November 11, 2011

Mr. Philippe Baechtold
Head, Patent Law Section
Standing Committee on Patent Law (SCP)
World Intellectual Property Organization
34, chemin des Colombettes,
1211 Geneva, Switzerland

Re: ITSSD Response to WIPO Circular C. 7998, and
Comments Regarding SCP/16/7; SCP/16/9; SCP/17/4

Dear Mr. Baechtold:

This ITSSD submission, in part, is intended to respond to the Circular C.7998 notification dispatched on June 28, 2011 by WIPO Director General Francis Gurry soliciting Member and Observer comments on the proposal by South Africa (SCP/16/7) on behalf of the African Group and the Development Group on Patents and Health, the WIPO Member and Observer comments to which have been compiled within SCP Document SCP/17/INF/3.

Document SCP/16/7 references not uncontroversial World Health Organization and World Trade Organization declarations providing political context for its recommendation that the SCP Secretariat undertake an ambitious work program intended ultimately to justify the adoption and aggressive exploitation at the national level by South Africa and other WIPO Development Agenda Group (DAG) members of WTO TRIPS flexibilities for the purpose of "taking measures to protect public health". Unfortunately, it appears that such work program as currently proposed, if not carefully reformulated, will have the unintended effect of minimizing the significance and reducing the economic value of pharmaceutical/biotechnology patents and related other intellectual property rights, namely, trade secrets and data/market exclusivities/data protections, and of thereby, sending the wrong signals to the international life science industry and investment communities.

This ITSSD submission has been delayed beyond the desired September 11, 2011 deadline in order to incorporate recent substantive research performed by the ITSSD concerning distinct patent-related intellectual property rights (data and market exclusivities/data protections) extended by government regulatory bodies to pharmaceutical and biotechnology originator companies for the express purpose of facilitating new biologic drug innovations. Such research, which not could be previously disclosed, and thus, incorporated within the ITSSD's desired timely response to C.7998, will soon appear in the Global Trade & Customs Journal, a publication of the Netherlands-based Kluwer law International. A working paper version of this article along with abstract, which is publicly accessible on the SSRN website, is referenced in footnote 20 herein.

We recognize, as you do, that the Secretariat has, in multiple instances in the recent and distant past, extended submission deadlines for SCP Member and Observer comments to various SCP and WIPO Secretariat documents. Therefore, the ITSSD would appreciate the same accommodation extended to SCP Members and other SCP Observers, namely, the SCP's acceptance of our acknowledged late substantive submission, especially given its relevance to the SCP's forthcoming discussion of the treatment of patents and health during the upcoming 17th Plenary Session, and the lack of any but passing mention (within Box 1, fns 9-10) of patent-related intellectual property rights within SCP Document SCP/17/INF/3.

Furthermore, this submission is relevant to and intended to clarify the ITSSD's prior comments made during the 16th SCP Plenary Session that took place in May 2011, as reflected in paragraph 57 of the SCP Draft Report SCP/16/9 Prov.2, which concerned the draft questionnaire contained in document SCP/16/3 addressed as part of Agenda Item 7: Exceptions and Limitations to Patent Rights. As I then stated,

> "...there was no question concerning the treatment of intellectual property rights that might be engendered as part of a regulatory submission, such as trade secrets, confidential information and data, including clinical testing data, the unauthorized disclosure of which to third parties would, if adequately marked by the IP right holder as a 'trade secret' or as 'proprietary and confidential', engender criminal penalty at least in the United States of America."

The ITSSD wishes to add further clarification to this point, namely, that The U.S. Freedom of Information Act (FOIA) provides trade secrets, including information submitted to the U.S. Food and Drug Administration (USFDA), with an exemption from public disclosure, even though the underlying policy purpose of the statute is to provide public disclosure.[1]. Furthermore, the disclosure, divulgence, or making known of commercial trade secrets or any information relating thereto by any federal employee in any manner not authorized by law can constitute a criminal offense punishable by fine and/or imprisonment[2]. However the USFDA may disclose trade secret information in limited situations when relevant in a judicial or administrative proceeding[3] or if it finds that disclosure would be "'in the public interest', promote the objectives of the act and the agency, and is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue regulatory activities without disruption."[4].

The ITSSD observes that many WIPO developing country members, especially South Africa (and other DAG members), sincerely seeking to advance towards a knowledge-based economy are aware that they need to attract knowledge-based foreign direct investment (FDI), to improve their national

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[1] See *FOIA Exemption 4, Freedom of Information Act Guide*, United States Department of Justice (May 2004) at: http://www.justice.gov/oip/exemption4.htm; *See also* 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.60-61.
[2] *See* 18 U.S.C. §1905.
[3] *See* 21 U.S.C. §331(j); 21 C.F.R.§20.83 and §20.86.
[4] *See* 21 C.F.R. § 20.20 and § 20.82.

education standards, and to facilitate the development of useful commercial and technical human capacity skills and abilities among their populations that are adequate to the task of absorbing technology transfers (as discussed within SCP/14/4 REV.) from multinational life science companies. The ITSSD also recognizes, however, that South Africa and other DAG members are simultaneously reticent, often on political/ideological grounds, to recognize that it is also in their best long term economic and technological interests to legally protect trade secret and other proprietary and confidential data and information that is submitted to regulators by foreign life science companies during the course of their developing, testing and seeking of market authorization for their new pharmaceutical products.

Unfortunately, the generally cause of national life science and, specifically, drug innovation, is unlikely to be furthered by the South African[5] and other DAG governments' (e.g., India)[6] ongoing refusal to extend legal protections to such intangible assets consistent with terms of Article 39.3 of the WTO Trade Related Aspects of Intellectual Property (TRIPS) Agreement and Article 10bis of the WIPO Paris Convention. While it is understandable that developing country members believe they need to first develop replication-based manufacturing expertise capable of supporting the import substitution of foreign brandname drugs within their domestic markets before they can cultivate the higher end skills typically associated with drug discovery and innovation, they risk losing the knowledge-based FDI that is essential to establishing a firm economic and technological foundation.

WIPO's recent report entitled, *WIPO Activities on Patents and Health* (SCP/17/4) is somewhat helpful in confirming for WIPO members that WIPO interprets its institutional mandate broadly as sanctioning its addressing of (cross-cutting) issues going beyond the promotion of intellectual property protections relating to public health, notwithstanding WIPO's acknowledged lack of comprehensive competence in the area of health. In particular, SCP/17/4 reflects the following:

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[5] *See, e.g.*, Christopher Maloney and Nick Segal, *The Growth Potential of the Pharmaceuticals Sector in South Africa*, G:ENESIS (May 29, 2007) at: http://www.imsa.org.za/files/Library/Speeches%20and%20Reports%20(7)/Research%20Reports%20on%20health%20matters/GENESIS%20Pharmaceuticals%20Report%20070529%20(2).pdf ("[Data exclusivity relates to data from the patent-holder being used by regulatory authorities in such a way that generic firms can get more quickly to market once the drug is off-patent. In South Africa, the 'black box' reputation of the MCC has led some innovator companies to fear that their data are not being effectively protected") *Id*., at p. 24. See also *SECTION27, TAC and MSF South Africa Call on the EU and India to Stop the Threats to People's Lives*, +Section 27 Press Release (March 9, ,2011) at: http://www.section27.org.za/2011/03/09/section27-tac-and-msf-south-africa-call-on-the-eu-and-india-to-stop-the-threats-to-people%E2%80%99s-lives/ ("Currently generic manufacturers are required only to show quality and bioequivalency to an existing medicine for registration. Data exclusivity provisions would prevent generic companies from relying on clinical trial data of a registered product during the period of data exclusivity. This requirement will delay the registration of generic medicines as it will be too costly and, in most cases, unethical to repeat clinical trials.") Id;

[6] See *No Data Exclusivity Clauses in Trade Pacts, Assures India*, Third World Network (July 8, 2011) at: http://www.twnside.org.sg/title2/FTAs/info.service/2011/fta.info.185.htm ("The Commerce and Industry Minister of India, Mr Anand Sharma, has given assurances that India will reject any efforts to include 'data exclusivity' clauses in bilateral trade agreements.") *Id*.

> "3. WIPO's determination to serve as a leading intergovernmental forum for addressing the intersection between intellectual property, innovation and global policy issues is expressed by one of the nine strategic goals of the Organization: *'Addressing IP in relation to global policy issues'* (emphasis added)."
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> "4. More specifically, based on the mandate established by the Program and Budget for the 2010/11 biennium under Program 18 on IP and Global Challenges, *WIPO created the Global Challenges Division to carry out work under that Program in close cooperation with relevant WIPO programs, other agencies and substantive engagement with other relevant stakeholders,* namely, the United Nations and other intergovernmental organizations (IGOs), civil society and non-governmental organizations (NGOs), as well as the private sector and academia (emphasis added)."
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> "5. WIPO's activities on patents and health, however, go beyond the work carried out under Program 18. Many activities of WIPO directly or indirectly relate to the topic of patents and health. Therefore, *this document intends to capture the wide range of activities covered by WIPO that relates to patents and health* (emphasis added)."
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> "6. WIPO is a specialized agency of the United Nations dedicated to intellectual property issues. *As WIPO alone does not have a comprehensive competence in the area of health,* and in view of the complexity of the challenges relating to the area of health, the Organization works closely with other IGOs and NGOs, having different, but relevant competencies (emphasis added)."
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> "8. Many activities relating to patents undertaken by WIPO are not specifically addressing the health area. Nevertheless, they may be relevant to the issues relating to patents and public health, since the general objectives of the patent system, i.e., *the promotion of technological innovation and the transfer and dissemination of technology, are of fundamental importance for improving public health*" (emphasis added).

Furthermore, WIPO's recent report entitled, *WIPO Activities on Patents and Health* (SCP/17/4) clearly reflects WIPO's recognition that Member States frequently provide legal protections for test data consistent with their WTO TRIPS and free trade agreement obligations:

> "28. During the period from June 2009 to June 2011, WIPO has provided legislative and policy advice in response to requests from the authorities of 18 countries19and one regional body.20... *Frequently, Member States pay particular policy attention to the protection of test data, either because of general TRIPS commitments or due to more precise obligations under bilateral or regional agreements* (emphasis added)."

To further elaborate on this issue, WIPO reported that its new Global Challenges Division had convened a symposium during February 2010 that "*focused on legal practice and experience in test*

data protection in the pharmaceutical industry" (emphasis added).[7] WIPO's perspective on this issue was presented by Nuno Carvalho, Deputy Director of the WIPO Global Challenges Division.[8] It conveyed several curious conclusions:

1) Testing and other data submitted to governments as a condition of obtaining drug product marketing approval are, to the extent otherwise undisclosed, recognized as trade secrets that, if developed as the result of considerable effort are subject to mandatory protection under TRIPS Article 39.3[9];

2) Testing data not qualifying as a trade secret but yet capable of differentiating a pharmaceutical product even though not otherwise incorporated into the characteristics of a pharmaceutical product, namely, external data about certain characteristics of a pharmaceutical product that is derived through simple observation rather than as the result of invention or creation, may not be subject to protection from unfair competition under TRIPS Article 39.3[10];

3) Article 10bis of the WIPO Paris Convention does not protect observed testing data because such testing data is like press reports and other information which has historically not been protected against unfair competition by Member States[11];

4) "[T]here is no authority in the history of the Paris Convention that permits us to say with certainty that Article 10bis covers trade secrets"[12];

5) "[A] literal reading of Article 10bis leads us to believe that its provisions aim at preventing confusion through the elimination of the external differentiation of the products, the establishments or the businesses. However, trade secrets, because they concern information, are elements of internal differentiation of products (or services). *Test data are a different sort of trade secrets*" (emphasis added)[13];

6) Although "test data are secret information with a value for competitors...*the business model at stake in [TRIPS Article] 39.3 is not one of a competitor (mis)appropriating valuable trade secrets that are in possession of another. Article 39.3 is about data that are submitted by private companies to governments* (emphasis added). This is a matter generally dealt with by constitutional, administrative or civil law. *Generally, it is a matter for each State to decide* what to do with confidential information submitted by citizens in the daily business of government administration.

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[7] See *The Evolution of the Regulatory Framework on Pharmaceutical Test Data*, WIPO Global Challenges Division (Feb. 2010) at: http://www.wipo.int/meetings/en/2010/wipo_ip_lss1_ge_10/program.html, reported in Paragraph 22 of SCP/17/4.
[8] *See* Nuno Carvalho, *WIPO Perspective of Test Data Information* WIPO Global Challenges Division (Feb. 2010) at: http://www.wipo.int/export/sites/www/meetings/en/2010/wipo_ip_lss1_ge_10/pdf/carvalho.pdf..
[9] *Id*., at p.9.
[10] *Id*., at pp. 10-17.
[11] *Id*., at p. 17.
[12] *Id*., at pp. 19-20.
[13] *Id*., at pp. 21-22.

The disclosure of that information by the governmental agencies in question may have a negative impact on the businesses that submit them, but it is not an act of competition" (emphasis added)[14];

7) Although "a large number of developing countries, during the TRIPS negotiations, denied the IP-dimension of trade secrets, the reality is that a large number of them have enacted measures to protect trade secrets as a modality of repressing unfair competition"[15];

8) "WTO Members may protect test data while ensuring effective protection against unfair competition, as provided in Article 10bis of the Paris Convention. But WIPO Member States that are not WTO Members are not obliged to do so or to give that same interpretation to Article 10bis;[16]"

9) "*It is up to society to establish the qualifiers that justify that a differentiating [intangible] asset [such as test data] be protected*. In the case of test data, that qualifier may very well be the investment and the efforts put in the origination of the data. And indeed the history of IP shows that society has resorted to proprietary protection for intangible assets the origination of which was based on noninventive or creative efforts" (emphasis added).

While reserving the opportunity to submit further comments at a later time concerning the various legal conclusions reached by Mr. Carvalho, the ITSSD devotes the remainder of this submission to address the following points.

In essence, the WIPO representative conveyed the clear impression that the thirty-one (31) (of the one-hundred eighty-four (184)) WIPO Member States that are not also (one of the one-hundred fifty-three (153)) WTO Member States may interpret international law as sanctioning the cost-free technology transfer of pharmaceutical testing data and know-how from developed to developing countries. Nevertheless, this course of action may not be consistent with their long term economic interests. Moreover, it does not equate to a reliable international standard that can be applied consistently in differing national jurisdictions and which is capable of bringing legal and economic certainty to international markets comprised of multinational businesses and investors.

The WIPO representative also conveyed the troubling impression that the submission of pharmaceutical and/or biologics testing data and confidential information to a government regulatory authority as a condition for obtaining chemical or biologic pharmaceutical product marketing approval is *not* an act of competition, and therefore should be disclosed to the public because of the 'public interest' at stake.[17] At least one commentator has similarly implied that the treatment of such data as a trade secret by the US Food & Drug Administration is no longer necessary because "Free-

[14] *Id*., at pp. 23-24.
[15] *Id*., at p. 18.
[16] *Id*., at p. 25.
[17] See e.g., *Public Disclosure of Clinical Trial Results by Health Canada Should Be Mandatory, Expert Argues*, ScienceDaily (Aug. 29, 2011) at: http://www.sciencedaily.com/releases/2011/08/110829131302.htm.

riding in obtaining regulatory approval became a non-issue in the U.S. after the Hatch-Waxman Act"[18].

Yet, these positions underestimate and undervalue the efforts and costs associated with pharmaceutical and biotech company clinical testing and other proprietary and confidential information which is generated and provided solely to secure the regulatory marketing authorization needed to advertise, offer for sale, sell and distribute their products within the drug marketplace, for the purpose of generating maximum revenues and profits, especially in advance of similar activities usually undertaken by competitors. Given the competitive advantages secured by simply being the first to enter the marketplace, there is an ongoing effort by other brandname manufacturers as well as generic manufacturers to secure as soon as possible, by direct and indirect means if necessary, the clinical testing and other data generated by brand name drug originators against which they can then submit satisfactory comparisons to establish safety and efficacy. While government regulators may not themselves be in competition with drug innovators in light of the gatekeeper role they perform, they are nevertheless capable of altering the marketplace by indirectly 'picking winners and losers'- (for example, by facilitating the disclosure of such proprietary information to competitors), whether they be other brandname drug companies or generic drug companies eagerly awaiting their chance to enter the market immediately upon the expiration of brandname drug company patents.

Indeed, competition is rather fierce not only between traditional brandname pharmaceutical and biologics companies within the same or different countries, but also between brandname pharmaceutical and biologics companies and generic pharmaceutical and biologics companies. If this were not actually the case, and such submissions were not of significant economic value deserving of legal protection, why then would the European Medicines Agency, when announcing during November 2010 its then new policy of broadening public access to documents related to medicines for human and veterinary use, have emphasized how the portions of any such documents containing trade secrets, personal data and commercial confidential information would be redacted or not otherwise subject to disclosure?[19]

There is arguably an even greater need to legally protect trade secrets, confidential information and related clinical testing data generated in connection with the research and development and commercialization efforts undertaken with respect to the larger, more complex and far more expensive biologic (as opposed to chemically synthesized) originator drugs, the safety, efficacy, market authorization and market penetration of which will take much longer to establish. In light of the heightened competition in this new very promising product category, producers of biosimilars (generic biologics) are likely to endeavor to secure more rapid access to such data and information for the purpose of entering and competing in the marketplace earlier in the process, especially since for biosimilars (generic biologics), the establishment of sufficient similarity or 'interchangeability' is

[18] *See* Mustafa Ünlü, *It Is Time: Why the FDA Should Start Disclosing Drug Trial Data*, 16 Mich. Telecomm. Tech. L. Rev. 511 (2010), at: http://www.mttlr.org/volsixteen/unlu.pdf

[19] *See European Medicines Agency Widens Public Access to Documents - Policy on Access to Documents Also Sets Out New Approach for Proactive Disclosure of Documents*, European Medicines Agency Press Release EMA/718259/2010 (Nov. 30, 2010) at: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2010/11/WC500099468.pdf.

likely to be far more difficult than it has been for establishing the 'identicalness' of a generic drug molecule to the original chemically synthesized molecule.

Taking these distinctions into account, the U.S. Biologic Price Competition and Innovation Act of 2009 (BPCIA) enacted and signed into law during early 2010 provides greater legal protection to the proprietary and confidential information and clinical testing data submitted to secure USFDA market authorization for a given biologic reference product (12 years of combined data and market exclusivity), than was previously accorded by the Hatch-Waxman Act to chemically synthesized originator drugs (5 years of combined data and market exclusivity). Granted, these longer exclusivity periods have generated post-enactment public debates among members of the U.S. Congress, U.S. and foreign pharmaceutical and biotechnology companies, and the academic and nongovernmental communities that risk undermining IP licensing transactions and related revenues and U.S. international trade negotiations. However, government officials as well as the investment and life science industries operating in advanced economies have increasingly acknowledged that the continued recognition and protection of such know-how and confidential information as economically valuable intellectual property that is distinct from a patent, will serve to enhance innovation and investment, as well as the prospect for more future high paying high technology jobs.[20]

The ITSSD strongly believes that South Africa and other DAG members sincerely seek to advance their societies so that they are capable of generating knowledge-based economic outputs for both domestic and international trade purposes, in this case, cutting edge drug innovations. However, South Africa and its fellow DAG members must also admit to themselves and to the world that they need to attract and retain knowledge-based FDI from the very same multinational pharmaceutical and biotechnology companies that they now criticize. and whose new and innovative patented drug technologies, trade secrets and other private and confidential information and data, including tetsting data, are denied strong legal protection within their jurisdictions.

Thank you, in advance, for your serious consideration of our comments and for ensuring their inclusion within Document SCP/17/INF/3 - *Patents and Health: Comments received from Members and Observers of the Standing Committee on the Law of Patents (SCP).*

Sincerely,

Lawrence A. Kogan

Lawrence A. Kogan
Director/President

[20] *See* Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, Global Trade and Customs Journal, Vol. 6, No. 11 & 12, 2011, Working Paper Available at SSRN: http://ssrn.com/abstract=1953316.