.org/Publications/IAL105-II(frompublisher)[2].pdf).

<sup>13</sup> See Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil’s Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, INT’L L J. OF ECON. DEV., Vol. 8, Nos. 1-2 (Sept. 2006) at 157-174, 224-248 at <http://www.itssd.org/White%20Papers/ijed-8-1-2-kogan.pdf>.



protection for intellectual property rights such as patents consistent with these international agreements. In other words, the WTO and the WIPO are the intergovernmental fora with specialized knowledge and jurisdiction in matters relating to intellectual property management; neither the WHO in general, nor the CIPIH IGWG, possesses the knowledge, expertise or jurisdiction to override these other organizations when it comes to either property rights or trade concerns. In fact, any effort made by the CIPIH IGWG and WHO to usurp jurisdiction from these other international organizations is arguably *ultra vires*, and thus, beyond the WHO's core competencies as spelled out by the WHO constitution.<sup>14</sup>

Paragraph 15 (4.3)(a) of the DGSPA recommends the promotion of “patent pools of upstream and downstream technologies”. This recommendation, however, fails to address a key problem. Even if industry members were compelled to donate an exclusive license to any insights, materials, and technologies they have patented to a common open source patent pool in exchange for a direct government grant or an indirect government grant made through a government owned corporation or public-private partnership, there is still the great expense of clinical testing usually borne by industry that can be compensated only through retention of exclusive rights in the resulting technology and the ability to charge market prices for it.

It should be noted at this juncture that that there is actually more than one model of open source methods practiced in the realm of computer software to choose from, and the definition of ‘open source’ software itself remains “very much in flux.” Unfortunately, the IGWG does not specify which model it favors to apply to the area of healthcare.

Pursuant to the General Public License (GPL) model, software authors who would otherwise possess or be entitled to exclusive private property rights (copyrights) in their expressed creations (i.e., the right to *exclude* others from use, reproduction and derivative works and distribution), affirmatively waive those rights, including the right to profit from them, when contributing their work to the software collective. They do so in exchange for the right to receive attribution, as a matter of contract (or license). They then leverage that resulting legal contract right to compel future creators of derivative works to waive also their otherwise *exclusive* private property rights. This ensures that they, too, will *not* profit from their creations. As a result, the software standard remains ‘open’ indefinitely, with the effect of forcing more code into the open community. This type of restriction is referred to as a ‘copyleft,’ as opposed to a ‘copyright,’ and it serves to remove the software from the ‘public domain.’<sup>15</sup> Experts have pointed out how the GPL model has a number of shortcomings.<sup>16</sup>

Pursuant to the Berkeley Software Distribution License (BSD) model, businesses are permitted to “build upon free software to create proprietary software.” This means that, the BSD License allows proprietary commercial use, and the software released under the license can be incorporated into proprietary commercial products. In addition, any works based on and/or derived from the free

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<sup>14</sup> See Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, supra at p.60.

<sup>15</sup> See Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, supra at pp. 76-78.

<sup>16</sup> *Id.*, at pp. 79-80.

software may be released under its own proprietary license.<sup>17</sup> Most companies prefer the BSD model since it preserves the legal notion of private property rights and the economic incentives underlying it.<sup>18</sup>

Paragraph 15 (4.3)(c) of the DGSPA recommends the examination of “best practices in areas such as competition, transparency and proper remuneration for patent holders”. As noted above, this recommendation engenders serious concerns. Any effort by the WHO and the IGWG to examine other additional areas outside its areas of core competencies would be perceived by national governments as unwarranted and perhaps illegal. The WHO’s constitution simply does not authorize the organization to determine competition policy and proper remuneration in the marketplace for patent holders, irrespective of the desires of key WHO bureaucrats and nongovernmental activists.

#### *Element 5. Management of intellectual property*

Paragraph 16 within Element 5 of the DGSPA appropriately cites the “crucial need to strengthen capacities in developing countries to manage intellectual property”. Reasonable persons can therefore agree that it is essential for developed countries to assist developing countries in expanding their technical capacity to preserve the economic and technological value of intellectual property rights within a market-enabling environment that recognizes and protects exclusive private property rights, including IP. Numerous studies have confirmed how, by establishing the proper institutional enabling environment, which includes recognition and strong protection of exclusive patents and trade secrets, emerging and developing countries may attract and shape the type and composition of foreign direct investment (FDI) that will promote their domestic industries and satisfy their national health and innovation needs.<sup>19</sup>

However, paragraph 16 also *inappropriately* focuses on R&D arrangements concerning *non-epidemic* type diseases. This is clearly beyond the scope and intent of the Doha Declaration on the TRIPS Agreement and Public Health as previously discussed, which must be taken into consideration by the IGWG.

Paragraph 17 (5.1)(a) of the DGSPA promotes “information sharing” in order to facilitate “capacity building in the management of intellectual property”. However, it does not specify how the kinds of information sharing to be undertaken would provide for confidentiality of proprietary information and data. While ‘experimental use’ agreements may be reached between and among the various parties participating in such information sharing efforts, no mention is made of this

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<sup>17</sup> *Id.*, at pp. 80-81.

<sup>18</sup> *Id.*, at pp. 81-82.

<sup>19</sup> See Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil’s Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, EXECUTIVE SUMMARY at p. 9 (Sept. 2006) at: <http://www.itssd.org/pdf/ITSSD-BrazilPaper-ExecSummaryI.pdf>, cited in “Intellectual Property and Growth in Global Economy – Regional and Country-Specific and Development Studies”, Center for Strategic and International Studies website at: [http://www.csis.org/component/option.com\\_csis\\_progi/task.view/id.839](http://www.csis.org/component/option.com_csis_progi/task.view/id.839).

possibility. The logical compliment to the sharing of information between and among nations is public and private education in the recognition and protection of private intellectual property rights which is the charge of national governments with assistance from both the WIPO and the WTO.

Paragraph 17 (5.1)(b) suggests that the type of information to be shared includes that of patent status contained within national databases. Paragraphs 17 (5.1)(b) and (c) speak alternatively of ‘exchange of information’ and ‘dissemination of relevant information.’, but do not define these terms, which is absolutely necessary if public-private partnerships are to evolve. The IGWG must remember that any confidential or otherwise proprietary information, trade secrets and/or testing data recognized as exclusive private property under law that a government acquires from a private company for the purpose evaluating the safety or efficacy of substances submitted for pre-market authorization, should not be permitted to be exchanged with other governments pursuant to such a program without strict protection of intellectual property rights.

Paragraph 17 (5.2) calls upon national governments, “upon request” to “provid[e] support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights”. Yet, it does not define the term ‘support’ for such purposes. Does it entail economic, social, legal, scientific, technical, moral, etc?? This term needs to be better defined. Furthermore, as most reasonable persons knowledgeable about the public debate between universal access to healthcare and intellectual property rights are aware, there is still no international consensus concerning what specific ‘flexibilities’ are consistent with the TRIPS Agreement. It is therefore not possible at the current time for governments to provide undefined ‘support’ for that which is still unsettled under international law.

Within paragraph 17 (5.2)(a) of the DGSPA, the IGWG recommends the promotion of legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements, by means including the dissemination of best practices.” Once again, there is no international consensus among WTO members concerning what specific ‘flexibilities’ are consistent with the WTO TRIPS Agreement. There is also a lack of international consensus regarding what are best practices’ in the exercise of such flexibilities. Furthermore, what ‘other international agreements’ does the IGWG have in mind? Certainly, the WIPO Paris Convention does not speak to TRIPS ‘flexibilities’. Reasonable persons could easily come to the conclusion that many national governments would find it difficult if not impossible to promote national legislation consistent with that which is unknown or unsettled in international law.

Paragraph 17 (5.2)(b) calls for the promotion of “bilateral trade agreements that do not incorporate ‘TRIPS-plus’ protections in ways that might reduce access to medicines in developing countries”. Have not the members of the IGWG seriously considered *why* developed nations with robust intellectual property systems and economies that depend increasingly on the ‘sale’ and/or ‘licensing’ of ideas and innovations as a share of Gross Domestic Product seek to protect those key private assets in international markets? Do they not see how such intangible economic assets indispensably contribute to national development and economic growth? Would it not behoove the IGWG members of the CIPIH and the WHO secretariat in general to find a way to promote



developing country healthcare WITHOUT compromising exclusive private intellectual property rights held by the citizens of the very nations that subsidize international healthcare?

TRIPS-plus protections incorporated in bilateral trade agreements are perhaps the only remaining mechanisms that such developed country governments can employ to protect and preserve the ‘right of exclusivity’ held by patent holder nationals for the purpose of ensuring a complete and reasonable market-rate of return to compensate for the costs, time and effort expended to discover new compounds and develop new and innovative healthcare products shipped, produced or otherwise used in bilateral trading partner jurisdictions. This is especially true currently since the WHO and certain foreign governments continue to promote a non-private property-based IP paradigm globally. Within the US, in particular, the President and the Congress have a special constitutional obligation to American citizens to protect and preserve their private property rights from actual or constructive expropriation (‘takings’ without payment of ‘just’ compensation) by government, whether that government is based in the US or abroad.<sup>20</sup>

Lastly, paragraph 17 (5.2)(c) calls for governments to “encourage trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health). However, as noted previously, there is arguably no international consensus among WTO members concerning what specific ‘flexibilities’ are consistent with the WTO TRIPS Agreement. If any ‘flexibilities’ are to be gleaned from the Doha Declaration, they are arguably limited in nature and scope, having been restricted to the issuance of “compulsory licenses”. As future research from the ITSSD will soon reveal, ‘compulsory licensing’ is an historical legal ‘term of art’ that is not as broad and inclusive of other mechanisms and scenarios as nongovernmental activists would have the world believe.<sup>21</sup> Indeed, the Doha Declaration itself restricts the term flexibilities to the use of ‘compulsory licenses’ to address ‘national emergencies’, including public health crises, or ‘other circumstances of extreme urgency’, “including those relating to HIV/AIDS, tuberculosis, malaria *and other epidemics*.”<sup>22</sup> This means clearly that any reference by the IGWG to medicines or treatments for diseases *other than epidemics* is, by definition, beyond the scope of the Doha Declaration, and thus inconsistent with international law.

Paragraph 17 (5.3)(a) and (b) of the DGSPA aims to encourage national governments and the IGWG explore the use of new top-down mechanisms to promote greater industry research and development efforts and lower healthcare product prices, including prize funds utilized mostly in the scientific and academic communities and advance-market commitments relied upon by the increasingly centrally planned economies within Europe and arguably even in Canada. It is believe

<sup>20</sup> See Lawrence A. Kogan, Brazil’s IP Opportunism Threatens U.S. Private Property Rights, *supra* at pp. 114-116.

<sup>21</sup> See “December 12 Letter from Jamie Love to USTR on Compulsory Licensing”, Consumer Project on Technology, at: <http://www.cptech.org/ip/health/c/thailand/ustr12dec2006thailand.html>.

<sup>22</sup> See “TRIPS and Pharmaceutical Patents: Fact Sheet”, World Trade Organization website at: [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm00\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm); “The Separate Doha Declaration Explained”, World Trade Organization website at: [http://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm](http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm) (“The TRIPS Agreement does refer to national emergencies or other circumstances of extreme urgency *in connection with compulsory licensing*”) (emphasis added).



that such non-market mechanisms will provide the necessary incentive for industry to invent and innovate. However, such national and regional regulatory frameworks models actually represent *at-or-below-cost*, fixed-price, volume-based business models that would likely be publicly supported, in some way, by national governmental subsidies or through imposition of national and/or local taxes. If ever harmonized at a global level, as implied, this might even ultimately result in the imposition of global taxes by the WHO.

Pursuant to an advance market commitment program, innovative product/service providers would essentially be guaranteed a minimal national and/or international market share in return for everyday low priced products and services. The IGWG should be well aware that this concept was previously floated before the G-8 member nations during February 2006, then considered by pharmaceutical companies as the least-worst alternative of a suite of bad options, and later rejected for sound economic and political reasons during July 2006. As the British and Japanese Governments plainly made clear, there were significant hidden costs to which they were reluctant to commit. In other words, not enough is yet known about the financial costs associated with such recommended arrangements, or about how they have impacted industries' incentive to innovate, invest, and generate new bio and pharmaceutical discoveries that ultimately result in commercialized products that actually improve human health.

The IGWG should take note that one of the main problems surrounding the use of top-down mechanisms such as R&D credits, subsidies, and contests and awards is that they do *not* compensate for the opportunity (time) and economic costs incurred to convert basic R&D into commercially relevant healthcare innovations. Markets are *profit-*, not cost-driven. Volume-based business models with tight profit margins are an extremely risky investment in the long term, even if supported by government efforts to artificially make markets by providing advance market commitments. Since the natural tendency of markets is to fluctuate in response to the sometimes volatile supply and demand of raw materials, goods-in-process, finished products, etc., as well as, to consumer perceptions and idiosyncrasies, it would be extremely difficult to gauge in advance the true economic value of such a guarantee in terms of profitability. After all, nothing can be guaranteed forever, let alone for the extended period of time that may be required to develop, manufacture and distribute a successful life-saving drug to needy patients free of complications. Consequently, if governments regulate company profit margins internationally and domestically without truly guaranteeing markets for more than the short-term, company and investor incentives to enter into any such arrangement are likely to evaporate very quickly.<sup>23</sup>

Lastly, paragraph 17 (5.3)(c) of the DGSPA recommends that all national governments “access the impact of data-exclusivity regulations.” As the IGWG knows all too well, in many countries trade secret information and other clinical testing data that qualify for data-exclusivity under statute are treated as exclusive private property with a temporary useful life. Such exclusivity has been proven effective in promoting discovery of new chemical entities and new uses of existing entities. Other

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<sup>23</sup> See Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, supra at pp. 304-306 and accompanying footnotes.



countries, in the meanwhile, either have enacted data exclusivity regulations but failed to enforce them, or have refused to enact data exclusivity regulations at all. In these latter cases, it is arguable that such governments truly lack an understanding of and an appreciation for the legal and economic underpinnings of data exclusivity within common law nations.<sup>24</sup> Consequently, IGWG members who are from these latter countries are especially not qualified to render any expert opinions as to their performance and viability within third countries.<sup>25</sup>

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<sup>24</sup> *Id.*, at pp. 144-157.

<sup>25</sup> Arguably, the CIPIH has once again transcended WTO jurisdictional and national sovereignty lines by opining as to the ‘correct’ meaning of the WTO/TRIPS data protection/exclusivity provisions. In fact, although a plain reading of TRIPS Article 39, which falls under Section 7 of the TRIPS agreement, entitled *Protection of Undisclosed Information*, reveals that its objective is to prevent the commission of the tort of *unfair* competition by protecting proprietary intellectual property rights inherent in both undisclosed information generally (trade secrets), and in the particular types of testing data and other information generated, composed, presented and submitted to governments or governmental agencies (which may or may not include trade secrets), the WHO has denied that any such property right exists at all! See Lawrence A. Kogan, *Brazil’s IP Opportunism Threatens U.S. Private Property Rights*, supra at p. 59 and accompanying footnotes.